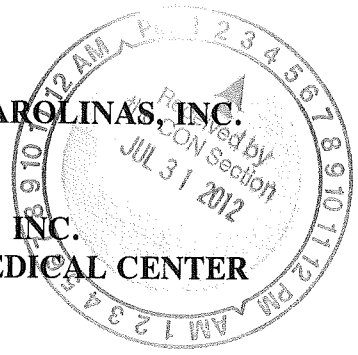

COMMENTS SUBMITTED BY FIRSTHEALTH OF THE CAROLINAS, INC.
IN OPPOSITION TO
PROJECT I.D. NO. M-008833-12
CUMBERLAND COUNTY HOSPITAL SYSTEM, INC.
ADD 28 ACUTE CARE BEDS TO CAPE FEAR VALLEY MEDICAL CENTER

I. INTRODUCTION

FirstHealth of the Carolinas, Inc. (FirstHealth) submits these comments in opposition to Cape Fear Valley Health System's (CFVHS) proposal to develop 28 new acute care beds. For the reasons explained below, CFVHS's application cannot be approved. There is a fatal flaw regarding Criterion (20) due to the number of immediate jeopardy and condition level deficiency citations that CFVHS has received in the recent past. In addition to the fatal flaw under Criterion (20), CFVHS's application is also non-conforming with several other CON criteria and therefore, the application cannot approved.

II. THE CFVHS APPLICATION CANNOT BE APPROVED UNDER CRITERION (20).

Criterion (20) provides that "an applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past." N.C. Gen. Stat. § 131E-183(a)(20). This criterion ties back to one of the foundations of the CON Law, N.C. Gen. Stat. § 131E-175(7):

> That the general welfare and protection of lives, health and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to the provisions of this Article prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served.

To determine whether an existing hospital satisfies Criterion 20, the Agency relies on the surveys conducted by the Acute and Home Care Licensure and Certification Section of DHSR. The Agency employs an 18-month "look back" period from the date of the decision in the pending review to determine compliance with Criterion 20. *See* Exhibit A, Final Agency Decision in 11 DHR 3173/3476 (Finding of Fact Nos. 38-39). The Agency usually uses immediate jeopardy and condition level deficiencies in its Criterion 20 analysis, though standard level deficiencies can also be used, depending on their severity and number.

Thus, assuming a decision in this review is rendered in November 2012, the 18-month "look back" period extends to May 2011.

In last year's 65-bed review for the Cumberland-Hoke service area, the Agency non-conformed CFVHS on Criterion 20 grounds because of an immediate jeopardy that was discovered on October 21, 2011. *See* Exhibit B. CFVHS was also determined to be out of compliance with four Medicare Conditions of Participation. The state survey agency recommended that CFVHS's participation with Medicare be terminated effective January 19, 2012. A copy of the survey findings is attached as Exhibit C.

The incidents that gave rise to the immediate jeopardy and condition level deficiencies concerned the death of a patient at CFVMC in April 2011. The findings state that " . . . the hospital failed to provide care in a safe setting, promote patients' rights, and ensure nursing staff supervised patient care by failing to ensure hospital staff in the ED implemented restraints in accordance with safe and appropriate restraint techniques and failing to ensure adequate nursing supervision of a restrained patient to prevent harm to the patient." Exhibit C, Survey, page 2 of 185.

The survey findings also state that "[b]ased on evaluation of the immediate corrective action plan, the Immediate Jeopardy was determined to be ongoing." Exhibit C, Survey, page 3 of 185.

The survey findings further reveal that the hospital failed to ensure that two other patients (identified in the Findings as Patient #7 and Patient #2) were monitored by trained staff. *See, e.g.*, Exhibit C, Survey, page 76 of 185. The October 25 cover letter indicates that Cape Fear Valley was non-compliant with four Medicare Conditions of Participation: (1) governing body; (2) patients' rights; (3) quality assessment/performance improvement; and (4) nursing services.

Given that the immediate jeopardy and conditions out of compliance were determined to exist as of October 21, 2011, which is within the 18-month look back window applicable to this review, CFVHS cannot be approved for 28 more beds.

FirstHealth is aware that CFVHS appealed the Agency's decision on the 65-bed application and that the 65-bed case has been settled. According to the settlement in the 65-bed case, CFVHS was able to address the Agency's Criterion (20) finding by demonstrating that it maintained continuous Joint Commission accreditation in 2012. *See* Exhibit D.

The 65-bed settlement does not relieve the Agency of its duty to review the 28-bed application under Criterion (20) and to enforce the law as written. The Agency did not admit that it erred by finding CFVHS non-conforming with Criterion (20) in the 65-bed review. *See* Exhibit D, page 3. The Agency settled only the 65-bed review, not the 28-bed review which, of course, had not even happened as of the time the Agency entered into the 65-bed settlement on April 20, 2012. The 28-bed application is entirely different from the 65-bed application, and the 28-bed application must be reviewed independently of the 28-bed application. Nothing in the 65-bed settlement should be construed to obligate the Agency to conform CFVHS to Criterion 20 in future CON applications.

Criterion (20) looks back at past events. Commitments to maintain quality in the future are forward looking, and therefore are not relevant to whether the applicant has provided quality care in the past. Thus, the 65-bed settlement and whether Cape Fear was able to maintain Joint Commission certification is not relevant to this 28-bed application. *See* Exhibit E, Deposition of Craig Smith in 11 DHR 3173/3476, pages 49 and 50 (testifying that a Plan of Correction is not relevant in Criterion (20) analysis). Criterion (20) does not state or imply that a settlement reached in a different case has any bearing on a pending review. The law must be enforced as written.

Moreover, there have been other survey findings of immediate jeopardy and condition level deficiencies that occurred after the incident that gave rise to the October 2011 finding of immediate jeopardy and condition level deficiencies. Specifically, a follow-up survey conducted November 9-17, 2011 showed non-compliance with six Medicare Conditions of Participation. The hospital was told that it would be terminated from the Medicare program effective January 19, 2012. *See* Exhibit F.

Then in a complaint investigation conducted on November 29-30, 2011, state surveyors found an immediate jeopardy and three condition-level deficiencies at CFVMC based on the fact that hospital staff had failed to revaluate a 30-year old cancer patient who died on November 22, 2011 after being involuntarily discharged from CFVMC. *See* Exhibit G.

Then in a December 20-22, 2011 survey, surveyors uncovered additional violations, including an immediate jeopardy and four condition level deficiencies. Once again, CFVHS was placed on a track for Medicare decertification. *See* Exhibit H.

In addition, on November 2, 2011, CMS informed CFVHS that based on a March 2011 survey that uncovered EMTALA violations, CFVHS was being terminated from the Medicare program effective December 29, 2012. *See* Exhibit I.

All told, during 2011, CFVHS was threatened with the loss of Medicare payments *five times* because of quality issues. This is an unusually high number for a North Carolina hospital. The number and severity of these incidents (three immediate jeopardy and seventeen condition level citations) demand a rigorous application of Criterion (20).

The problems continued into 2012. On January 26, 2012, a complaint investigation was conducted, which resulted in four condition level deficiencies and several standard level deficiencies. *See* Exhibit J. *See also* Exhibit 35 to CFVHS's 28-bed application. When The Joint Commission did its unannounced survey of CFVMC in March 2012, The Joint Commission uncovered deficiencies regarding the following Medicare Conditions of Participation: § 482.24: Medical Record Services; § 482.41: Physical environment; and § 484.51: Surgical Services. *See* Exhibit 35 to the 28-bed application, which is a June 1, 2012 letter from The Joint Commission to CFVHS. While these deficiencies were eventually resolved, they illustrate the ongoing nature of the quality problems at CFVHS.[1]

[1] A January 6, 2012 survey resulted in a standard level deficiency for failure to supervise contract staff. *See* Exhibit K.

CFVHS may suggest that one of the reasons it has had so many immediate jeopardy and condition level deficiency citations is that it is overcrowded and needs more beds. The quality problems at CFVMC appear to be multi-faceted. They cannot be reduced to a single issue such as a lack of beds.

The Agency does not need to, and should not speculate whether these incidents could have been avoided if there had been more beds at CFVMC. There is no evidence that having more beds would have made any difference at all. It cannot be debated that these incidents actually occurred and that CFVHS has a duty to provide quality care to all of its patients regardless of how busy the hospital is. Criterion (20) does not make allowances for occupancy levels.

The law requires the applicant to demonstrate that it has provided quality care in the past, and the evidence available during the 18-month look back period shows that CFVHS did not do so on multiple occasions. Ensuring the safety of North Carolina citizens is one of the fundamental tenets of the CON Law. Thus, the application must be denied pursuant to Criterion (20).[2]

III. THE CFVHS APPLICATION IS NONCONFORMING WITH CRITERION (3) BECAUSE THE APPLICANT DOES NOT DEMONSTRATE THE NEED FOR THE 28 BEDS.

CFVHS has recently received a CON for Project I.D. M-8689-11 to develop a 65-bed hospital in northern Cumberland County. The new hospital is called CFV North, and it is projected to open on April 1, 2015. In the CON application for CFV North, CFVHS stated "[t]he proposed location in Cumberland County will expand access to the residents of northern Cumberland County while decompressing congestion on the CFVMC campus in Fayetteville. CFVMC has determined that the proposed project provides the most effective alternative for the development of acute care hospital services." Application for Project I.D. M-8689-11, page 79. *See also* page 83 ("Development of the proposed 65 new acute care beds at CFV North, in addition to meeting the primary and secondary acute care needs of the defined service area, will allow the shift of patient day volume out of the existing beds at CFVMC relieving the high utilization at CFVMC and relieving congestion on the CFVMC campus."); page 112 (baseline CY 2010 patient days shifted to CFV North is 14,694 acuity adjusted patient days); page 136 ("Projected utilization for CFV North is based upon a shift of volume from CFVMC to CFV North."). These application excerpts are found in Exhibit L.

Although the Agency initially disapproved the 65-bed application pursuant to Criterion (20), it did find that CFVHS had demonstrated the need for the project. Thus, the Agency accepted as reasonable CFVHS's representations that there would be a significant volume shift from CFVMC to CFV North.

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[2] Failure to conform to Criterion (20) also renders the application non-conforming with Policy Gen-3 and Criterion (1).

Hoke Community Medical Center, with 41 beds, is also projected to decompress CFVMC. HCMC is projected to open on May 1, 2014. *See* page 53 and Exhibit 30 to the 28-bed application. In the HCMC application, excerpts of which are attached as Exhibit M, CFVHS represented that "[t]he proposed location [of HMCMC] in Hoke County will expand access to the residents of Hoke County and southwest Cumberland County while decompressing congestion on the Owen Drive Campus of CFVHS." *See* Exhibit M, page 26. *See also* statements on pages 90, 94-96 of Exhibit M, which reference the decompressing effect that HCMC will have on the Owen Drive campus of CFVMC.

In the HCMC application, CFVHS stated:

"Developing the 41 acute care beds at HCMC, in addition to meeting the primary and secondary acute care needs of the defined service area, will allow the shift of patient day volume out of the existing beds at CFVMC, thus allow3ing additional specialty level admissions that currently leave Cumberland County. Exhibit M, page 95.

"One of the many reasons for the development of the proposed community hospital is to allow less acute patients from Hoke and southwest Cumberland County to receive care in a community hospital setting closer to home. This would free up acute care beds at CFVMC to permit additional admissions for specialty patients currently leaving the area for care." Exhibit M, page 96.

"Projected volumes for HCMC will be shifted from CFVMC reducing congestion on the current campus and improving access for the population of southwest Cumberland and Hoke Counties." Exhibit M page 127.

Using the data on page 127 of the HCMC application, this accounts for a volume shift of 28,661 patient days between 2014-1016. Notably, CFVHS claimed that it was being conservative in its projection of volume shifts from CFVMC to HCMC. *See* Exhibit M, page 142. Data documenting the projected volume shifts to HCMC for all services proposed to be offered at HCMC is contained in Exhibit M, pages 140-171.

In the HCMC application, CFVHS also represented that approximately:

- 60% of HCMC's inpatients;
- 70% of HCMC's outpatient visits;
- 63% of HCMC's emergency visits; and
- 61% of HCMC's surgery cases

would originate from Cumberland County. Exhibit M, pages 183-184.

Thus, in 2012, CFVHS has received CONs that allow it to develop a total of 106 beds in two new hospitals, both of which will significantly decompress the Owen Drive campus of CFVMC due to the shift of patient days to those facilities.

These two projects should be developed *before* the Agency awards CFVHS any additional beds. By doing so, CFVHS is held to the statements it made in its HCMC and CFV North applications. The State also has the opportunity to see how the decompression has worked before it awards more beds. This is logically and orderly health planning, which is exactly what the SMFP and North Carolina's health planning process are designed to accomplish.

CFVHS is not disadvantaged at all because CFVHS is allowed to seek relief from the State for a 10% increase in licensed bed capacity as many times as it wants. *See* 10A NCAC 13B.3111. The North Carolina Administrative Code does not impose any limits regarding how many times a hospital can seek, or how many times the State can grant a temporary increase in licensed bed capacity. CFVHS has been very successful using this process on a repeated basis. *See* Exhibit 6 to the CON Application. In fact, the temporary increase procedure yields CFVHS significantly more beds than are available in this 28-bed review (the 10% yields 49 temporary beds currently, and this will increase to 60 beds once the 65 beds are implemented at CFV North and the 41 beds are implemented in Hoke County).

The Agency should also consider the impact of the 50-bed Harnett Health Central Campus (HHCC) hospital in Lillington. This new hospital is scheduled to open in late 2012 or early 2013. As CFVHS acknowledges on page 53 of the application, "CFVMC meets the needs of 13% of total admissions from Harnett County." The premise of HHCC is to recapture some of those patients who now leave Harnett County for their hospital care. Presumably, some of the 13% who now go to CFVMC will stay in Harnett County once HHCC opens. Yet CFVHS unreasonably chose not to consider the availability of this additional resource in developing its utilization projections.

CFVHS cites the fact that HHCC did not oppose or appeal the CFV North application as proof that CFVHS did not need to consider the opening of HHCC. The lack of comments or an appeal by HHCC is irrelevant. It is CFVHS's responsibility, as the applicant, to consider the availability of additional resources to alleviate congestion at CFVMC. It was unreasonable for CFVHS to summarily reject the opening of a new hospital by a competitor as a factor that could aid in decompressing CFVMC, when CFVHS acknowledges that its own new hospitals, CFV North and HCMC, will decompress CFVMC.

The opening of HHCC *and* the opening of CFV North *and* the opening of HCMC are three significant events that will undoubtedly lead to some decompression on the Owen Drive campus of CFVMC.

It should also be noted that FirstHealth's pending 28-bed application expects that approximately 6% of the patients at FirstHealth Hoke Community Hospital will come from Cumberland County. *See* FirstHealth's 28-bed application, page 89. Some of these patients could be patients who currently use CFVMC for hospital services. Further, in FirstHealth's 8-bed application, FirstHealth projected that 100% of its patients for FHCH would come from Hoke County. Some of these Hoke residents could also be patients who chose CFVMC for hospital services. Thus, FHCH could also have a decompressing effect on CFVMC.

All told, before 2018, there will be four new hospitals in the region. Together and separately, these four new hospitals will lead to decompression at CFVMC.

CFVHS also failed to mention Bladen County Hospital. Almost 18% of Bladen County's hospital admissions go to CFVMC. *See* Application, page 45. CFVHS leases Bladen and controls Bladen's operations. Though Bladen is a critical access hospital, CFVHS advertises that "Bladen County Hospital offers a wide range of patient services close to home to meet all your healthcare needs." http://www.capefearvalley.com/bladen/services.html. According to its 2012 Hospital License Renewal Application, Bladen's average daily census during FFY 2011 was only 10.5. Thus, Bladen is another resource that is available to provide some relief to CFVHS.

Attached as Exhibit N is a chart showing CFVHS's utilization at various levels through 2018, with the assumption that CFVHS in total is licensed for no more than 596 acute care beds (490 current plus 41 plus 65), and that CFVMC is licensed for no more than 490 acute care beds (*i.e.*, it does not add 28 beds). While the chart shows that CFVMC remains very highly utilized through 2018 (just slightly under the 90% occupancy target needed for temporary increase in licensed bed capacity), the CFVHS system as a whole has an occupancy range in the low to mid eighties, and there is definite room for growth at *both* CFV North and HCMC. Significantly, this chart does not reflect decompression due to the new hospital in Harnett County or FirstHealth's hospital in Hoke County.

While none of these new hospitals will be a tertiary hospital, these four facilities will have the ability to treat a range of cases. They can alleviate some of the stress put on CFVMC's occupancy levels, especially with respect to lower acuity cases. And again, the relief valve offered by the temporary increase in licensed bed capacity in 10A NCAC 13B.3111 is a vital tool that CFVHS has used successfully.

Judging from the discussion on pages 19 and 20 of the application, it appears that there are some facility issues in the patient rooms at CFVMC. It is important that the Agency distinguish the need for beds from the needs of the facility, as these are entirely separate issues. The facility needs can be addressed *without* adding more beds.

The Agency should also consider the fact that CFVHS has a well-documented history of not developing, for a very long time, some of the beds it has been awarded. As the Agency will recall, it was back in 2004 that CFVHS applied for the 41 beds that are now going to Hoke County. Those 41 beds, similar to the 28 beds in the current application, were supposed to be developed at CFVMC at a relatively low capital cost. Those 41 beds were never developed at CFVMC. Five years after it applied for these beds, CFVHS announced in 2009 that it would develop the beds in Hoke County. Hoke Community Medical Center is scheduled to open in 2014, ten years after the application was filed.

Exhibit O contains excerpts from the 2004 application. These excerpts show that CFVHS made many of the same arguments then that it is making now – extremely high occupancy levels at CFVMC creating an urgent need to add beds. Despite the high occupancy

levels at CFVMC, CFVHS did not develop 41 of the beds on anything close to the schedule set forth in the application.

In a competitive review, the Agency should carefully consider the applicant's track record of developing – or not developing – in a timely manner resources that have been determined by the SHCC to be needed by citizens of this State. This is especially true in this case, where one of the potential locations for these beds, Hoke County, is a growing but medically underserved community. Cumberland County, by contrast, is already richly served by health care assets, and there are more assets coming on line, *e.g.*, CFV North.

It is also important to note that both of the Hoke hospital projects are proposed to be developed with beds that either exist in another location (Moore County) or were originally approved for another location (Cumberland County). The 65 beds from the 2011 review were awarded to Cumberland County. The 2012 review is the first time for the Agency to award new beds to Hoke County, and it may be the only time for several years to come. Once a hospital is developed in Hoke County, Hoke County will become its own planning area for purposes of the SMFP. The Agency should pay particular attention to the needs of this growing community and ensure that the Hoke hospitals have the ability to accommodate what is expected to be significant demand. By doing so, the Agency not only helps Hoke County residents but also addresses some of the capacity issues at CFVMC, as more Hoke residents will be able to stay in Hoke County for their health care. Further, CFVMC always has the "relief valve" offered by 10A NCAC 13B.3111.

IV. THE APPLICATION IS NON-CONFORMING WITH CRITERIA (4), (5), AND (6).

Since the applicant cannot demonstrate the need for the project, it follows that the applicant cannot demonstrate that it has chosen the least costly or most effective alternative (Criterion 4); that its project is financially feasible (Criterion 5); and that its project does not cause unnecessary duplication of existing or approved services (Criterion 6).

The least costly or most effective alternative is for CFVHS to continue doing what it has been doing, apparently at no additional capital cost: seek temporary increases in licensed bed capacity. As discussed above, this proposed project also causes unnecessary duplication of services because of the development of CFV North and HHCC.

In addition, CFVHS does not discuss whether and to what extent Highsmith Rainey Specialty Hospital can provide a relief valve for CFVMC. While the 66 beds at HRSH have a high occupancy (58.3 average daily census based on its 2012 Hospital License Renewal Application), CFVHS does not discuss the extent to which some of CFVMC's more medically complex patients who are appropriate for LTACH services could be transferred to HRSH. Interestingly, CFVHS has used HRSH's assets (*e.g.*, operating rooms) to facilitate the development of other projects, such as CFV North and HCMC.

Concerning Criterion (6), the Agency should also consider the fact that many of the hospitals in CFVMC's service area are underutilized. *See, e.g.*, page 68 of the 28-bed application. This is relevant for two reasons: (1) there is significant available capacity among existing hospitals in CFVMC's service area; and (2) by allowing the largest hospital in the area to expand even further, the Agency may be making it even less likely that these smaller hospitals that compete with CFVMC will ever reach target occupancy. Giving CFVMC more beds will enhance CFVMC's ability to draw patients from these underutilized providers, and therefore create an even greater imbalance. CFVHS dismisses the capacity of the other providers by noting that only CFVHS could apply for the 28 beds, as none of the other providers is located in the Hoke/Cumberland service area. Whether a provider is able to apply for beds has no bearing on Criterion (6); the point is that there is significant excess capacity in the service area among the existing hospitals and CFVHS may only be exacerbating the situation by expanding its Owen Drive campus.

V. THE APPLICATION IS NON-CONFORMING WITH CRITERION (18a).

Criterion (18a) states:

> The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, *quality* and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, *quality* and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

N.C. Gen. Stat. § 131E-183(18a)(emphasis added).

Quality is an important element of Criterion (18a). For the reasons stated above, CFVHS has failed to demonstrate that it has provided quality care on multiple occasions. Competition is not enhanced by awarding more beds to a provider that has had difficulties providing quality care. Therefore, CFVHS's proposal should be found non-conforming with Criterion (18a).

Moreover, adding more beds to the sole existing provider of acute care hospital services in Cumberland County cannot "enhance" competition *when there is no competition,* at least not in Cumberland County. In order for competition and Criterion (18a) to be meaningful, the 28 beds should be awarded to FirstHealth in Hoke County, where it will compete head to head with CFVHS's 41-bed hospital.

VI. CONCLUSION

For the reasons stated above, the CFVHS application should be denied. FirstHealth appreciates the Agency's consideration of these comments.

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
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March 15, 2012

CERTIFIED MAIL

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RE: Final Agency Decision for Contested Case of RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers-Concord v. North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section and Total Renal Care of North Carolina, LLC: 11 DHR 03173 and Total Renal Care of North Carolina, LLC v. North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section and RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Center-Concord: 11 DHR 03476

Dear Counsel:

Enclosed is the Department of Health and Human Services' final agency decision in the above-referenced matter. You may obtain judicial review of this decision, pursuant to N.C. General Statute §131E-188(b). The appeal shall be to the N.C. Court of Appeals as provided in N.C. General Statute §7A-29(a).

If you choose to seek judicial review, you must file notice of appeal with the Division of Health Service Regulation, Department of Health and Human Services. Your notice of appeal must be filed within 30 days after you receive your copy of the final agency decision. You must also file copies of the notice of appeal with all other affected persons who were parties of the contested case hearing. The procedure for the appeal shall be as provided by the N.C. Rules of Appellate Procedure.

Sincerely,

Jeff Horton

JH:peb

Enclosure

EXHIBIT
tabbies
A

Contested Case of
11 DHR 03173 and 11DHR 03476
March 15, 2012

cc: Brian B. Axelroth, Esq., Associate General Counsel, Renal Advantage, Inc.
William L. Hyland, Director of Healthcare Planning, DaVita, Inc.
Emery Edwards Milliken, General Counsel, Legal Affairs
Drexdal Pratt, Director, DHSR
Craig Smith, Chief, Certificate of Need Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
Kim Hausen, Chief Hearings Clerk, Office of Administrative Hearings

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA
11 DHR 03173 and 11 DHR 03476

RAI CARE CENTERS OF NORTH CAROLINA II, LLC d/b/a RAI CARE CENTERS-CONCORD Petitioner, v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION Respondent, and TOTAL RENAL CARE OF NORTH CAROLINA, LLC, Respondent-Intervenor.	**FINAL AGENCY DECISION**
TOTAL RENAL CARE OF NORTH CAROLINA LLC .Petitioner, v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION Respondent, and RAI CARE CENTERS OF NORTH CAROLINA II, LLC d/b/a RAI CARE CENTERS-CONCORD Respondent-Intervenor.	

I, the undersigned designee of the Secretary of the Department of Health and Human Services, having reviewed the record in the above - referenced matter, including Administrative Law Judge Joe L. Webster's 15th December, 2011 Decision, having considered the parties' written exceptions and written oral arguments do hereby adopt as my own the Findings of Fact, Conclusions of Law and the Decision of the Administrative Law Judge which is attached hereto and incorporated by reference as if fully set out herein.

This the 15th day of March, 2012.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

Filed
2011 DEC 15 PM 5:06
Office of
Administrative Hearings

STATE OF NORTH CAROLINA

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS

COUNTY OF CABARRUS

RAI CARE CENTERS OF NORTH CAROLINA II, LLC d/b/a RAI CARE CENTERS-CONCORD,

Petitioner,

v.

N.C. DEPT. OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent,

and

TOTAL RENAL CARE OF NORTH CAROLINA, LLC,

Respondent-Intervenor.

File No. 11 DHR 3173

TOTAL RENAL CARE OF NORTH CAROLINA, LLC,

Petitioner,

v.

N.C. DEPT. OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent,

and

RAI CARE CENTERS OF NORTH CAROLINA II, LLC d/b/a RAI CARE CENTERS-CONCORD,

Respondent-Intervenor.

File No. 11 DHR 3476

This matter came for hearing before Joe L. Webster, Administrative Law Judge ("ALJ"), on October 3-7 and 11, 2011, in Raleigh, North Carolina. Having heard all of the evidence in the case, and having considered the exhibits, arguments, and relevant law, the undersigned makes the Findings of Fact, by a preponderance of the evidence, enters his Conclusions of Law thereon, and makes the following decision.

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APPLICABLE LAW

1. The procedural statutory law applicable to this contested case hearing is the North Carolina Administrative Procedure Act ("APA"), N.C. Gen. Stat. § 150B-1, *et seq.*

2. The substantive statutory law applicable to this contested case hearing is the North Carolina CON Law, N.C. Gen. Stat. § 131E-175, *et seq.*

3. The administrative rules applicable to this contested case hearing are the North Carolina Certificate of Need Administrative Rules, 10A N.C.A.C. 14C.0101, *et seq.*, the Criteria

and Standards for End-Stage Renal Disease Services, 10A N.C.A.C. 14C.2200, *et seq.*, and the Office of Administrative Hearings Rules, 26 N.C.A.C. 3.0001, *et seq.*

BURDEN OF PROOF

RAI, TRC Harrisburg and TRC Cabarrus each bears the burden of showing by the greater weight of the evidence that the Agency substantially prejudiced their respective rights, and that the Agency also acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule:

1. In finding RAI's competing application to develop a 23 station dialysis facility in Cabarrus County nonconforming with statutory review Criteria 1, 3, 4, 5, 6, 13(c), 18a and 20 and rules 10A N.C.A.C.14C.2203(a).

2. In finding TRC Harrisburg's competing application to add stations to its existing dialysis facility in Cabarrus County, nonconforming with statutory review Criteria 1, 4, 18a and 20 and rules 10A N.C.A.C.14C.2204(7) and (1).

3. In finding TRC Cabarrus's competing application to develop a 10 station dialysis facility in Cabarrus County nonconforming with statutory review Criteria 1, 4, 18a and 20.

N.C. Gen. Stat. § 150B-23(a); *Britthaven, Inc. v. N.C. Dept. of Human Resources, et al.*, 118 N.C. App. 379, 455 S.E.2d 455, 459, *disc. rev. denied*, 341 N.C. 418, 461 S.E.2d 754 (1995). *Also see generally*, Jt. Ex. 1 at 1264-1332.

ISSUES PRESENTED

1. Whether the Agency exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule law by finding the RAI Application nonconforming with multiple statutory review criteria in N.C. Gen. Stat. § 131E-183(a) and regulatory criteria in 10A N.C.A.C. 14C.2200 *et seq.*, and denying the RAI Application.

2. Whether the Agency exceeded its authority or jurisdiction, acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule by finding the TRC Harrisburg Application nonconforming with multiple statutory review criteria in N.C. Gen. Stat. § 131E-183(a) and regulatory criteria in 10A N.C.A.C. 14C.2200 *et seq.*, and denying the TRC Harrisburg Application.

3. Whether the Agency exceeded its authority or jurisdiction, acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule by finding the TRC Cabarrus Application nonconforming with multiple statutory review criteria in N.C. Gen. Stat. § 131E-183(a), and denying the TRC Cabarrus Application.

4. It was stipulated by the Parties that the following statutory review criteria are not at issue in this contested case: N.C. Gen. Stat. § 131E-183(a)(3a), Criterion 3a, § 131E-183(a)(7), Criterion 7, § 131E-183(a)(8), Criterion 8, § 131E-183(a)(9), Criterion 9, § 131E-183(a)(10), Criterion 10, § 131E-183(a)(12), Criterion 12, § 131E-183(a)(13(a-e)), Criterion 13, § 131E-183(a)(14), Criterion 14. (Joint Prehearing Order, p. 13)

WITNESSES

A. Witnesses for RAI

1. Angela Allen Matthes. Ms. Matthes currently is employed as an investigator at the North Carolina Board of Nursing. (Matthes, Vol. 1; p. 27) Ms. Matthes also worked at the Agency, first as a Project Analyst and then a Team Leader. (Matthes, Vol. 1, p. 28)

2. Martha Frisone. Ms. Frisone is currently employed as the Assistant Chief by the Agency, a position she has held since March 1, 2010. (Frisone, Vol. 1, pp. 133-34) Ms. Frisone has been employed by the Certificate of Need Section since 1994 and has served as a Project Analyst and Team Leader. (Frisone, Vol. 1, p. 134)

3. Tanya Rupp. Ms. Rupp is currently employed as a Project Analysis with the Agency. (Rupp, Vol. 1, p. 187) Ms. Rupp was the Project Analyst for the review of the RAI Application, the TRC Harrisburg Application, the TRC Cabarrus Application and the TRC Copperfield Application. (Rupp, Vol. 1, p. 190)

4. Celine Marie McGill. Ms. McGill is Regional Director for Renal Advantage, Inc. She has been employed by RAI since 2005. (McGill, Vol. 2, pp. 272-73)

5. Craig Richard Smith. Mr. Smith is the Chief of the Certificate of Need Section and has held that position since December 2009. (Smith, Vol. 2, p. 231) Mr. Smith has been employed by the Certificate of Need Section first as a Project Analyst and then as Assistant Chief since 1988. (Smith, Vol. 2, pp. 330-31)

6. Sawsan Yateem. Ms. Yateem is a Registered Nurse and Center Director of the RAI Glenwater facility in Charlotte. She has worked in dialysis care since 1993. (Yateem, Vol. 2, pp. 398, 400)

7. Maura Theresa McCann. Ms. McCann is a Registered Nurse and the Regional Quality Administrator for RAI and is responsible for thirteen outpatient dialysis clinics in both North Carolina and South Carolina. (McCann, Vol. 2, p. 438-39) She has been working in dialysis since the early 1970s. (McCann, Vol. 2, p. 439) She was admitted by the Court as an expert witness is the field of quality assurance and outpatient dialysis clinics. (McCann, Vol. 2, p. 446)

8. David Stephen Legarth. Mr. Legarth is the owner of DanEs Planning, Inc., a health care planning firm specializing in CON preparation and other related CON regulatory issues primarily in the State of North Carolina. (Legarth, Vol. 2, p. 488) Mr. Legarth was the

preparer of the RAI Application. He holds a bachelor's degree in business administration from East Carolina University and a master's degree in health care administration from the University of North Carolina at Chapel Hill. He has prepared approximately 90 CON applications as the sole preparer and has assisted with the preparation of approximately 40 to 50 additional CON applications concerning a variety of proposals and modalities. (Legarth, Vol. 2, pp. 487-89) Mr. Legarth was admitted by the Court as an expert witness in CON preparation and analysis and health planning. (Legarth, Vol. 2, p. 496)

B. Witnesses for TRC Harrisburg and TRC Cabarrus

1. William K. Halstenberg, M.D. Dr. Halstenberg is a nephrologist licensed to practice medicine in the State of North Carolina. (Halstenberg, Vol. 1, p. 89) Dr. Halstenberg is employed at Central Carolina Nephrology in Concord, Cabarrus County, North Carolina.

2. Tammy Leahy. Ms. Leahy is a Registered Nurse and Regional Operations Director for DaVita. (Leahy, Vol. 3, pp. 738-39) She has been employed in that capacity for six years and as of the date of the TRC Applications was responsible for TRC Copperfield and TRC Harrisburg facilities. (Leahy, Vol. 3, p. 739)

3. Celine Codd. Ms. Codd is a Registered Nurse and is employed as the Director of Clinical Services for DaVita. (Codd, Vol. 4, pp. 844-45) She has held that position for seven to eight years and is responsible for high level overview of facilities in North Carolina, Virginia and South Carolina as it related to quality, education and survey preparedness. (Codd, Vol. 4, p. 846) Ms. Codd was admitted as an expert witness by the Court in matters relating to quality assurance in outpatient dialysis facilities. (Codd, Vol. 4, p. 847)

4. Daniel J. Sullivan. Mr. Sullivan is employed by Sullivan Consulting Group, Inc. (Sullivan, Vol. 4, p. 968) Mr. Sullivan holds a master's degree in health administration from Duke University. He has worked in the health care industry since 1974. (Sullivan, Vol. 4, p. 969) Mr. Sullivan was admitted by the Court as an expert witness in the areas of CON preparation and analysis and health planning. (Sullivan, Vol. 4, p. 972)

5. William Lawrence Hyland. Mr. Hyland is the Director of Health Care Planning for DaVita, Inc. where he has been employed nearly twelve years. (Hyland, Vol. 4, p. 1111) He prepared the TRC Harrisburg, TRC Cabarrus and TRC Copperfield Applications. Mr. Hyland was admitted by the Court as an expert witness in dialysis certificate of need preparation and analysis.

C. Witnesses for Agency

1. Tanya S. Rupp. Ms. Rupp holds a Bachelor of Arts degree in political science and a Juris Doctor degree. (Rupp, Vol. 5, p. 1228) She has been employed as a Project Analyst by the CON Section since 2005. *(Id.)*

2. Craig Richard Smith. Mr. Smith is the Chief of the CON Section and has worked for the CON Section for over 23 years. (Smith, Vol. 6, p. 1283) He holds a bachelor's degree in

political science from the University of New Hampshire and a master's degree in urban and regional planning from Virginia Tech. (Smith, Vol. 6, p. 1285) He has been responsible for approximately 600 dialysis decisions over his tenure at the CON Section. *(Id.)*

EXHIBITS ADMITTED INTO EVIDENCE

Joint Exhibits

1. Agency File
2. CON Application of TRC Cabarrus, Project I.D. No. F-8581-10
3. CON Application of TRC Copperfield, Project I.D. No. F-8584-10
4. CON Application of TRC Harrisburg, Project I.D. No. F-8577-10
5. CON Application of RAI, Project I.D. No. F-8590-10

RAI Exhibits

101. Respondent's Objections and Responses to Petitioner's First Set of Interrogatories and First Request for Production of Documents
104. Map: Projected Population Growth, 2010-2020
105. Chart: Annual County Population Totals, 2010-2019
106. Web Page: University Medical Associates/Medical Providers
107. Web Page: Carolinas Medical Center/Carol Anne Rupe, M.D.
108. Licensee Information – Amir Ishak Kaldas, M.D.
109. Licensee Information – Curtis William DeSena, M.D.
110. Licensee Information – Ronnie Thurston Beamon, M.D.
111. Licensee Information – Shalini Mundra, M.D.
112. Licensee Information – Roberto Fulvio Ferraro, M.D.
113. Tally of RAI Physician Letters in RAI Application Number 12
114. Web Page: Town of Huntersville

115. Chart: Census figures for Mecklenburg County

116. Chart: Zip Code of Residence for Patients Currently Dialyzing in Network 6 Units (grouped by State and County and current as of 1/3/2011)

117. Chart: Zip Code of Residence for Patients Currently Dialyzing in Network 6 Units (grouped by State and County and current as of 10/6/2010)

118. Total Renal Care of North Carolina, LLC's Responses and Objections to RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers-Concord's First Set of Interrogatories and First Request for Production of Documents

119. Required State Agency Findings dated 2/10/09 issued to Total Renal Care of North Carolina, LLC d/b/a Davie County Dialysis Center, Project I.D. No. G-8222-08 and Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center, Project I.D. No. G-8227-08

120. C.V. of Maura Traynor McCann

123. TRC Copperfield August 3, 2009 Licensure and Certification Survey Report, RAI Bates-Stamp RAI CABARRUS 2757-2774

125. Dialyzer

126. Dialyzer with top off to expose fibers

127. Clamp

134. DaVita Mission Statement

139. Dr. Van Wyck's PowerPoint Presentation entitled *Governance, Administrative & Supervisory Issues for the Medical Director*

140. Letter dated 3/18/10 to North Charlotte Dialysis Center from Acute and Home Care Licensure and Certification Section regarding Recertification Survey and attached March 4, 2010 survey report (for impeachment purposes only)

141. Letter dated 2/16/11 to Southeastern Dialysis-Wilmington from Acute and Home Care Licensure and Certification Section regarding Follow-Up Survey, ESRD CMS Certification Number (CCH): 34-2511 and attached January 21, 2011 survey report (for impeachment purposes only)

142. Letter dated 3/30/09 to Dialysis Care of Richmond County from Acute and Home Care Licensure and Certification Section regarding Medicare Complaint Survey, CMS Certification Number (CCN): 342539 (for impeachment purposes only)

143. Letter dated 1/10/11 to Charlotte East Dialysis from Acute and Home Care Licensure and Certification Section regarding Follow-Up Survey, ESRD CMS Certification Number (CCN): 34-2627 and attached October 21 and 28, 2010 survey reports (for impeachment purposes only)

145. January 15, 2009 Dialysis Care of Kannapolis Survey Report (for impeachment purposes only)

146. Letter dated 4/21/09 to Goldsboro South Dialysis from Acute and Home Care Licensure and Certification Section regarding Medical Recertification Survey, CMS Certification Number (CCH): 342587 and attached April 9, 2009 survey report (for impeachment purposes only)

147. Letter dated 8/2/10 to Vance County Dialysis from Acute and Home Care Licensure and Certification Section regarding Medicare Recertification Survey, CMS Certification Number (CCH): 342543 and attached July 16, 2010 survey report (for impeachment purposes only)

149. David Legarth Expert Opinion, June 24, 2011

152. Documents Produced by TRC (p. 467 only)

154. Chart: List of Patients in Cabarrus County and Huntersville

155. Excerpt from RAI Care Center's CON Application, Project I.D. No. F-7674-06

161. CON Application of Jacksonville Diagnostic Imaging, LLC

169. Agency Findings, April 8, 2009 New Hanover County, pp. 38-58; Richmond County, 59-75; and Wake County, 76-95 only)

170. Documents produced by RAI (p. 430 only)

179. Deposition transcript of William Hyland dated 8/31/2011 (cover page and pp. 90-92 only

182. Deposition transcript of Kathleen A. Doman, M.D. dated 9/13/2011

183. Deposition transcript of Charles Stoddard, M.D. dated 9/20/2011

185. Deposition transcript of Steve Quarles dated 9/8/2011

186. Deposition transcript of Jim Tarwater dated 9/8/2011

187. Chapter 14 of the 2010 State Medical Facilities Plan

188. Photograph: Cuffed Hemodialysis Catheter

189. Photograph: Dialysis Machine with Central Venous Line

190. Photograph: Dialysis Machine with AV Fistula Connection

191. Dialyzer with tubing

TRC Exhibits

202. Resume for Daniel J. Sullivan

203. Curriculum Vitae for Celine M. Codd

206. Total Renal Care of North Carolina, LLC's First Supplemental Responses and Objections to RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers-Concord's First Set of Interrogatories and First Request for Production of Documents

207. Respondent's Objections and Responses to Petitioner's First Set of Interrogatories and First Request for Production of Documents

211. E-mail string from Tarwater to Oman and McGill re: Cabarrus County CON site search

212. E-mail from Quarles to McGill, cc: Tarwater re: Cabarrus Co. Real Estate – FYI; and 09/02/10 E-mail from Tarwater to Quarles and McGill re: Cabarrus County, NC with attachment

213. E-mail string from Oman to Tarwater re: Concord NC-CON Sites

214. E-mail string from Tarwater to McGill cc: Quarles re: Cabarrus County, NC

218. E-mail string from Donohoo to Tarwater re: FW: Floor Plan for Cabarrus County

220. E-mail string from Legarth to Tarwater and Sundock re: Cabarrus County

225. E-mail string from Tarwater to Donohoo

229. E-mail string from Hyland to Stillings cc: Santillo re: Counties for pts. 587 hemo-home-hemo and pd

231. Dan Sullivan's Expert Report

232. Supplement to Dan Sullivan's Expert Report

234. Supplement to Dan Sullivan's Expert Report

238. E-mail string from McGill to Quarles re: NC Dialysis Report (SDR)

239. E-mail string from Quarles to McGill re: Concord, NC potential center site search with map of Cabarrus County showing TRC facilities and CMC-NE locations

240. E-mail from Doman to McGill

241. E-mail string from Doman to McGill re: Urgent questions for CON

242. E-mail string from Quarles to McGill

245. E-mail string from McGill to McCann re: FW: CON with attachments

252. RAI Glenwater CON Application - without exhibits

255. Required State Agency Findings for Project I.D. No. F-7674-06 – RAI's Application to develop a new 10-station dialysis facility in Huntersville

256. Excerpts from RAI's Application to relocate 10 stations to Huntersville (including patient support letters) – Project I.D. No. F-7674-06

261. Codd's Summary of the issues based on her review of the CON Findings

262. DaVita Hemodialysis Policies, Procedures & Guidelines

263. DaVita Website Information

264. TRC In-Service Records

266. Excerpt from Fresenius Medical Care - 2008K Hemodialysis Machine Operator's Manual

267. Letter from DHHS to Luke Santillo at Copperfield re: Recertification and Complaint Investigation with clean copy of 1/28/2010 survey

271. Initial Harrisburg Survey and Cover Letter

272. Correspondence from DHHS to Amanda Herring re: 05/13/2010 Harrisburg Dialysis Complaint Survey

BASED UPON careful consideration of the sworn testimony of the witnesses presented at the hearing, the documents and exhibits received and admitted into evidence, and the entire record in this proceeding, the Undersigned makes the following Findings of Fact. In making the Findings of Fact, the Undersigned has weighed all the evidence and has assessed the credibility of the witnesses by taking into account the appropriate factors for judging the credibility, including but not limited to, the demeanor of the witnesses, any interests, bias, or prejudice the witness may have, the opportunity of the witness to see, hear, know, or remember the facts or occurrences about which the witness testified, whether the testimony of the witness is reasonable, and whether the testimony is consistent with all other believable evidence in the case.

FINDINGS OF FACT

1. On or about September 15, 2010, RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers-Concord ("RAI") submitted a certificate of need ("CON") application to develop a 23 station dialysis facility in Concord, Cabarrus County, North Carolina, identified as Project I.D. No. F-8590-10 (the "RAI Application"). (Jt. Ex. 5)

2. On or about September 15, 2010, Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center ("TRC Harrisburg") submitted a CON application to add five dialysis stations to an existing facility for a facility total of 20 stations in Concord, Cabarrus County, North Carolina, identified as Project I.D. No. F-8577-10 (the "TRC Harrisburg Application). (Jt. Ex. 4) The parent company of TRC Harrisburg is DaVita, Inc. (Jt. Ex. 4, p. 2) The entity names TRC and DaVita were used interchangeable throughout the application, contested case hearing and this Recommended Decision to refer to the same entity and company.

3. On or about September 15, 2010, Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis ("TRC Cabarrus") submitted a CON application to develop a new 12 station dialysis facility in Concord, Cabarrus County, North Carolina, identified as Project I.D. No. F-8581-10 (the "TRC Cabarrus Application"). (Jt. Ex. 2) The parent company of TRC Cabarrus is DaVita, Inc. (Jt. Ex. 4, p. 2) The entity names TRC and DaVita were used interchangeable throughout the application; contested case hearing and this Recommended Decision to refer to the same entity and company.

4. On or about September 15, 2010, Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center ("TRC Copperfield") submitted a CON application to add 6 dialysis stations to an existing facility for a facility total of 27 stations in Concord, Cabarrus County, North Carolina, identified as Project I.D. No. F-8584-10 (the "TRC Copperfield Application"). (Jt. Ex. 3) The parent company of TRC Copperfield is DaVita, Inc. (Jt. Ex. 3, p. 2) The entity names TRC and DaVita were used interchangeably throughout the application, contested case hearing and this Recommended Decision to refer to the same entity and company.

5. The 2010 State Medical Facilities Plan ("SMFP") and the July 2010 Semiannual Dialysis Report ("SDR") provide a county need methodology for determining the need for additional dialysis stations. According to Section 2(E) of the dialysis station county need methodology found on page 333 of the 2010 SMFP, "*If a county's December 31, 2010 projected station deficit is ten or greater and the July SR shows that utilization of each dialysis facility in the county is 80% or greater, the December 31, 2010 county station need determination is the same as the December 31, 2010 projected station deficit.* ..." The county need methodology for 2010 resulted in a need determination for 23 dialysis stations in Cabarrus County. (Jt. Ex. 1, pp. 458-59)

6. By letter dated February 25, 2011, the Agency informed RAI that its application had been denied. (Jt. Ex. 1, pp. 78-80) The Agency Findings denying the RAI Application were dated March 4, 2011. (Jt. Ex. 1, pp. 458-531).

7. By letter dated February 25, 2011, the Agency informed TRC Harrisburg that its application had been denied. (Jt. Ex. 1, pp. 17-19) The Agency Findings denying the TRC Harrisburg Application were dated March 4, 2011. (Jt. Ex. 1, pp. 458-531)

8. By letter dated February 25, 2011, the Agency informed TRC Cabarrus that its application had been denied. (Jt. Ex. 1, pp. 47-49) The Agency Findings denying the TRC Cabarrus Application were dated March 4, 2011. (Jt. Ex. 1, pp. 458-531)

9. On March 22, 2011, RAI filed a petition for contested case hearing with the Office of Administrative Hearings ("OAH"), in which it appealed the denial of the RAI Application.

10. On March 28, 2011, TRC Harrisburg and TRC Cabarrus filed a petition for contested case hearing with OAH, in which it appealed the denial of the TRC Harrisburg Application and the TRC Cabarrus Application. TRC Copperfield did not appeal the denial of the TRC Copperfield Application.

11. On April 1, 2011, RAI, TRC Harrisburg, TRC Cabarrus and the Agency filed a joint motion to intervene and petition to consolidate. The joint motion to intervene was entered on April 6, 2011, by the Undersigned, and the petition to consolidate was entered on April 6, 2011 by Chief Administrative Law Judge Mann.

I. Application Review Process

12. The Project Analyst for this competitive review was Tanya S. Rupp. CON Section Chief Craig R. Smith was the cosignor of the Agency Findings. (Jt. Ex. 1, p. 458)

13. A competitive review is one in which the CON Section receives multiple applications competing for the same service and when the approval of one application necessitates the disapproval of another application. (Rupp, Vol. 5, p. 1230)

14. In competitive reviews, Project Analyst Tanya Rupp first reviews each application individually to determine its conformity or non-conformity with each of the applicable statutory and regulatory review criteria. After drafting a set of findings for each application, Ms. Rupp then conducts a comparative analysis using different factors depending on the specific type of review at issue. (Rupp, Vol. 5, pp. 1230-31)

15. Initially, the review of the RAI and TRC Applications was assigned to Project Analyst Dalizza Marques. After Ms. Marques left the Agency, Project Analyst Tanya Rupp was assigned to the review. Ms. Rupp conducted the review by reviewing the tape of the public hearing, reading the competitive comments, the applications and any other materials submitted in support of the applications. (Rupp, Vol. 1, p. 190)

16. Criterion 3 of the CON Law, N.C. Gen. Stat. § 131E-183(a)(3), addresses need. Ms. Rupp testified that the standard for finding an application conforming with Criterion 3 is not perfection. Rather, the application has to be reasonable. (Rupp, Vol. 1, p. 201) For example, Ms. Rupp did not hold certain errors, including mathematical and typographical errors, against the TRC Cabarrus, TRC Harrisburg, or TRC Copperfield Applications in her review and analysis. (Rupp, Vol. 1, pp. 211, 214, 220)

17. The Agency File was compiled by Project Analyst Tanya Rupp and contains all correspondence to or from the Agency regarding the review from the initial submission of the applications, the certification and fee sheets, competitive comments and response to comments, public hearing remarks, notes made by the Project Analyst and copies of any extra sources (including prior Agency Findings) that the Project Analyst utilized in the review of the applications. (Rupp, Vol. 5, pp. 1240-41)

18. CON Section Chief Craig Smith has worked at the CON Section since 1988. (Smith, Vol. 2, p. 330) During his tenure, Mr. Smith has served as a Project Analyst, Assistant Chief, and since December 2009, as Section Chief. (Smith, Vol. 2, p. 331; RAI Ex. 101, Attachment B)

19. Mr. Smith has reviewed applications and prepared Agency Findings as a Project Analyst and has assisted other project analysts by cosigning Agency Findings as the Assistant Chief and Section Chief. (Smith, Vol. 2, p. 332)

20. A cosigner reviews the draft findings, competitive comments, responses to comments in opposition, relevant portions of the applications under review and agrees with the decision. It is a joint decision between the Project Analyst and the cosigner. (Smith, Vol. 2, p. 338) Mr. Smith was the cosigner of the Agency Findings at issue in this review. (Jt. Ex. 1, p. 458)

21. Mr. Smith has particular expertise in the review of dialysis applications. He has been the primary cosigner of dialysis reviews since approximately August 1994 when he became Assistant Chief. (Smith, Vol. 2, pp. 331-32) Former CON Section Chief Lee Hoffman gave Mr. Smith virtually exclusive decision making authority over dialysis reviews when he was made Assistant Chief. (Smith, Vol. 6, p. 1284) Over the course of his 23 years with the CON Section, Mr. Smith estimates he has been responsible for approximately 600 dialysis reviews. (Smith, Vol. 6, p. 1285)

22. During the course of the review of the RAI and TRC Applications, Mr. Smith had a conversation with Bill Hyland, preparer of the TRC Applications, in which Mr. Smith indicated that the need determination for 23 dialysis stations in Cabarrus County was based in part on the zip code for the City of Kannapolis which straddles both Cabarrus and Rowan Counties. It was Mr. Smith's belief that because the Kannapolis zip code was attributed exclusively to Cabarrus County for purposes of determining the need for additional dialysis stations, there was a chance that the need in Cabarrus County and the surplus in Rowan County were overstated. Mr. Smith stated he believed that not all Kannapolis zip code residents dialyzing were actually residents of Cabarrus County. (Smith, Vol. 2, pp. 333-34)

23. Mr. Smith acknowledged in his testimony that the Agency is bound by the need determination in the Semiannual Dialysis Report and is without the authority to change that need determination. (Smith, Vol. 2, p. 334; Rupp, Vol. 1, p. 193)

II. TRC/DaVita Applications

A. Criterion 20

24. Criterion 20 states: "An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past." (Jt. Ex. 1, p. 515) Criterion 20 looks at past behavior. (Smith, Vol. 2, p. 351)

25. The provision of quality care in the past by an applicant is relevant in a CON review because quality of care affects patients served in those facilities. As CON Section Chief Craig Smith testified, "facilities that are having problems addressing care to the current patients need not to be expanding and adding more capacity to serve more patients until they have resolve satisfactorily the issue that they have been dealing with, the quality of care issue." (Smith, Vol. 2, p. 339)

26. Moreover, the CON Law specifically addresses quality of care: "That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services. . . ." *See* N.C. Gen. Stat. § 131E-175(7); (Smith, Vol. 2, p. 340)

27. The CON Section is required to make a determination under Criterion 20 when Criterion 20 is applicable to the review. (Frisone, Vol. 1, pp. 139-40)

28. When analyzing a dialysis application under Criterion 20, the Agency consistently follows a specific process for analyzing past quality of care. First, the Agency completes a form and sends it to the Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section ("Licensure and Certification Section") asking it a series of questions specifically relating to quality of care, including the past track record of the facility. The CON Section has developed a questionnaire specific to facilities proposing expansion and one specific to newly-proposed facilities. (Smith, Vol. 2, p. 341; Matthes, Vol. 1, pp. 33, 74; Frisone, Vol. 1, p. 141)

29. The Licensure and Certification Section is the agency responsible for surveying dialysis facilities in North Carolina. (Smith, Vol. 2, p. 341) The CON Section does not determine the Conditions of Participation in the Medicare program, but only utilizes the data provided by the Licensure and Certification Section. (Frisone, Vol. 1, p. 148) The Licensure and Certification Section is under contract with Medicare to conduct these quality surveys and provide written reports of the same. (Matthes, Vol. 1, p. 30)

30. The CON Section first makes an inquiry to the Licensure and Certification Section concerning the quality of care provided by the facility specifically involved in submitting the CON application. If the applicant also has a facility in the same county as the proposed service, the CON Section inquires about the quality of care in those other facilities located within the same county. (Smith, Vol. 6, pp. 1319-20; Matthes, Vol. 1, p. 33)

31. If the applicant does not have an existing facility in the county in which the service is proposed, the CON Section inquires about the quality of care in facilities owned by the applicant in counties contiguous to the county where the service is proposed. (Smith, Vol. 6, p. 1320; Matthes, Vol. 1, pp. 33-34)

32. In looking at quality of care issues at facilities other than the specific facility involved in the application, the CON Section investigates the relationship between the facilities where any problems with quality of care are reported. This involves a determination of whether there is a sufficient nexus between the Medical Director, the medical staff and the administrative staff of the facilities. (Smith, Vol. 6, p. 1320; Frisone, Vol. 1, p. 175)

33. A nexus can be established where a new facility is proposed but will be utilizing the same Medical Director or administrative staff as an existing facility. In such instances where there is a sufficient nexus, it is relevant and proper for the Agency to look at the quality of care track record of the existing facility in a county contiguous to the proposed facility. (Frisone, Vol. 1, pp. 175-76)

34. Typically, the Agency does not rely upon quality of care issues at facilities owned by the applicant beyond the county contiguous to the service at issue in the application

and would not do so without discussing it with the Licensure and Certification Section if a systemic quality problem was indicated. (Smith, Vol. 6, p. 1324)

35. However, the Agency has the discretion to take a broader view of quality under Criterion 20 and is not limited to investigating on the county in which the service is proposed or contiguous counties. (Smith, Vol. 6, p. 1325)

36. TRC owns multiple dialysis facilities throughout North Carolina in counties contiguous to and not contiguous to Cabarrus County. (Jt. Ex. 3, pp. 74-75) The Agency did not have to conduct a quality of care inquiry for TRC outside of Cabarrus County because the quality of care issue identified was at a facility (TRC Copperfield) located within Cabarrus County.

37. The questionnaire sent to the Licensure and Certification asks a series of questions relating to a facility's quality of care including its past track record. The CON Section also sends the Licensure and Certification Section a copy of the staffing pattern and facility layout to inquire about any potential issues under CMS guidelines with prospective staffing patterns or facility design and patient supervision. (Smith, Vol. 2, p. 341; Jt. Ex. 1, pp. 380, 385)

38. The questionnaire specifically asks whether the facility in question has met all Medicare Conditions of Participation for the 18 month period immediately preceding the date of the Agency's decision on the relevant CON application. (Smith, Vol. 2, p. 342; Jt. Ex. 1, p. 385) The Agency begins with the date of the decision and counts backwards 18 months from that date to calculate the relevant time period for the inquiry to the Licensure and Certification Section. (Smith, Vol. 6, p. 1320)

39. The Agency has consistently utilized a look back period of 18 months in its analysis of quality of care under Criterion 20. (Smith, Vol. 2, p. 342; Frisone, Vol. 1, p. 141; Matthes, Vol. 1, p. 158) The 18-month look back period has been in place since 1988 or shortly thereafter. It was developed after consultations between then CON Section Chief Lee Hoffman and her supervisors and after consideration of issues surrounding quality of care. The only benchmark in the CON Law is a five year look back period for civil rights and equal access complaints, which the Agency determined was too far for quality issues. (Smith, Vol. 2, pp. 342-43)

40. The 18-month look back period is fair and reasonable. (Smith, Vol. 6, p. 1325) It allows the Agency to look at the provision of quality of care over a period of time, not just on a single day. (Frisone, Vol., 1, p. 173)

41. If the Licensure and Certification Section responds to the CON Section that there were no issues of quality of care in the relevant 18 month period, the Agency finds the applicant conforming with Criterion 20. (Smith, Vol. 2, p. 341)

42. If the Licensure and Certification Section reports an issue during the relevant 18 month time frame that rose to the level of Conditions of Participation out of conformance or findings of immediate jeopardy at the facility, the CON Section does additional investigation by contacting the surveyor or Licensure and Certification Section Chief to learn more about the problems. (Smith, Vol. 2, p. 341)

1. TRC Copperfield Survey

43. At the time of the review, Angie Matthes was a Team Leader at the CON Section where she had been employed for approximately three years. (Matthes, Vol. 1, p. 28) Ms. Matthes has a wealth of experience analyzing quality of care issues at dialysis facilities. Prior to joining the CON Section, Ms. Matthes was employed as a surveyor for the Licensure and Certification Section for four years where she was responsible for surveying dialysis facilities, hospitals, home health agencies and critical access hospitals. She is also a trained nurse. (Matthes, Vol. 1, p. 27)

44. Ms. Matthes has also done independent contract work for the Centers for Medicare and Medicaid Services, the Division of Medical Assistance and Gambro Healthcare. Gambro was an outpatient dialysis provider. At Gambro, Ms. Matthes was responsible for conducting internal quality audits at facilities, similar to the audits she conducted as a surveyor for the Licensure and Certification Section. (Matthes, Vol. 1, pp. 27-28)

45. In addition, Ms. Matthes served as a technical expert panel participant for the Health Care Financing Administration to develop software to be used by surveyors conducting quality surveys of dialysis facilities. (Matthes, Vol. 1, p. 28)

46. While at the CON Section, Ms. Matthes had access to the federal ASPEN database which provides survey reports and write ups of facility deficiencies from the Licensure and Certification Section and other agencies throughout the United States. Not everyone at the CON Section had access to ASPEN, but because of her experience as a surveyor, Ms. Matthes did. (Matthes, Vol. 1, p. 34)

47. Due to her previous experience as a nurse and former surveyor with the Licensure and Certification Section, Ms. Matthes was routinely used as a resource by the CON Section in analyzing quality of care issues and survey reports. Ms. Matthes would typically access survey reports from the ASPEN database and interpret the levels of deficiencies cited in order for the CON Section to make an informed decision with respect to a facility's past provision of quality of care. (Matthes, Vol. 1, pp. 35-36)

48. Ms. Matthes routinely consulted and utilized the ASPEN database to access survey reports and results from the Licensure and Certification Section when the CON Section received information indicating there was a quality of care issue at a particular facility. Ms. Matthes found the ASPEN database to be reliable. (Matthes, Vol. 1, p. 36)

49. As Ms. Matthes testified, based on her time as a surveyor with the Licensure and Certification Section, there were four different types of surveys of dialysis facilities that might be conducted: initial surveys for newly opened facilities; complaint investigations resulting from a complaint; periodic full surveys which included patient observations and interviews, reviews of patient records, staff interviews, personnel record reviews and general facility observations that may last up to five days; and follow-up surveys to review previously cited deficiencies. (Matthes, Vol. 1, pp. 29-30)

50. At the conclusion of the survey, the surveyor gives the facility an informal closing statement of the results of the survey, followed by receipt of the written survey findings report. (Matthes, Vol. 1, p. 30)

51. Upon inquiry with the Licensure and Certification Section regarding quality of care at TRC Copperfield, the CON Section was informed that TRC Copperfield had failed to meet all Medicare Conditions of Participation during the 18-month look back period. (Jt. Ex.

1, p. 385) The Licensure and Certification Section further informed the Agency that condition level and standard level deficiencies were found at TRC Copperfield during a January 28, 2010 recertification survey and complaint investigation. It was also reported that standard level deficiencies were cited at TRC Copperfield at an August 3, 2009 survey. (Id.)

52. Due to her experience and the routine practice of the Agency, Ms. Matthes was asked to follow up on the information provided by the Licensure and Certification Section regarding TRC Copperfield. Ms. Matthes retrieved the January 28, 2010 survey report from the ASPEN database and provided it to CON Section Chief Craig Smith. (Matthes, Vol. 1, p. 38)

53. In the context of Medicare surveys of dialysis clinics, a condition level deficiency is used to identify a situation where a facility is not in compliance with the Medicare Conditions of Participation. It is more serious than a standard level deficiency. (Matthes, Vol. 1, pp. 31-32)

54. In the context of Medicare surveys of dialysis clinics, a standard level deficiency is a subpart of a condition level deficiency. (Matthes, Vol. 1, p. 32)

55. The report from the Licensure and Certification Section survey dated January 28, 2010 cited the TRC Copperfield facility for having two condition level deficiencies. The deficiencies are denoted on the survey report by specific "tags" which are codes that identify the Medicare condition for coverage for which the facility was out of compliance. (Matthes, Vol. 1, p. 46; Jt. Ex. 1, pp. 410-26) The deficiencies cited were based on such factors as personal observations of the surveyor, review of policies, review of patient clinical records and interviews with staff. (Jt. Ex. 1, pp. 410-26)

56. As noted in the survey report, a patient, referred to as "Patient #2," bled out and died as a result of her central venous catheter becoming disconnected from the dialysis machine. (Jt. Ex. 1, pp. 420-23)

57. The first condition level deficiency identified in the January 28, 2010 TRC Copperfield survey report was tag V400 Physical Environment. TRC Copperfield was cited as out of compliance as follows: "This CONDITION is not met as evidenced by: Based on observations, staff interview and policies and procedures review, it was determined that the facility failed to develop, and implement effective safeguards to prevent patient medical emergencies related to central venous catheter disconnections. The facility failed to monitor and prevent a bloodline disconnection from a central venous catheter, failed to ensure that its emergency suction machine equipment used in patient care remained clean and sanitary and failed to ensure a two person patient identification verification was completed on patients dialyzed on reprocessed dialyzers. The cumulative effective of these systemic problems resulted in the facility's inability to safeguard against patient medical emergencies." (Jt. Ex. 1, pp. 417-18; Matthes, Vol. 1, pp. 46-47)

58. A central venous catheter is a catheter that connects the patient to the dialysis machine. The report indicates that the tubing connecting the patient's catheter to the machine became disconnected. (Matthes, Vol. 1, p. 47)

59. The second condition level deficiency identified in the January 28, 2010 TRC Copperfield survey report was tag V750 Governance. TRC Copperfield was found out of compliance as follows: "This CONDITION is not met as evidenced by: Based on observations, staff interview, policies and procedures review and quality assurance documentation, it was determined that the facility's governing body failed to assume full

responsibility for determining, implementing and monitoring policies and interventions for the safety of central venous catheter patients from accidental bloodline disconnection, patient dialyzer error and potential of infections. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality care in a safe environment." (Jt. Ex. 1, p. 425; Matthes, Vol. 1, p. 52)

60. The governing body referenced in the survey report included Tammy Leahy, Regional Operations Director, Luke Santillo, Facility Administrator, and Dr. William Halstenberg, Medical Director. (Leahy, Vol. 4, p. 955)

61. Additionally, TRC Copperfield was cited for seven standard level deficiencies in the January 28, 2010 survey report including multiple issues related to infection control and cleanliness. Those standard level deficiencies are summarized as follows:

a. V119: "Based on observations and staff interview, the facility's staff failed to prevent potential cross contamination from blood of clean supplies used in the patient treatment area." (Jt. Ex. 1, pp. 410-11)
b. b.V122: "Based on review of the facility's policies and procedures, observations and staff interview, the facility's staff failed to ensure cleaning and disinfection infection control standards for patient used equipment were followed and implemented." (Jt. Ex. 1, pp. 411-14)
c. V143: "Based on the facility's policies and procedures review, observations and staff interview, the facility's staff administered intravenous medications from cross-contaminated syringes in 1 of 3 observed patients receiving intravenous medications (Patient #1)." (Jt. Ex. 1, pp. 414-16)
d. V348: "Based on clinical record review, staff interview and policies and procedures review, the facility staff failed to ensure a two person patient identification verification for 1 of 5 sampled patients dialyzed on reprocessed dialyzers (Patient #2)." (Jt. Ex. 1, pp. 416-17)
e. V401: "Based on observations, staff interview and policies and procedures review, the facility failed to ensure that its emergency suction machine equipment used in patient care remained clean and sanitary." (Jt. Ex. 1, pp. 418-19)
f. V520: "Based on staff interview, medical record review and policies and procedures, the facility failed to ensure that monthly reassessments were completed for patient's document as unstable in 1 of 2 sampled unstable patients (Patient #6)." (Jt. Ex. 1, pp. 423-25)
g. V407: "Based on facility policies and procedures review, medical record review and staff interviews, the facility's staff failed to monitor and prevent a bloodline disconnection from a central venous catheter in 1 of 6 sampled hemodialysis patients (Patient #2)." (Jt. Ex. 1, pp. 419-23)

62. Dr. William Halstenberg, the TRC Copperfield Medical Director and proposed Medical Director of the proposed TRC Cabarrus clinic, testified that cleanliness and infection control are important in dialysis facilities. (Halstenberg, Vol. 1, p. 118)

63. With respect to standard V407, the surveyor further reported that on November 2, 2009, Patient #2 was scheduled for hemodialysis treatment. The documentation revealed that the facility's patient care technician failed to obtain a second staff member identification check for the patient's reprocessed dialyzer. (Jt. Ex. 1, p. 420) A reprocessed dialyzer is one that is designed to be used for multiple treatments by the same patient. The Medicare Conditions of Participation indicate that a reprocessed dialyzer cannot be utilized on multiple patients due to the risk of contamination or infection or disease transfer. (Matthes, Vol. 1, p. 51)

64. Medicare requires two staff members verify the identification of the patient and the reprocessed dialyzer to ensure the reprocessed dialyzer is not utilized on the wrong patient. (Matthes, Vol. 1, p. 51) It was a serious deficiency in this case that the TRC Copperfield facility failed to ensure that two staff members identified Patient #2 and the reprocessed dialyzer on November 2, 2009. (Matthes, Vol. 1, p. 51; McCann, Vol. 2, p. 461)

65. Dr. Halstenberg, testified that using a reprocessed dialyzer on the wrong patient presents a small chance of contamination and demonstrates a problem with customer service. Dr. Halstenberg also testified that he would not want someone else's reprocessed dialyzer to be used on him. (Halstenberg, Vol. 1, p. 122)

66. Ms. Tammy Leahy, who at the time of the filing of the TRC Copperfield application was the CEO of TRC Copperfield, testified at the contested case hearing that she believed the two person identification of Patient #2's reprocessed dialyzer had in fact occurred. She believed that due to a computer "glitch," the two person identification was not noted in the computer, when in fact, it had occurred. (Leahy, Vol. 3, p. 780) Yet, there is no reference to a computer "glitch" at TRC Copperfield in the survey or the Plan of Correction. (Jt. Ex. 1, p. 420; Codd, Vol. 4, p. 915)

67. The surveyor also reported that the TRC Copperfield staff failed to properly monitor the same patient (Patient #2) in order to prevent the blood line disconnection from the central venous catheter. (Matthes, Vol. 1, p. 48) As Dr. Halstenberg testified, even where the dialysis machine has an alarm on it, the patient care technician needs to monitor the patient. (Halstenberg, Vol. 1, p. 117)

68. The Fresenius Medical Care-2008K Hemodialysis Machine Operator's Manual warns against relying solely upon the machine alarm system: "Warning! Check all blood lines for leaks after the treatment has started. Keep access sites uncovered and monitored. Improper blood line connections or needle dislodgements can result in excessive blood loss, serious injury, and death. Machine alarms may not occur in every blood loss situation." (TRC Ex. 266, p. 456; Codd, Vol. 4, pp. 914-15)

69. Celine Codd, Director of Clinical Services for DaVita, testified on behalf of TRC/DaVita as an expert witness in quality assurance in outpatient dialysis clinics. (Codd, Vol. 4, p. 847) Ms. Codd is accountable for the TRC facilities in Cabarrus, Rowan and Mecklenburg Counties, among others. Ms. Codd has oversight responsibility for quality of care, education and survey preparedness. (Codd, Vol. 4, p. 846)

70. Regarding the dialysis machines and its alarm, Ms. Codd testified that patient care cannot be delegated to a machine. (Codd, Vol. 4, p. 913)

71. The surveyor further reported that during the dialysis treatment of Patient #2, the patient's central venous catheter bloodline became disconnected and the patient lost 500 milliliters of blood. The TRC Copperfield staff performed Cardiac Pulmonary Resuscitation ("CPR") on the patient, called 911, and as the facility's nurse manager reported to the surveyor, Patient #2 "went to the hospital and died after the bleed out." (Jt. Ex. 1, p. 422)

72. The amount of blood Patient #2 lost equals about a tenth of her blood. (Halstenberg, Vol. 1, p. 101) Stated another way, 500 milliliters would be about two cups. (Matthes, Vol. 1, pp. 83-84)

73. The survey report quoted the registered nurse assigned to Patient #2 as stating: "When I responded, I saw the nurse and [the] patient care technician beside the patient and some blood on the floor." (Jt. Ex. 1, p. 422) She went on to state: "I was assigned to 16 patients that day. I was called by (patient care technician assigned to patient) and I noticed blood on the floor and the patient unresponsive." (Jt. Ex. 1, p. 423)

74. TRC Copperfield did not use any clamps or ties to secure central venous catheter lines to the dialysis lines in order to prevent disconnection. (Jt. Ex. 1, p. 422)

75. None of the eyewitnesses, including the patient care technician or registered nurse assigned to Patient #2, could explain how the central venous catheter line became disconnected. (Jt. Ex. 1, pp. 410-26)

76. The patient care technician responsible for Patient #2's care was Cedric Brown. (Halstenberg, Vol. 1, p. 115; Leahy, Vol. 4, p. 952) The registered nurse assigned to Patient #2 was Viola James and the facility's nurse manager was Tempest McCombs. (Leahy, Vol. 4, p. 953)

77. The surveyor interviewed Mr. Brown, Ms. James and Ms. McCombs and included in the survey report direct quotes from those witnesses as to the incident on November 2, 2009. (Jt. Ex. 1, pp. 421-23)

78. Based on her experience and investigation, Ms. Matthes concluded that the patient death was a very serious incident because Patient #2 died after an untoward event that occurred in the TRC Copperfield dialysis facility. (Matthes, Vol. 1, p. 50) Ms. Matthes further concluded that the TRC Copperfield facility was not providing a safe environment for patients. (Matthes, Vol. 1, p. 57)

79. Ms. Codd testified that the November 2, 2009 bleed out and patient death indicated that TRC Copperfield failed to provide quality care to that patient. (Codd, Vol. 4, p. 881)

80. Ms. Codd further testified that Patient #2's blood loss was preventable. (Codd, Vol. 4, p. 909) There was no evidence in the survey report to suggest that the patient disconnected herself from the dialyzer. (Id.)

81. Ms. Codd further testified that it is an outlier or not a normal occurrence for a patient to experience blood loss such as that experienced by Patient #2. (Codd, Vol. 4, p. 887) It is an unacceptable occurrence. (Codd, Vol. 4, p. 908)

82. Maura McCann, Regional Quality Administrator for RAI, was admitted as an expert witness in the field of quality assurance and outpatient dialysis clinics. (McCann, Vol. 2, p. 446; RAI Ex. 120) Ms. McCann is a nurse, board certified in nephrology and has been working in nephrology for nearly forty years. (McCann, Vol. 2, p. 439) Ms. Celine Codd testified that she knew and had worked with Ms. McCann in the past and found her to be competent in her job. (Codd, Vol. 4, p. 906)

83. Prior to joining RAI, Ms. McCann served as regional director for Gambro Healthcare where she assisted in the preparation of North Carolina CON applications. Ms. McCann also served as Quality Improvement Coordinator for the Southeastern Kidney Council Network 6. The Southeastern Kidney Council contracts with the Centers for Medicare and Medicaid Services ("CMS") and oversees the quality of care provided to Medicare dialysis patients. (McCann, Vol. 2, pp. 439-40)

84. In her current position as Regional Quality Administrator for RAI, Ms. McCann is responsible for the quality of care, including staff training and implementing and enforcing quality policies and procedures in the thirteen outpatient dialysis clinics she oversees in North and South Carolina. (McCann, Vol. 2, pp. 438-39, 441)

85. Based on her training, experience and review and analysis of the January 28, 2010 TRC Copperfield survey report, Ms. McCann testified that the TRC Copperfield facility had serious infection control issues, failures to adhere to policies, and two conditions out of compliance that involved a patient death. (McCann, Vol. 2, p. 447)

86. Specifically, the failure of TRC Copperfield to prevent a bloodline disconnection from a central venous catheter was a terrible event. Patient #2 had a reported venous pressure of only 20 at the time the central venous catheter was in place. This is extremely low and one would expect more resistance and a venous pressure of 150 to 200 for a patient receiving dialysis. (McCann, Vol. 2, pp. 449-50)

87. Ms. Codd agreed that a venous pressure of 20 is low and the pressure would typically be 150 once the patient's dialysis is running. (Codd, Vol. 4, pp. 911-12)

88. Ms. McCann testified that the survey report noted a blood flow rate of 300, venous pressure of 20, and blood pressure of 215/80. (Jt. Ex. 1, p. 421; McCann, Vol. 2, p. 451) The blood pressure of Patient #2 should have been lower because blood pressure decreases as blood begins to flow into the dialysis machine. The fact that the blood flow rate was 300 and the venous pressure was 20 clearly indicated to Ms. McCann that the patient's venous line that returns the filtered blood to the patient was not connected. (McCann, Vol. 2, p. 451)

89. The loss of 500 milliliters of blood as Patient #2 experienced is not normal. (McCann, Vol. 2, p. 452) It is not a normal occurrence to see blood on the floor during a dialysis treatment. (McCann, Vol. 2, p. 454)

90. The January 28, 2010 TRC Copperfield survey reported that Patient #2 had a history of altered mental status and "has been know[n] to grab her lines." (Jt. Ex. 1, p. 421) Ms. McCann testified that based on her experience, most dialysis patients suffer from multiple co-morbidities. Because of the known altered mental status reported by TRC Copperfield, the patient should have had a sitter to prevent her from potentially removing any lines. (McCann, Vol. 2, pp. 452-53)

91. In addition, unstable patients should be reassessed on a monthly basis until they become stable, as required by the Conditions of Participation. (McCann, Vol. 2, p. 462) TRC Copperfield failed to reassess Patient #2, even though it described her as unstable. (McCann, Vol. 2, p. 463)

92. Ms. McCann testified that the interviews with the patient care technician and registered nurse cited in the survey report were confusing because if a central venous catheter came out of a patient or was disconnected, it would be obvious and visible. The catheter is approximately 8 inches long, white in color and has additional limbs that are two to three inches long and hang outside the chest wall. (McCann, Vol. 2, p. 455)

93. Moreover, the connections for the catheter and dialyzer use a device called a Luer-Lock. A Luer-Lock connection does not pull out, but is screwed in and when properly

done forms a snug tight connection known as a female and male connection. (McCann, Vol. 2, pp. 456-57)

94. Ms. Codd agreed in her testimony that a Luer-Lock connection is supposed to be tight and there was no evidence in the survey report to indicate Patient #2 undid her own Luer-Lock connection. (Codd, Vol. 4, p. 910)

95. Patient #2 had had a stroke. (Halstenberg, Vol. 1, p. 99) It would be very difficult for someone who has had a stroke to unscrew a Luer-Lock connection. (McCann, Vol. 2, pp. 456-57)

96. Importantly, however, if a central venous catheter was pulled out, there would be no connection to the dialysis machine and at most the patient would have lost the 200 milliliters in the dialyzer machine and blood line and not the greater amount of 500 milliliters reported in the survey. (McCann, Vol. 2, p. 454) Ms. McCann referred to RAI Ex. 188, a photograph of a cuffed hemodialysis catheter to further illustrate her testimony. There is a cuff in the catheter that helps anchor it in place. (Id.)

97. As an additional measure of safety to prevent blood lines from being pulled out or tugged at, RAI utilizes blue plastic scissor-like clamps that can be used to clamp the line to the patient's sleeve. Lines can also be secured with tape. (McCann, Vol. 2, p. 443) Ms. McCann referred to RAI Exhibits 125-127 and 188-191 which are an actual clamp, dialyzer with tubing, dialyzer with filter exposed and photographs of patients receiving dialysis treatments to illustrate her testimony.

98. In addition to the bleed out and death of Patient #2, the TRC Copperfield survey cited the facility for multiple serious infection control problems observed by the surveyor including the failure to fully sanitize reusable items between use by different patients. The disinfectant solutions utilized to prevent cross contamination were not dated and common supplies (used with multiple patients) were placed directly on top of contaminated hemodialysis machines. Even though the dialysis machines are cleaned with bleach, the machines themselves are considered contaminated because there is the potential for blood residue to still be on the machines. (McCann, Vol. 2, p. 458) Clean instruments were placed on designated dirty countertops and some common instruments were not cleaned between patient uses to prevent cross contamination. (Jt. Ex. 1, pp. 410-15; McCann, Vol. 2, pp. 457-60)

99. It is important to keep equipment in a dialysis facility clean because of the potential for bacterial growth and contamination. (McCann, Vol. 2, p. 462) Dialysis patients have compromised immune systems. Thus, they are at higher risk for infections. (Codd, Vol. 4, p. 906)

100. The surveyor also observed sterile syringes of medication were placed on top of contaminated hemodialysis machines. It is important to note that these machines may contain the blood residues of patients. (Jt. Ex. 1, p. 415) This could result in potential contamination and spread of diseases among patients because the barrels of the syringes were exposed. (McCann, Vol. 2, pp. 458, 460)

101. Ms. Matthes' investigation of TRC Copperfield also yielded an August 3, 2009 survey where standard level deficiencies were cited. (RAI Ex. 123, pp. 2757-74; Jt. Ex. 1, p. 409)

102. Ms. Tammy Leahy was the Regional Operations Director at TRC Copperfield at the time of the survey. Ms. Leahy testified that she was aware of the survey results. (Leahy, Vol. 3, p. 811)

103. The survey report for August 3, 2009 cited three standards out of compliance at TRC Copperfield, including a deficiency tag V122 Procedures for Infection Control. That is the same tag encompassing infection control for which TRC Copperfield was cited as non-compliant in the January 2010 survey. (Leahy, Vol. 3, p. 813)

104. Ms. Matthes also researched survey reports on ASPEN within the 18-month look back period for the TRC Harrisburg facility and made written notes which were included in the Agency File. Ms. Matthes noted an initial certification survey was conducted on August 6, 2009 and a complaint investigation survey was conducted on May 13, 2010. There were no deficiencies cited by the Licensure and Certification Section for those surveys. (Jt. Ex. 1, p. 409; Matthes, Vol. 1, pp. 59-60)

105. Ms. Matthes reviewed the ASPEN database for quality of care issues at TRC facilities located in counties contiguous to Cabarrus County, consistent with Agency practice. Ms. Matthes determined that although a complaint investigation survey was conducted at Dialysis Care of Rowan County, a TRC/DaVita clinic, on November 18, 2010, no deficiencies were cited. Ms. Matthes determined that a review of TRC's Kannapolis facility in Rowan County and its facility in Anson County either yielded no surveys or no deficiencies during the 18-month look back period. (Jt. Ex. 1, p. 409; Matthes, Vol. 1, pp. 59-60)

106. Ms. Matthes' investigation did show, however, a March 4, 2010 survey report with standard level deficiencies at TRC North Charlotte in Mecklenburg County, contiguous to Cabarrus County. Her investigation also noted a survey at TRC Charlotte East, also in Mecklenburg County, where an immediate jeopardy situation was cited and three Conditions of Participation were out of compliance, including Governance, Infection Control and Physical Environment. (Jt. Ex. 1, p. 409; Matthes, Vol. 1, pp. 60-61)

107. Because TRC Copperfield had two Conditions of Coverage out of compliance within the 18-month look back period, consistent with Agency practice, the TRC Copperfield Application was found non-conforming with Criterion 20. (Matthes, Vol. 1, p. 46)

108. Tammy Leahy was serving as Regional Operations Director with oversight responsibility for the TRC Copperfield facility when the November 2, 2009 patient bleed out and death occurred. Ms. Leahy regarded that as a serious incident. (Leahy, Vol. 3, p. 802)

109. None of the witnesses for TRC/DaVita (Dr. Halstenberg, Ms. Codd, Ms. Leahy, Mr. Sullivan or Mr. Hyland) was present at the TRC Copperfield clinic on November 2, 2009. None of the TRC/DaVita witnesses testifying at the hearing was an eyewitness to the events or staff responses that are reported in the 2010 survey. (Halstenberg, Vol. 1, p. 113; Leahy, Vol. 3, p. 805; Leahy, Vol. 4, pp. 952-54; Hyland, Vol. 5, p. 1169) Mr. Luke Santillo, the facility administrator at TRC Copperfield at the time of the November 2, 2009 incident, was not involved in Patient #2's care on that day. (Leahy, Vol. 3, pp. 806-07)

110. While Dr. Halstenberg disputed that Patient #2 bled out, Dr. Halstenberg's testimony was not based upon any examination of Patient #2 on November 2, 2009. (Halstenberg, Vol. 1, pp. 98, 113-14) Dr. Halstenberg admitted in his testimony that he had not even reviewed the entire survey report for the January 28, 2010 survey. (Halstenberg, Vol. 1, p. 117)

111. Dr. Halstenberg testified that he spoke with the surveyor, Mr. Ralph Mills, but in doing so, he did not dispute anything Mr. Mills put in his report and did not provide any information for the report. (Halstenberg, Vol. 1, p. 118) Ms. Celine Codd, TRC's expert witness in matters of quality assurance in outpatient dialysis clinics, admitted that she knows Mr. Mills to be competent in his job as a surveyor. (Codd, Vol. 4, p. 905) Ms. Codd also knew Angie Matthes from Ms. Matthes's days as a surveyor. Ms. Codd found Ms. Matthes to be competent in her job. (Codd, Vol. 4, pp. 905-06)

112. TRC and DaVita did not appeal the determinations of the January 28, 2010 TRC Copperfield survey report and findings. (Halstenberg, Vol. 1, p. 119; Leahy, Vol. 3, p. 805; Codd, Vol. 4, p. 905)

113. No one at TRC or DaVita had any written communication with the Licensure and Certification Section disputing any of the findings or determinations in the January 28, 2010 TRC Copperfield survey report. (Halstenberg, Vol. 1, p. 119; Leahy, Vol. 3, p. 806)

114. TRC Copperfield did not self-report the November 2, 2009 incident that led to the death of Patient #2 to the Licensure and Certification Section or any other regulatory agency or to the Southeastern Kidney Council. (Leahy, Vol. 3, p. 806; Leahy, Vol. 4, p. 960)

115. Ms. Codd testified that she did not dispute anything in the January 28, 2010 survey statement of deficiencies. (Codd, Vol. 4, p. 905) Daniel Sullivan, TRC/DaVita's expert witness on CON, testified that he did not dispute the Agency's determination that TRC Copperfield was non-conforming with Criterion 20. (Sullivan, Vol. 4, p. 1063)

116. Ms. Tammy Leahy testified on behalf of TRC that the TRC facilities have not had issues with providing quality of care other than a few isolated instances. (Leahy, Vol. 3, p. 759) Ms. Celine Codd testified similarly that DaVita facilities are in compliance. (Codd, Vol. 4, p. 882).

117. However, a January 15, 2009 survey report from the Licensure and Certification Section cited Dialysis Care of Kannapolis for having twelve standards out of compliance, including tag V122 for Infection Control, one of the same standards found out of compliance at TRC-Copperfield. (RAI Ex. 145)

118. Dialysis Care of Kannapolis is a DaVita facility located in Rowan County. (RAI Ex. 145)

119. Ms. Leahy testified that she was both the Regional Operations Director and Acting Facility Administrator at Dialysis Care of Kannapolis at the time of the survey. She testified that she was aware of those survey results. (Leahy, Vol. 4, pp. 946-47)

120. DaVita did not appeal the Dialysis Care of Kannapolis survey results or findings. (Leahy, Vol. 4, p. 948)

121. A March 2-4, 2010 survey of the North Charlotte Dialysis Center yielded standard level deficiencies relating to Infection Control, Physical Environment, Reuse, and Responsibilities of Medical Director. (RAI Ex. 140)

122. North Charlotte Dialysis Center is a DaVita clinic and Ms. Leahy testified that she was the Regional Operations Director responsible for that facility at the time of the March 2010 survey. She was aware of the results of that survey. (Leahy, Vol. 4, pp. 950-51)

123. On February 26, 2011, Licensure and Certification surveyor Ralph Mills transmitted a letter to Southeastern Dialysis-Wilmington citing a January 21, 2011 survey where the facility was cited for immediate jeopardy and condition level deficiencies, including Infection Control, Patient Plan of Care and Performance Improvement. (RAI Ex. 141)

124. Ms. Codd testified that Southeastern Dialysis-Wilmington is a DaVita clinic for which Ms. Codd has responsibility. (Codd, Vol. 1, p. 916)

125. Ms. Codd further testified that the immediate jeopardy citation was assessed because a patient's old dialysis access port began to bleed after he was sent home from the Wilmington facility. The patient bled out and died. (RAI Ex. 141; Codd, Vol. 4, p. 918) The surveyor reported that "facility staff failed to provide monitoring and assessment for a vascular access with impending failure in 1 of 1 sampled patients that expired after uncontrolled bleeding occurred from the vascular access site (patient #14)." (RAI Ex, 141; Codd, Vol. 4, p. 923)

126. On March 30, 2009, the Licensure and Certification Section transmitted a letter to Dialysis Care of Richmond County summarizing the results of a March 23-24, 2009 survey. The facility was not in compliance with two Conditions of Coverage including Responsibilities of the Medical Director and Governance. (RAI Ex. 142) Dialysis Care of Richmond County is also a DaVita clinic. (Codd, Vol. 4, p. 924)

127. The TRC Copperfield January 28, 2010 survey report also cited the facility for being out of compliance with the Medicare Condition for Coverage regarding Governance. Ms. Codd testified she was aware of that fact. (Codd, Vol. 4, p. 925)

128. On November 15, 2010, the Centers for Medicare and Medicaid Services transmitted a letter to the Charlotte East Dialysis Facility notifying it that the facility had been cited for immediate jeopardy and being out of compliance with three Medicare Conditions for Coverage including Infection Control, Physical Environment and Governance. (RAI Ex. 143; Codd, Vol. 4, p. 925)

129. Ms. Codd was aware of this survey. Like TRC Copperfield, Charlotte East was also cited for Infection Control, Physical Environment and Governance. (Codd, Vol. 4, p. 926)

130. On April 21, 2009, the Licensure and Certification Section transmitted a letter to Goldsboro South Dialysis summarizing the results of an April 7-9, 2009 survey at that facility. (RAI Ex. 146)

131. Goldsboro South Dialysis is a DaVita clinic for which Ms. Codd has oversight responsibility. Ms. Codd testified she was aware of this survey. (Codd, Vol. 4, p. 927)

132. The Goldsboro South Dialysis facility was out of compliance with the Medicare Condition of Coverage for Governance, which was one of the same Conditions for which the TRC Copperfield facility was found non-compliant in the January 28, 2010 survey. (RAI Ex. 146)

133. On August 2, 2010, the Licensure and Certification Section transmitted a letter to Vance County Dialysis citing two Conditions of Coverage which were out of compliance including Responsibilities of Medical Director and Governance. (RAI Ex. 147)

134. Ms. Codd testified that Vance County Dialysis is a DaVita clinic for which she has oversight responsibilities. Ms. Codd was also aware of this survey report. (Codd, Vol. 4, p. 928)

2. TRC Harrisburg and TRC Cabarrus Applications

135. CON Section Chief Craig Smith, CON Assistant Chief Martha Frisone, CON Team Leader Angie Matthes and CON Project Analyst Tanya Rupp consulted with each other regarding the results of the survey and decision to find all three TRC Applications non-conforming with Criterion 20. All were in agreement to find the three TRC Applications non-conforming with Criterion 20. (Matthes, Vol. 1, pp. 38-39; Frisone, Vol. 1, p. 138; Rupp, Vol. 1, p. 194; Smith, Vol. 2, p. 348; Smith, Vol. 6, p. 1323; Rupp, Vol. 5, p. 1254)

136. Based upon the quality of care deficiencies at TRC Copperfield cited in the January 28, 2010 survey report from the Licensure and Certification Section, the CON Section also found the TRC Harrisburg and TRC Cabarrus Applications non-conforming with Criterion 20. (Jt. Ex. 1, p. 515; Smith, Vol. 6, p. 1321; Rupp, Vol. 5, p. 1237)

137. Ms. McCann, RAI's Regional Quality Administrator and expert witness in the field of quality assurance in outpatient dialysis clinics, opined that the Agency correctly denied the TRC Copperfield, TRC Harrisburg and TRC Cabarrus Applications based on the serious issues identified at the TRC Copperfield facility in the January 28, 2010 survey report. (McCann, Vol. 2, p. 447)

138. Specifically, in Ms. McCann's opinion, it was relevant to note that Dr. Halstenberg was both the Medical Director of TRC Copperfield and the proposed TRC Cabarrus clinic. Likewise, Dr. Stoddard, Dr. Halstenberg's partner, was the Medical Director at TRC Harrisburg. Additionally, there is overlap with the Regional Quality Director and policies and procedures between the facilities. (McCann, Vol. 2, p. 448)

139. The January 28, 2010 survey and November 2, 2009 bleed out incident cited therein were within the 18-month look back period used by the Agency for quality of care analysis under Criterion 20. (Smith, Vol. 6, p. 1323)

140. There was a sufficient factual nexus between the TRC Copperfield, TRC Harrisburg and TRC Cabarrus Applications to find all three non-conforming with Criterion 20 as summarized in the table below. It is undisputed that all three facilities shared common applicants, common ownership, common county location, common medical directorship, common governance, common medical practice providing clinical coverage, common clinical services specialists, common quality policies and procedures and common staff.

	TRC Copperfield	TRC Harrisburg	TRC Cabarrus
Applicant	Total Renal Care of North Carolina	Total Renal Care of North Carolina	Total Renal Care of North Carolina
Owner	DaVita, Inc.	DaVita, Inc.	DaVita, Inc.
Location	Concord, Cabarrus County	Concord, Cabarrus County	Concord, Cabarrus County
Medical Director	Dr. Halstenberg (Central Carolina Nephrology)	Dr. Stoddard (Central Carolina Nephrology)	Dr. Halstenberg (Central Carolina Nephrology)
Governance	Medical Director: Dr. Halstenberg CEO/Regional Operations Director: Jenny Richeson	Medical Director: Dr. Stoddard CEO/Regional Operations Director: Jenny Richeson	Medical Director: Dr. Halstenberg CEO/Regional Operations Director: Jenny Richeson

	TRC Copperfield	TRC Harrisburg	TRC Cabarrus
	Facility Administrator: Luke Santillo	Facility Administrator: Amanda Herring	Facility Administrator: to be named
Clinical Coverage	Central Carolina Nephrology	Central Carolina Nephrology	Central Carolina Nephrology
Clinical Services Specialist	Michele Brandt-Becher	Michele Brandt-Becher	Michele Brandt-Becher
Policies/Procedures	DaVita, Inc.	DaVita, Inc.	DaVita, Inc.
Staff	Shared/transferred as needed	Shared/transferred as needed	Shared/transferred as needed

141. The legal name of the applicant for the TRC Copperfield Application was Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center. (Jt. Ex. 3, p. 2; Rupp, Vol. 5, pp. 1253-54)

142. The legal name of the applicant for TRC Harrisburg was identified as Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center. (Jt. Ex. 4, p. 2; Rupp, Vol. 5, p. 1253).

143. The legal name of the applicant of TRC Cabarrus was identified as Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis. (Jt. Ex. 2, p. 2; Rupp, Vol. 5, p. 1253)

144. Criterion 20, N.C. Gen. Stat. § 131E-183(a)(20), provides that "*[a]n applicant* already involved in the provision of health services shall provide evidence that quality care has been provided in the past." (Emphasis added) (Jt. Ex. 1, p. 515)

145. The applicant, Total Renal Care of North Carolina, is the same for the TRC Copperfield, TRC Harrisburg and TRC Cabarrus Applications. (Rupp, Vol. 5, p. 1254; Smith, Vol. 6, p. 1327; Hyland, Vol. 4, pp. 1147-48)

146. The parent company of TRC Copperfield is DaVita, Inc. (Jt. Ex. 3, p. 2)

147. The parent company of TRC Harrisburg is DaVita, Inc. (Jt. Ex. 4, p. 2)

148. The parent company of TRC Cabarrus is DaVita, Inc. (Jt. Ex. 2, p. 2)

149. It is undisputed that TRC Copperfield, TRC Harrisburg and TRC Cabarrus are all owned by the same company, DaVita, Inc. (Codd, Vol. 4, pp. 892-93; Hyland, Vol. 4, pp. 1147-48)

150. It is undisputed that TRC Copperfield and TRC Harrisburg are located in Concord, Cabarrus County and that TRC Cabarrus is a proposed new facility to be located in Concord, Cabarrus County. (Jt. Ex. 1, p. 459)

151. The Medical Director of TRC Copperfield is Dr. Halstenberg. (Jt. Ex. 1, p. 501; Halstenberg, Vol. 1, p. 123; Matthes, Vol. 1, p. 41; Codd, Vol. 4, p. 893)

152. The proposed Medical Director of TRC Cabarrus is also Dr. Halstenberg. (Jt. Ex. 1, p. 501; Halstenberg, Vol. 1, p. 123; Matthes, Vol. 1, pp. 40-41; Codd, Vol. 4, p. 893; Smith, Vol. 6, p. 1323)

153. The Medical Director of TRC Harrisburg is Dr. Stoddard, (Jt. Ex. 1, p. 499; RAI Ex. 183, p. 10; Matthes, Vol. 1, p. 39)

154. Both Dr. Halstenberg and Dr. Stoddard are physician partners practicing at Central Carolina Nephrology. (Jt. Ex. 2, p. 175; RAI Ex. 183, p. 15)

155. At times, Dr. Halstenberg and Dr. Stoddard share coverage or provide backup coverage for each other at the TRC facilities for which they serve as Medical Director. (Halstenberg, Vol. 1, pp. 122-23; RAI Ex. 183, p. 16)

156. Dr. Stoddard and Dr. Halstenberg have a similar approach when it comes to patient care. (RAI Ex. 183, p. 16)

157. The fact that Central Carolina Nephrology provides medical direction at TRC Copperfield and TRC Harrisburg, and will provide medical direction at the proposed Cabarrus County facility was considered important by the Agency because the Medical Director of a facility is primarily responsible for directing patient care, patient safety and ensuring that facility staff are properly trained to do their jobs. The Medical Director bears ultimate responsibility for the quality of care at a dialysis clinic. (Smith, Vol. 2, p. 348; Vol. 6, p. 1323; RAI Ex. 183, p. 10) The Medical Director is also part of the governing body of a dialysis facility. (RAI Ex. 183, p. 10; Matthes, Vol. 1, pp. 42-43)

158. The Medical Director is ultimately responsible for quality of care at TRC clinics. (Codd, Vol. 4, p. 900) In a recent presentation, Dr. David B. Van Wyck, Vice President of Clinical Services for DaVita, Inc., stressed that: "The medical director has the responsibility of ensuring that all policies and procedures relative to patient care and safety are followed by all who treat the patient . . . The medical director is accountable to the governing body for the quality of medical care provided to patients." (RAI Ex. 139; Codd, Vol. 4, pp. 903-04)

159. The Medical Director also participates in quality meetings. (Codd, Vol. 4, p. 893)

160. The governing body of a TRC facility is responsible for managing the facility. It has decision-making responsibilities for the facility and is charged with reviewing the policies and procedures of a given facility. (Leahy, Vol. 3, p. 800)

161. The governing body consists of the Medical Director, Regional Operations Director and Facility Administrator. (Leahy, Vol. 3, pp. 742-43) The Regional Operations Director is responsible for ensuring positive clinical outcomes. (Leahy, Vol. 3, p. 804)

162. The governing body of TRC Copperfield at the time the application was submitted included: Dr. Halstenberg, Medical Director, Tammy Leahy, CEO and Regional Operations Director, and Luke Santillo, Facility Administrator. (Leahy, Vol. 3, p. 743; Jt. Ex. 3, pp. 44-45; Matthes, Vol. 1, p. 55)

163. The governing body of TRC Harrisburg at the time the application was submitted included: Dr. Stoddard, Medical Director, Tammy Leahy, CEO and Regional Operations Director, and Amanda Herring, Facility Administrator. (Leahy, Vol. 3, p. 743; Jt. Ex. 3, pp. 44-45)

164. The proposed governing body of TRC Cabarrus at the time of the application was: Dr. Halstenberg, Medical Director, Tammy Leahy, CEO and Regional Operations Director, and a Facility Administrator to be named. (Jt. Ex. 2, p. 46; Leahy, Vol. 3, p. 744)

165. As of January 1, 2011, Ms. Leahy is no longer responsible for the TRC Copperfield, TRC Harrisburg or proposed TRC Cabarrus facilities. Ms. Jenny Richeson will be the CEO and Regional Operations Director at the three named facilities. She has the same title and responsibilities as Ms. Leahy. (Leahy, Vol. 3, pp. 802-03)

166. It is undisputed that at the time of the applications, Ms. Leahy was CEO and Regional Operations Director for all three TRC/DaVita facilities and served on the governing bodies.

167. It is undisputed that Central Carolina Nephrology is the physician practice that provides clinical services to TRC Copperfield and TRC Harrisburg and will provide clinical services to TRC Cabarrus. (Jt. Ex. 2, p. 173; Codd, Vol. 4, p. 893; Leahy, Vol. 3, pp. 801-02) Thus, the same physician practice will provide clinical services at all three TRC/DaVita facilities. (Smith, Vol. 6, p. 1323)

168. The physicians at Central Carolina Nephrology have similar approaches relating to patient care. (RAI Ex. 183, p. 16)

169. TRC/DaVita has nine volumes of policies and procedures generally applicable to all of its dialysis facilities. (Codd, Vol. 4, pp. 895-96)

170. Generally, the same policies and procedures, including quality of care policies and procedures, are in place at all TRC facilities, including TRC Copperfield, TRC Harrisburg, and TRC Cabarrus. (Halstenberg, Vol. 1, p. 123; Codd, Vol. 4, p. 895; Jt. Ex. 2, pp. 541-68; Jt. Ex. 3, pp. 338-65; Jt. Ex. 4, pp. 329-56)

171. Clinical services specialists are licensed nurses who primarily provide clinical support, education and survey preparedness services to TRC facilities. They report to Celine Codd, Director of Clinical Services. (Codd, Vol. 4, pp. 893-94)

172. Ms. Angie Pesich was the clinical services specialist for TRC Copperfield and TRC Harrisburg in 2010. Effective January 1, 2011, Michele Brandt-Becher took over that role for both the TRC Copperfield and TRC Harrisburg clinics. Ms. Brandt-Becher would also serve as clinical services specialist for the proposed TRC Cabarrus clinic. (Codd, Vol. 4, p. 894)

173. Staff members move between facilities on an as-needed basis. There have been times when staff was shared between the TRC Copperfield and TRC Harrisburg clinics. (Leahy, Vol. 4, p. 961) Moreover, as opportunities are available, staff can transfer between TRC clinics. (Codd, Vol. 4, p. 899)

174. Ms. Codd testified that DaVita fosters a culture where its staff are like family and are certainly a community. She noted that TRC Copperfield, TRC Harrisburg and TRC Cabarrus are part of the TOPCATS division of DaVita. (Codd, Vol. 4, pp. 896-97)

175. For example, Cedric Brown, the patient care technician responsible for Patient #2 on the day of the November 2, 2009 bleed out incident, no longer works at TRC Copperfield, but now works at a TRC facility in Charlotte. (Leahy, Vol. 4, p. 962)

176. The TRC employees for the proposed new center, TRC Cabarrus, will be trained at TRC Harrisburg and TRC Copperfield. (Jt. Ex. 2, p. 53)

177. It was reasonable for the Agency to rely upon the TRC Copperfield survey in finding the TRC Cabarrus Application non-conforming with Criterion 20 even though TRC Cabarrus was a proposed new facility with no track record because the proposed new facility shared common applicants, common ownership, common county location, common medical directorship, common governance, common medical practice providing clinical coverage, common clinical services specialists, common quality policies and procedures, and common staff with TRC Copperfield. (Smith, Vol. 2, p. 344; Smith, Vol. 6, p. 1326; Matthes, Vol. 1, p. 61)

178. It was reasonable for the Agency to find TRC Harrisburg non-conforming with Criterion 20 even though there were no quality of care issues reported at that facility because it shared common applicants, common ownership, common county location, common medical directorship, common governance, common medical practice providing clinical coverage, common clinical services specialists, common quality policies and procedures and common staff with TRC Copperfield. (Smith, Vol. 3, p. 344; Smith, Vol. 6, p. 1326; Matthes, Vol. 1, p. 61).

179. Daniel Sullivan, an outside expert witness in CON preparation and analysis and health planning hired by TRC/DaVita, testified that the Agency should not have found TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 20 on the basis of the TRC Copperfield survey results. However, Mr. Sullivan presented no Agency Findings, Final Agency Decisions or Court decisions in support of his opinion. Upon examination by the Court, Mr. Sullivan admitted that he had not undertaken an analysis of prior Agency decisions and practice on this point. (Sullivan, Vol. 4, pp. 1060-61)

180. Although none of the TRC/DaVita witnesses disagreed with the Agency's determination that the TRC Copperfield facility was non-conforming with Criterion 20 based upon the January 28, 2010 survey report and condition level deficiencies, Mr. William Hyland, TRC's expert witness in the field of dialysis CON preparation and analysis and preparer of the three TRC/DaVita Applications, opined that the Agency should not have found TRC Harrisburg and TRC Cabarrus non-conforming with Criterion 20. (Hyland, Vol. 4, pp. 1113, 1138, 1149)

181. However, upon examination by the Court, Mr. Hyland admitted that the "applicant" for all three TRC applications was Total Renal Care of North Carolina, which is a subsidiary of DaVita. Therefore, all three facilities are owned by Total Renal Care of North Carolina and ultimately by DaVita, Inc. (Hyland, Vol. 4, pp. 1147-48)

182. Moreover, Mr. Hyland admitted he was aware of the Agency's February 10, 2009 Findings in a Davie County dialysis review because he prepared the TRC Davie application. In those findings, the Agency found the applicant TRC Davie non-conforming with Criterion 20 due to a quality of care issue at a TRC facility in Rowan County, Dialysis Care of Rowan. Davie County and Rowan County are contiguous counties. (RAI Ex. 119, p. 25; Hyland, Vol. 5, p. 1172-73)

183. As is the case with the proposed TRC Cabarrus facility, the TRC Davie facility was also a proposed facility that did not exist at the time the Agency found TRC Davie non-conforming with Criterion 20. (RAI Ex. 119)

184. Mr. Hyland further testified that he had reviewed the Agency's determination under Criterion 20 for the Davie review and had discussed the same with Angie Matthes, Project Analyst for the Davie review. TRC did not appeal the Agency's decision in the Davie review. (RAI Ex. 119; Hyland, Vol. 5, pp. 1173-74)

185. Dr. Halstenberg, the Medical Director at TRC Copperfield, and the Medical Director of the proposed TRC Cabarrus County facility, was the Medical Director of TRC's Rowan facility and the Medical Director of its proposed Davie facility. (Hyland, Vol. 5, p. 1173; RAI Ex. 119, p. 25)

186. Mr. Hyland further admitted he was aware of the April 8, 2009 Agency Findings for TRC Cape Fear. Mr. Hyland also prepared that application for TRC Cape Fear and was aware that the Agency relied upon the overlap in Medical Directors and governing bodies at the existing Southeastern Dialysis Center—Wilmington and TRC Cape Fear clinics to find TRC Cape Fear non-conforming with Criterion 20 based on quality of care issues at Southeastern Dialysis Center—Wilmington. (Hyland, Vol. 5, pp. 1175-76)

187. However, in the present case, the Agency did not rely upon quality of care issues at TRC facilities in counties contiguous to Cabarrus County to find TRC Harrisburg and TRC Cabarrus non-conforming with Criterion 20. TRC Copperfield is located in Cabarrus County, as are TRC Harrisburg and the proposed TRC Cabarrus facility. (Jt. Ex. 1, p. 459)

188. Although data points arguably related to quality are requested in the rules applicable to End Stage Renal Disease ("ESRD") reviews, those are not utilized by the Agency in its analysis under Criterion 20. (Frisone, Vol. 1, p. 170) The purpose of the CON rules in 10A N.C.A.C. 14C.2200 *et seq.* is to provide guidance to the applicant and not to the Project Analyst. (Frisone, Vol. 1, p. 178)

189. The Agency approached the Criterion 20 analysis of the TRC Applications in a manner consistent with the way it has approached other Criterion 20 analyses. (Matthes, Vol. 1, p. 66; Smith, Vol. 2, p. 344)

190. The Agency's determination that the TRC Copperfield, TRC Cabarrus and TRC Harrisburg Applications were non-conforming with Criterion 20 was consistent with the Agency's practice. The Agency would not approve TRC/DaVita to develop additional resources in a county where they have a facility with conditions out of compliance. (Frisone, Vol. 1, p. 137)

191. The Agency bases its decision on the law and previous Agency Findings and resulting Final Agency Decisions or Court decisions and is charged with ensuring consistency with both the law and previous decisions. (Frisone, Vol. 1, p. 145) However, each review is different and each application must be analyzed in light of the facts of the specific application(s) under review. (Frisone, Vol. 1, p. 185)

192. Although the Agency Findings state that TRC Copperfield failed to conform to four Medicare Conditions of Participation, Project Analyst Tanya Rupp understood that there were only two Conditions of Participation out of conformance at the time the decision was made. The statement that there were four Conditions out of compliance was merely a typographical error made when she cut and pasted the standard language: "The files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation indicate that a survey . . ." and failed to change the non-conformity from four to two. (Rupp, Vol. 5, pp. 1238-39) The same is true regarding the same error that appears in the Comparative Analysis discussion of Provision of Quality of Care. (Rupp, Vol. 5, p. 1240)

193. The fact that the number four was cited in the Agency Findings instead of the number two did not affect the decision made by the Agency because the number of failures to

conform to Conditions of Participation does not have that much bearing on the Agency's decision. (Rupp, Vol. 5, p. 1239)

194. Criterion 20 examines whether quality care has been provided in the past. (Frisone, Vol. 1, p. 140) The Agency cannot conditionally approve an applicant under Criterion 20 because it cannot condition past performance. (Frisone, Vol. 1, p. 138; Smith, Vol. 2, p. 346)

195. Ms. Frisone has never seen the Agency conditionally approve an applicant under Criterion 20 in her seventeen years with the CON Section. (Frisone, Vol. 1, pp. 133, 139) Likewise, Ms. Rupp has never seen the Agency conditionally approve an applicant under Criterion 20. (Rupp, Vol. 1, p. 230)

196. Consistent with that practice, the fact that a facility takes remedial measures to correct deficiencies or problems, as Tammy Leahy testified DaVita has done at the TRC Copperfield facility, it is not relevant to the CON Section's analysis of the provision of quality of care *in the past*. Furthermore, the fact that a facility enters into a Plan of Correction to address deficiencies reported in a survey is not relevant to the CON Section's analysis under Criterion 20. (Smith, Vol. 2, p. 350; Matthes, Vol. 1, p. 58)

197. The Licensure and Certification Section is primarily responsible for ensuring a facility's compliance with Medicare Conditions of Coverage and Participation. (Matthes, Vol. 1, p. 81) As such, the CON Section has no authority over what is required in a Plan of Correction to eliminate a facility's failure to comply with certain Conditions of Participation. (Smith, Vol. 2, p. 351)

198. Moreover, a Plan of Correction is forward looking whereas Criterion 20 looks at past behavior. (Smith, Vol. 2, p. 351)

199. Additionally, based on the Agency's practice, a Plan of Correction is not relevant to the Criterion 20 analysis. (Matthes, Vol. 1, p. 58)

200. As testified to by Mr. Smith, it is important to remember that "the instances when the survey produces a negative finding is usually—does not mean that the problem is always an isolated incident that only occurred once." (Smith, Vol. 2, p. 351)

201. Thus, even though the CON Section found all three DaVita applications (TRC Cabarrus, TRC Harrisburg and TRC Copperfield) demonstrated the need for the 23 dialysis stations, it could not approve the applicants due to the concerns over the provision of quality care in the past as analyzed under Criterion 20. (Rupp, Vol. 1, p. 230)

3. <u>Other Relevant Criterion 20 Agency Findings</u>

202. The Agency relies upon past Agency Findings and decisions as guidance for decisions in order to ensure decisions are consistent with the law and past Agency practice. Project Analysts are expected to look at previous decisions, including both findings and applications when necessary, to determine how the Agency has handled something in the past. (Frisone, Vol. 1, p. 145)

203. In the February 10, 2009 TRC Davie County Dialysis Center Agency Findings, the Agency found TRC Davie County non-conforming with Criterion 20 because: "The applicant currently provides dialysis services at other facilities in North Carolina, including Dialysis Care of Rowan County. The current Medical Director at Dialysis Care of Rowan

County, William K. Halstenberg, M.D., has agreed to serve as the Medical Director of the proposed Davie County facility. The files in the Acute and Home Care Licensure and Certification Section . . . indicate that a survey of Dialysis Care of Rowan County in January 2008 identified immediate jeopardy and failure to conform to three Medicare Conditions of Participation. Therefore, the application is nonconforming to this criterion." (RAI Ex. 119, p. 25)

204. Dr. Halstenberg was identified as the Medical Director of Dialysis Care of Rowan County and the proposed TRC Davie County facility. (RAI Ex. 119, p. 25) He is still serving as Medical Director of Dialysis Care of Rowan County. (Halstenberg, Vol. 1, pp. 119-20)

205. The Davie Findings based the non-conformity with Criterion 20 on the overlap with the applicant TRC Davie County and Dialysis Care of Rowan County; the fact that the facilities are located in contiguous counties; and the fact that the two entities shared the same Medical Director. (RAI Ex. 119, p. 25; Matthes, Vol. 1, p. 63)

206. Rowan County is contiguous to Davie County. (Matthes, Vol. 1, p. 63)

207. The immediate jeopardy citation was due to a dialyzer mix-up where one patient was put on the dialysis machine with another patient's reprocessed dialyzer. (Matthes, Vol. 1, p. 63) The reprocessed dialyzer that was used on the wrong patient belonged to a patient with HIV. (Halstenberg, Vol. 1, pp. 121-22)

208. Mr. Hyland, preparer of the TRC Applications and expert witness for TRC, was aware of the February 10, 2009 Davie County Agency Findings and the Agency's analysis under Criterion 20 because he prepared the TRC Davie application. (Hyland, Vol. 5, pp. 1173-74)

209. On April 8, 2009, the CON Section issued a set of Agency Findings which were cosigned by CON Assistant Chief Martha Frisone for a New Hanover County project proposing to relocate 28 existing dialysis stations from Southeastern Dialysis Center-Wilmington to Cape Fear Dialysis Center. (Frisone, Vol. 1, pp. 141-42; RAI Ex. 169, pp. 38-58)

210. The applicants in that case were DaVita clinics. (Frisone, Vol. 1, p. 142)

211. The Agency found DaVita non-conforming with Criterion 20 because a June 5, 2008 survey identified immediate jeopardy and failure to conform to Medicare Conditions of Participation at the existing facility at Southeastern Dialysis Center-Wilmington, from which the applicant proposed to relocate stations. (Frisone, Vol. 1, p. 143; RAI Ex. 169, p. 53)

212. Although the proposed new facility, Cape Fear Dialysis Center, did not exist at the time, the Agency disapproved it under Criterion 20 due to the non-conformity with the existing Southeastern Dialysis Center-Wilmington. (Frisone, Vol. 1, p. 143)

213. Ms. Frisone testified that the facts of the present case where TRC Cabarrus does not yet exist but was found non-conforming with Criterion 20 based upon quality of care issues at TRC Copperfield were very similar to the New Hanover County Findings in RAI Exhibit 169. She testified that the New Hanover County findings would be precisely one of the prior decisions she would have relied upon in discussions with Mr. Smith regarding research on how to handle the TRC Copperfield situation. (Frisone, Vol. 1, pp. 144-45)

214. On February 19, 2010, the Agency issued Agency Findings in a review for Dialysis Care of Richmond County, a DaVita facility. The Project Analyst for that review was Ms. Matthes. (Matthes, Vol. 1, pp. 64-65; RAI Ex. 169, pp. 59-75)

215. In that review, the applicant was found non-conforming with Criterion 20 because a March 2009 survey cited the facility for immediate jeopardy and failure to conform to two Medicare conditions of participation. (Matthes, Vol. 1, p. 65; RAI Ex. 169, p. 72)

216. On February 26, 2010, the Agency issued Agency Findings for the Bio-Medical Applications of North Carolina d/b/a FMC New Hope ("BMA") review where BMA proposed to add two dialysis stations to an existing facility. (RAI Ex. 169, pp. 76-95)

217. The Agency found BMA non-conforming with Criterion 20 based upon a survey conducted in 2008 where the facility was cited for immediate jeopardy and failure to conform with two Medicare Conditions of Participation. (Hyland, Vol. 5, p. 1213; RAI Ex. 169, p. 91)

218. TRC introduced a set of Agency Findings issued on July 8, 2011, cosigned by Martha Frisone in the BMA-East Charlotte review, nearly five months after the issuance of the Agency Findings at issue in this case. In that review, BMA-East Charlotte was found conforming with Criterion 20. (TRC Ex. 277)

219. TRC attempted to further rely upon an affidavit from the Licensure and Certification Section which reported an immediate jeopardy issue at a different BMA facility, BMA-West Charlotte, within the 18-month look back period for the BMA-East Charlotte application. (Frisone, Vol. 1, p. 160)

220. Ms. Frisone testified that she was not aware of the immediate jeopardy finding at BMA-West Charlotte and that there may be a sufficient nexus between the facilities so as to result in a non-conformity with Criterion 20. However, because Ms. Frisone was not aware of those survey results, she was not able to take that into consideration in making her decision with respect to the BMA-West Charlotte proposal. (Frisone, Vol. 1, pp. 160-61, 184)

B. Criterion 1

221. Criterion 1 provides: "The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved." (Jt. Ex. 1, p. 458)

222. The 2010 SMFP and July 2010 Semiannual Dialysis Report ("SDR") provided "a county need methodology for determining the need for additional dialysis stations. According to Section 2(E) of the dialysis station county need methodology, found on page 333 of the 2010 SMFP, *"If a county's December 31, 2010 projected station deficit is ten or greater and the July SDR shows that utilization of each dialysis facility in the county is 80% or greater, the December 31, 2010 county station need methodology is the same as the December 31, 2010 projected station deficit,"* The county need methodology for 2010 results in a need determination for 23 dialysis stations in Cabarrus County. In the July 2010 *Table B: ESRD Dialysis Station Need Determinations by Planning Area;* a total of 187.4 in-center dialysis patients and 30.4 home patients are projected in Cabarrus County as of December 31, 2010." (Jt. Ex. 1, pp. 458-59)

223. The TRC Applications and RAI Application were each found conforming with the need determination in the 2010 SMFP because each proposed to develop no more than 23 dialysis stations in Cabarrus County. (Jt. Ex. 1, pp. 459-60)

224. There was one policy applicable to the Cabarrus County ESRD review, which was Policy GEN-3. Policy GEN-3 states: "A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." (Jt. Ex. 1, p. 460)

225. Although the TRC Applications provided information and discussion regarding their approach to safety and quality clinical outcomes, the TRC Cabarrus, TRC Harrisburg and TRC Copperfield Applications were each non-conforming with Policy GEN-3 and Criterion 1 because "the applicant[s] did not adequately demonstrate that it has provided quality care in its existing Copperfield Dialysis Center. See Criterion (20) for discussion. Therefore, the applicant[s] did not adequately demonstrate that the proposal would ensure quality care." (Jt. Ex. 1, pp. 461, 463, 465; Rupp, Vol. 1, p. 197)

226. Daniel Sullivan, an outside expert witness in CON preparation and analysis and health planning hired by TRC/DaVita, testified that in his opinion, the Agency should not have found the TRC Applications non-conforming with other criteria based on their analysis of Criterion 20 quality of care issues. However, Mr. Sullivan admitted on examination from the Court that this is often the practice of the Agency and offered no past Agency Findings or decisions in support of his opinion. (Sullivan, Vol. 4, p. 1060)

C. Criterion 4

227. Criterion 4 provides: "Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed." (Jt. Ex. 1, p. 492)

228. The Agency found TRC Copperfield, TRC Harrisburg and TRC Cabarrus non-conforming with Criterion 4 because the applicant[s] failed to demonstrate that it has provided quality dialysis care to patients served within the 18-month look back period. The Agency cited its discussion under Criterion 20. For the TRC Copperfield and TRC Harrisburg facilities, the Agency also cited the non-conformities with the ESRD rules at 10A N.C.A.C. 14C.2204(7) and (10). (Jt. Ex. 1, p. 492)

229. Non-conformity with any of the applicable statutory criteria can result in a non-conformity with Criterion 4. (Smith, Vol. 6, p. 1306)

D. Criterion 18a

230. Criterion 18a provides: "The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any

enhanced competition will have a positive impact upon the cost effectiveness, quality and access to the services propose; and in the case of applications for services where competition between providers will not have a favorable impact on cost effective, quality and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact." (Jt. Ex. 1, p. 514)

231. Criterion 18a was applicable to this review and deals in part with competition. (Rupp, Vol. 1, p. 229)

232. Ms. Rupp testified that "competition is a good thing because it helps to contain the cost of health care." (Rupp, Vol. 5, p. 1257) Competition can also have a positive impact on the quality of health care provided because competitors may try to outdo each other in terms of providing greater quality of care. (Rupp, Vol. 5, p. 1258)

233. At the present time, a patient seeking in-center dialysis treatment in Cabarrus County has only two choices in Cabarrus County to receive that treatment: TRC Harrisburg or TRC Copperfield, both of which are DaVita facilities. (Rupp, Vol. 1, p. 229; Smith, Vol. 2, pp. 394-95)

234. If a patient wants to seek dialysis services from a provider other than DaVita, they have no choice but to leave Cabarrus County. (McGill, Vol. 2, p. 279; Hyland, Vol. 5, p. 1160)

235. Patients deserve a choice of provider to seek a higher quality of care. (McGill, Vol. 2, p. 280)

236. Ms. Rupp was aware of the fact that DaVita had two in-center dialysis clinics in Cabarrus County while RAI had no in-center dialysis clinics in Cabarrus County at the time of the review. (Rupp, Vol. 1, p. 190)

237. The Agency was also aware, however, that RAI was an established provider of dialysis services in North Carolina. (Rupp, Vol. 1, pp. 190-91)

238. If DaVita were awarded additional dialysis stations to develop in Cabarrus County, it would not bring a new provider of in-center dialysis to that county and would not enhance competition. (Rupp, Vol. 1, p. 229)

239. If patients moved across the Cabarrus County line to Rowan County, they could receive in-center dialysis treatment at TRC Kannapolis, also a DaVita facility. (Halstenberg, Vol. 1, p. 124)

240. Dr. Halstenberg, Medical Director and member of the governing body of TRC Copperfield and the proposed TRC Cabarrus facility, testified that his practice, Central Carolina Nephrology, provides medical direction for five DaVita facilities and that his practice receives income from those medical directorship positions. (Halstenberg, Vol. 1, p. 125)

241. Dr. Halstenberg testified that he does not want RAI to open a dialysis clinic in Cabarrus County. (Halstenberg, Vol. 1, p. 125)

242. William Hyland, expert witness for TRC/DaVita and preparer of the three TRC Applications, testified that TRC does not want RAI to enter the Cabarrus County market. Mr. Hyland admitted that filing the TRC Applications was, in part, a defensive move by DaVita. (Hyland, Vol. 5, pp. 1161-63; RAI Ex. 179, p. 90)

243. Dr. Halstenberg acknowledged that Dr. Kathleen Doman, the Medical Director of RAI's proposed Cabarrus facility, is a competitor of his practice and that Dr. Doman would be more knowledgeable regarding her practice than Dr. Halstenberg would be. (Halstenberg, Vol. 1, p. 125)

244. The TRC Applications were found non-conforming with Criterion 18a because they "did not adequately demonstrate that any of [their] proposals would have a positive impact on the quality of the proposed dialysis services," which related back to the Criterion 20 non-conformity. (Rupp, Vol. 1, p. 228)

E. 10A N.C.A.C. 14C.2204(7) and (10)

245. TRC Harrisburg was found non-conforming with the rule at 10A N.C.A.C. 14C.2204(7) because it failed to demonstrate that blood bank services are available. (Jt. Ex. 1, p. 523)

246. Although the Agency has the discretion to condition an applicant under this rule, TRC Harrisburg was not conditioned because it was otherwise non-conforming with Criterion 20. (Rupp, Vol. 1, p. 231)

247. TRC Harrisburg was found non-conforming with the rule at 10A N.C.A.C. 14C.2204(10) because it failed to demonstrate that vascular surgery for dialysis treatment patients services are available. (Jt. Ex. 1, p. 524)

248. Although the Agency has the discretion to condition an applicant under this rule, TRC Harrisburg was not conditioned because it was otherwise non-conforming with Criterion 20. (Rupp, Vol. 1, p. 231)

III. RAI Application

Criterion 3

249. The RAI Application proposed to develop a 23-station dialysis facility located near Interstate 85 in the northwestern portion of Cabarrus County, close to the Cabarrus-Mecklenburg border. (Jt. Ex. 5, p. 32)

250. According to the testimony of RAI's Regional Director, Ms. McGill, RAI is aware that applicants must provide data in their applications that the CON Section can analyze to determine if an application complies with applicable review criteria. (McGill, Tr. Vol. 2, p. 321-22)

251. Mr. David Legarth was the person who prepared the entire RAI Application. He collected information from RAI, prepared answers to the questions in the CON application form and compiled the exhibits submitted to him by RAI. (Legarth, Tr. Vol. 2, p. 498)

252. The RAI Application presented data from the July, 2010 SDR, indicating that there were 201 dialysis patients living in Cabarrus County as of December 31, 2009, and that only 109 of them were receiving in-center hemodialysis at a facility located in Cabarrus County. (Jt. Ex. 5, p. 30)

253. The data in the July, 2010 SDR, which is included in the RAI Application as Exhibit 7, shows that 28 of the 201 dialysis patients were home-trained and not receiving in-center hemodialysis at all, so the actual number of Cabarrus County residents receiving in-center hemodialysis was 173. With 109 of those 173 hemodialysis patients getting their treatments in a Cabarrus County facility, that means 64 Cabarrus County patients were receiving in-center hemodialysis at a facility outside Cabarrus County, as of the date the SDR data was collected on December 31, 2010. (See, Table B of July, 2010 SDR, in Jt. Ex. 5, p. 158)

254. RAI agrees that applicants for a certificate of need have a duty to present evidence to demonstrate that they are proposing a service that will be utilized; and that even with the need for stations shown in the SDR, RAI still had to demonstrate under Criterion 3 the need that the population it identified has for the facility it proposed. (McGill Vol. 2, pp. 295, 322; Legarth, Vol. 2, p. 499)

255. Mr. Legarth agrees that RAI had to show how it would actually garner the patients that it identified in the application. (Legarth, Vol. 3, p. 594)

256. Mr. Craig Smith, Chief of the CON Section, has been involved in the review of approximately 600 dialysis projects during his employment at the Certificate of Need Section as a Project Analyst, Assistant Chief and most recently as Chief of the Section. (Smith, Vol. 6, pp. 1282-84)

257. In analyzing the projections in the RAI Application, the CON Section was looking for a basis for the start-up population and a basis for the incremental growth of 6 patients per month that was projected on page 69 of the RAI Application. (Smith, Vol. 6, pp. 1291-920

RAI's Projected Start-Up Population

258. The RAI Application contained a chart on page 69 which projected the number of in-center hemodialysis patients during the first year of operation, on a month-by-month basis:

- The first line of the chart showed the number of hemodialysis patients projected to be admitted during each month of the first year of operation, beginning with January of 2012 and continuing through December of that year.

- The chart projected that 9 in-center hemodialysis patients would be admitted in January and 6 more patients would be admitted each month thereafter through December of 2012, resulting in a total of 75 patients being admitted during the first year of operation.

- In narrative that appears below the chart on page 69, the RAI Application stated that after the initial month of operation, when existing hemodialysis patients of Dr. Doman would relocate to the facility, a majority of the 6 in-center patients admitted each month will be existing Cabarrus County dialysis patients who must travel outside of Cabarrus County to receive their treatment.

259. Exhibit 13 in the RAI Application contained a letter from Dr. Kathleen Doman, the RAI Medical Director, confirming her agreement to serve as the Medical Director of the proposed RAI facility, but there was no information in this letter or elsewhere in the RAI Application that presented the number of Dr. Doman's patients who already were receiving in-center hemodialysis treatments at the time the Application was filed; nor was there any indication of a projected number of dialysis patients who would be under treatment by Dr. Doman when the proposed facility was projected to open, in January of 2012. (Jt. Ex. 5, p. 226)

260. The CON Section would expect Dr. Doman, to know how many patients she has, including the number of her patients who are receiving dialysis or are expected to need dialysis in the future; but Dr. Doman provided no information about this in her letter on page 226 in Exhibit 13 of the RAI Application to support the assumption that 9 patients would transfer in the first month of operation. (Smith, Vol. 6, p. 1387)

261. Dr. Doman has a database which shows which of her patients are Cabarrus County residents, but at her deposition before the contested case hearing, she could not identify how many of her patients are in-center dialysis patients; and RAI never requested this information from her while the RAI Application was being prepared. Ex. 182, pp. 78-79

262. Dr. Doman had some general discussions with RAI about demonstrating that she provides services to patients from Cabarrus County. (Ex. 182, pp. 30-31) However, there is no information about this in her letter, or in Section III of the RAI Application. (Jt. Ex. 5, pp. 30-43, 226)

263. It was Dr. Doman's understanding that RAI planned to contact her patients in the Glenwater facility to see if they would sign a support letter, but that they were not planning to contact the patients that other physicians were caring for at the facility. (Ex. 182, p. 37)

264. Exhibit 5 in the RAI Application contained seven identical form letters each of which was signed by a person who indicated that the person was a patient of Dr. Doman. Jt. Ex. 5, pp. 126-32. The text of these form letters was prepared by someone in the RAI central office and they were provided to Ms. McGill, who gave them Ms. Sawsan Yateem, the center director of the RAI Glenwater facility in Mecklenburg County. (McGill, Vol. 2, p. 296, Yateem, Vol. 2, p. 428)

265. In the email message that transmitted the form patient support letter for the RAI Application to Ms. McGill, an RAI officer stated "Last year in that Alexander County application, we had 20 support letters from patients. What process do you propose to get similar or better numbers for us?" (TRC Exhibit 245; McGill, Vol. 2, p. 299)

266. The instructions that Ms. McGill gave Ms. Yateem with regard to the patient letters for the RAI Application was to approach patients of Dr. Doman in the RAI Glenwater facility to obtain a sampling of letters of support. (McGill, Vol. 2, p. 286; Yateem, Vol. 2, p. 410)

267. In a prior application to establish a 10-station facility in Huntersville, RAI had submitted 44 letters which documented that the patients were current dialysis patients at the RAI Glenwater facility. (McGill, Vol. 2, pp. 301-02)

268. In its application to establish a 23-station facility in Cabarrus County, RAI only submitted seven patient support letters. Each of the letters contains the statement "If I require dialysis services to treat my kidney disease, I will want to use this dialysis center . . . ." None of these letters contains information to indicate that the individual who signed the letter already is receiving in-center dialysis services or is expected to be in need of dialysis services on or before December 31, 2012, the projected end date of the first year of operation of RAI's proposed facility. (Jt. Ex. 5, pp. 126-32)

269. The CON Section determined that there is no data in the patient letters found in Exhibit 5 on pages 126-132 of the RAI Application, or elsewhere in Section III of the RAI Application, to support RAI's assumption that nine existing patients would relocate to the facility in the first month of operation. (Smith, Vol. 6, pp. 1293-94, 1384-85) The CON Section also determined that there was nothing in Section III or in the text of the patient letters that supports the projection of six additional patients coming to the proposed RAI facility each month after the initial month of operation. (Smith, Vol. 6, p. 1385)

270. The letters on pages 127, 131, and 132 were signed by individuals who reported an address within Cabarrus County. The other four letters were signed by individuals with an address in Huntersville or Charlotte, in Mecklenburg County. (Jt. Ex. 5, pp. 126-132)

271. Even if the CON Section had assumed that each of the Cabarrus County residents who signed a letter in the RAI Application was receiving in-center dialysis, there is no indication in any of the letters where any of these persons is receiving dialysis. Thus, the RAI Application contained no information which demonstrated that any of the 64 in-center hemodialysis patients identified in the July, 2010 SDR who were leaving Cabarrus County to receive in-center dialysis were receiving treatment at the RAI Glenwater facility or any other facility operated by RAI.

272. Even if the CON Section had assumed that each of the three persons who signed letters and listed an address in Cabarrus County was a current dialysis patient receiving dialysis at the RAI Glenwater facility or another facility operated by RAI, those three individuals would constitute less than five per cent of the 64 in-center hemodialysis patients identified in the July, 2010 SDR who were leaving Cabarrus County to receive dialysis treatments.

273. At the RAI Glenwater and Latrobe facilities in Mecklenburg County, the only physicians who are credentialed to admit patients and prescribe dialysis treatments are nephrologists. (McGill, Vol. 2, p. 320; Yateem, Vol. 2, 432)

274. The RAI Application contained letters from physicians in Exhibit 12 (Jt. Ex. 5, pp. 208-25). Among the physicians who wrote those letters, the only nephrologists are Dr. Mundra, who is a member of Dr. Doman's practice, and Dr. Kaldas (Jt. Ex. 5, pp. 216, 224) Dr. Kaldas had moved to North Carolina from New Jersey in 2010, and at the time of the RAI

Application, he had not yet admitted a patient to the RAI Glenwater facility. (Yateem, Vol. 2, pp. 412, 421)

275. There is an established care relationship between the patient and the physician so it is important that the nephrologist who is caring for a patient be contacted about any plans to relocate a patient to a different dialysis facility. (182, p. 38)

276. Dialysis patients also develop a close relationship with the staff of the facility where they receive their patients. (McGill Vol. 2, pp. 278-79)

277. None of the letters in Exhibit 12 of the RAI Application contain any statement that the physician signing the letter would refer patients to Dr. Doman or to the proposed RAI facility. Only one of these letters was signed by a physician who has an office in Cabarrus County (Dr. Revis on page 214). (Jt. Ex. 5, pp. 208-25)

278. The CON Section determined that there is no information in the physician letters set forth in Exhibit 12 on pages 208-25 of the RAI Application to support either the projection of nine patients coming to the proposed RAI facility in its first month of operation or the projection of six additional patients per month in each of the remaining 11 months of the first operating year. (Smith, Vol. 6, pp. 1294, 1386)

279. The letters in Exhibit 5 (the patient letters) and in Exhibits 12 and 13 (the letters from other physicians and from Dr. Doman) present no information to support the assumption stated on page 69 of the RAI appl. that nine patients of Dr. Doman would transfer into the facility to receive in-center hemodialysis during the first month of operation.

RAI's Projected Growth

280. In order to meet the requirements of the Performance Standards Rule, RAI had to demonstrate that the facility would be utilized at a rate of at least 3.2 patients per station by the end of the first operating year. In addition, the Performance Standards Rule also requires applicants to provide their assumptions and the methodology by which they are projecting patient utilization. (Smith, Vol. 6, pp. 1298, 1329-30)

281. The RAI Application projected that a certificate of need would be issued in late February of 2011, that construction would be completed by November 15, 2011, and that this proposed facility would open and begin to offer services on January 1, 2012, completing its first year of operation on December 31, 2012. (Jt. Ex. 5, p. 89) Therefore, for purposes of measuring compliance with the Performance Standards Rule, the first operating year of RAI's proposed facility would end on December 31, 2012.

282. The RAI Application projected that of the 75 patients who were projected to receive in-center hemodialysis at some point during Operating Year 1, 65 would be residents of Cabarrus County and 10 would be residents of Mecklenburg County. (Jt. Ex. 5, p. 42)

283. Mr. Legarth acknowledged that the growth projected by RAI from its starting population of the nine patients in the first month of operation to 65 Cabarrus County patients at the end of the first operating year would represent a 700 per cent growth over the course of 11 months. (Legarth, Vol. 3, pp. 613-14)

284. On page 15 of the RAI Application, RAI provides a list of the pages within the Application itself where documentation of compliance with each of the special rules for dialysis facilities is found, including the Performance Standards Rule codified at 10A NCAC 14C .2203. The RAI Application indicates that information addressing the performance standard rule is found in Section III.1 and Section III.7 of the RAI Application. (Jt. Ex. 5, p. 15)

285. Sections III.1 and III.7 are two separate questions in the standard dialysis application form and the RAI Application indicates on pages 39-41 that Questions III.2 – III.6 are not applicable to its Application. Thus, the only Sections of the RAI Application itself (as opposed to Exhibits) that provide information concerning the need or demand for its proposed service are the pages that respond to Questions III.1 or III.7:

- The information found on page 30 of the RAI Application in response to question III.1 provides general information about the need for dialysis stations identified in the July, 2010 SDR and historical data concerning Cabarrus County dialysis patients.

- The information on page 31 of the RAI Application provides general information about the general population growth throughout Cabarrus County.

- The information on page 32 of the RAI Application in response to Question III.1 presents information that RAI considered in choosing the proposed location of the RAI facility; and there is a reference on that page to location of the local nephrology practice in Cabarrus County as a factor in RAI's site choice, even though that local nephrology practice is the Central Carolina Nephrology practice and the RAI Application has indication of support from that Nephrology practice.

- The information on page 33 of the RAI Application in response to Question III.1 simply presents a zip code map showing the zip codes that are located in any portion of Cabarrus County, including those zip codes that cross over into other counties.

- The information on page 34 of the RAI Application in response to Question III.1 simply presents the number of patients in the 65 and older age range who live in any of the Cabarrus County zip codes in 2010 and the projected numbers of such persons in 2015.

- The information on page 35 of the RAI Application in response to Question III.1 simply presents the number of in-center patients by ESRD network.

- The information on page 36 of the RAI Application in response to Question III.1 simply presents general information concerning the entire population within Network 6, comprised of the Carolinas and Georgia.

- The information on pages 37-38, in response to question III.1, presents data about the number of persons across Cabarrus County who are 60 years old or older and the number of African-American residents of Cabarrus County in that age range.

- The information on pages 41 and 42, which responds to Question III.7, presents historical and projected in-center patients in Cabarrus County.

(Jt. Ex. 5, pp. 30-42)

286. Mr. Legarth, who prepared the RAI Application and was offered by RAI as an expert witness, testified that in his opinion, RAI had demonstrated the need for the facility it proposed "based on the population of dialysis patients that are currently leaving the county, based on the information that that number is not expected to decrease into the future, based on the letters of support that we include, the physicians' letters that we received, the experience and reputation of the company, that yes, we will be able to reasonably meet the utilization requirements to operate this facility with 23 stations." (Legarth, Vol. 2, p.550)

287. However, the population data mentioned by Mr. Legarth in his testimony is simply a projection of the number of Cabarrus County patients who will need dialysis in the future, the same sort of general population data that is contained in the SDR. The existence of this group of patients does not demonstrate that they will come to the proposed RAI facility. As Mr. Legarth acknowledged, RAI also had to show how it would actually garner patients from among the population it identified. The letters from physicians and others that were presented in the RAI Application do not show how RAI will garner patients to come to the proposed RAI facility.

288. At one point during his direct examination, Mr. Legarth alluded to the four to six new patients that Dr. Halstenberg's practice is starting on dialysis treatments each month, and related this to the six new patients per month projected to come to the RAI facility, (Legarth II, p. 520) However, elsewhere in his testimony, Mr. Legarth was frank to acknowledge that RAI's proposal was not supported by Dr. Halstenberg's practice. (Legarth, Vol. 3, p. 622-23)

289. However, Mr. Legarth testified that ". . . we are not a provider of dialysis services in Cabarrus County yet. And it is 100 per cent reasonable to assume that an existing provider in Cabarrus County will be will be the primary focus of patients in that county and where they go to." (Legarth, Vol. 3, p. 593)

290. Mr. Legarth also testified that since RAI was not an existing provider in Cabarrus County, it had to show that it would be active and develop a network in Cabarrus County. He agreed that the network documented by the physician letters in Exhibit 12 in the RAI Application was primarily composed of Mecklenburg County physicians and that only one of them has a Cabarrus County address. (Legarth, Vol. 3, pp. 626-27)

291. In the response to question VII. 8, the RAI Application, which was submitted in September of 2010, stated that Dr. Doman "is actively seeking admitting privileges at CMC

NorthEast," the hospital in Cabarrus County; but Dr. Doman testified at her deposition about a year later that she had not sought privileges at that hospital. (Jt. Ex. 5, p. 58; Exhibit 182, p. 51)

292. Mr. Legarth testified that he had provided RAI information about agencies in Cabarrus County which RAI could contact to gather support for its application before the application was submitted. The RAI Application did contain some letters in Exhibits 11 and 14 that RAI wrote to local community organizations and agencies, but contained no responses from those agencies to would provide a basis for the ongoing referral of patients to the proposed RAI Facility. (Legarth, Vol. 3, pp. 630-32; Jt. Ex. 5, p. 206, 234-46)

293. Mr. Smith is familiar with a number of situations in the past where companies that have not been providing dialysis services in a particular locality or county have contacted local authorities to garner support for the application and make advance efforts to make people aware of its plans. (Smith, Vol. 6, pp. 1388-90)

294. Even though RAI did not have services in Cabarrus County at the time it applied, it still could have made arrangements to make the local community aware of its plans for a dialysis facility and to garner support for its application.

295. The testimony by Mr. Legarth, who justified the lack of documentation of actual support for the RAI Application from community agencies by saying that he was reticent to make such local community contacts because of the possibility of exposing or disclosing RAI's plans in advance, is not a credible justification or excuse for RAI's failure to develop and present evidence of community support in its application in support of its projections.

296. The RAI Application did contain a letter from the hospital in Cabarrus County, confirming that hospital's willingness to provide certain support services to dialysis patients, that letter was presented to satisfy other review criteria relating to the availability of support services for patients, and it offers no support for RAI's projections that dialysis patients would be referred to or admitted to its proposed facility. (Jt. Ex. 5, p. 183)

297. A careful review of the information that is contained throughout Section III of the RAI Application demonstrates that it does not explain or support the underlying assumptions, or the methodology used to develop the patient projections that appear on page 42 and page 69 of the RAI Application, including its stated assumption that six patients would be admitted to the proposed RAI facility each month during the last 11 months of the first operating year (February, 2012 – December, 2012).

298. A careful review of the information that is contained throughout Section III of the RAI Application demonstrates that it contained no information to support RAI's projection that the stations proposed to be operated in the RAI facility would reach the minimum utilization threshold of 3.2 patients per station at the end of Operating Year 1 on December 31, 2012, as required by the Performance Standards Rule at 10 NCAC 2203(a).

299. A careful review of the information that is contained throughout Section III of the RAI Application demonstrates that RAI also failed to provide a methodology to explain how it

was reasonable to believe that patients would choose or would be referred to the proposed RAI facility, to support its patient utilization projections, as required by 10 NCAC .2203(c).

It Would Not Be Possible To Conditionally Approve The RAI Application

300. In the chart on page 69 of its application, RAI did not take the approach of documenting the basis for an initial patient population and projecting forward from that initial population. Instead, it simply provided an unsupported assumption of 9 patients in the first month, followed by an influx of six more patients each month through the rest of the first operating year. (Smith, Tr. Vol. 6, p. 1396)

301. If RAI had been able to demonstrate that it was reasonable for nine patients to be admitted to the facility in its first month of operation, then RAI could have forecast the growth of that initial patient population from the date of the application through the CON review period, the facility construction schedule, and the first year of operation to project a number of patients who would receive in-center hemodialysis treatments in the facility at the end of the first year of operations. To do that, RAI could apply the average annual change rate of 8.5 percent defined in the July, 2010 SDR as follows:

- For each full 12-month period, multiply the starting in-center population by 1.085 to account for a full 12 months of population growth at the rate of 8.5 percent per year.

- For each fraction of a 12-month period, multiply the starting in-center population by the appropriate fraction of 1.085 to account for growth during that shorter period.

(Smith, Vol. 6, pp. 1394-96)

302. However, even assuming as a starting point that RAI already had a patient population of nine patients on the date it applied, the computation identified by Mr. Smith would not yield a sufficient number of patients to justify even a 10-station facility:

- Multiply 9 by one-third of 1.085 to account for the growth in the one-third of a year from September to December 2010.

(1) [9 X 1.0283 = 9.25 patients as of 12/31/2010]

- Multiply 9.25 times 1.085 to account for a full year of growth during calendar year 2011 up to the date the facility was projected to open.

(2) [9.25 X 1.085 = 10.04 patients as of 12/31/2011]

- Multiply 10.04 times 1.085 to account for the full year of growth during the first operating year.

(3) [10.04 X 1.085 = 10.9 patients as of the end of first operating year at 12/31/2012]

303. Thus, this computation results in a patient population at the end of the first operating year of approximately 11 patients. (Smith, Vol. 6, pp. 1418-21)

304. Even if the CON Section had considered approving the RAI Application with fewer stations, RAI had to show that it would have at least a sufficient number of patients to justify a 10-station facility, which is the minimum size facility that can be approved except in unusual circumstances defined by the pertinent SDR, and this was not such a situation. Therefore, to justify a minimal sized facility of 10 stations, RAI had to demonstrate that it was reasonable to project at least 32 patients at the end of the first operating year. (Smith, Vol. I p. 1396)

305. The result of the computation above is a total population of 11 in-center hemodialysis patients at the end of the first operating year, the point at which the Performance Standards Rule measures the population against the 3.2 patients per station standard, and a population of 11 patients is only enough to justify at most 4 stations. It would not be reasonable for the CON Section to issue a conditional approval of the RAI Application for 4 stations.

306. Although the CON Section can, and on occasion does, condition applications to downsize the number of stations from the number for which an applicant has applied, in this case there is insufficient information in the RAI Application to include such a condition, and the RAI Application cannot be approved at any number of stations. (Smith, Vol. 6, p. 1351)

Other Findings Relating to Criterion 3 and the Performance Standards Rule

307. Since RAI's Application failed to show that its proposed facility would be well utilized, the establishment of RAI's proposed facility would create unused capacity which would duplicate other health care capacity and result in unneeded costs being incurred; and this is a negative factor which relates directly to whether RAI's proposed service would constitute an unnecessary duplication under Review Criterion 6.

308. Of the applications (Jt. Ex. 5, pp. 67-74) RAI's revenue projections were tied directly to its projected patient utilization in Section X (pages 67-74). Since RAI's projections of patients in the chart on page 69 were unreliable, the operating revenue forecasts that are based on the patient projections also are unreliable and unsupported; and this has a direct negative impact on the financial feasibility of RAI's proposed facility under Review Criterion 5.

Findings regarding Competition under Criterion 18a

309. Under Criterion (18a), the Agency is not just looking at the competition that a new provider will bring to an area, but also how that competition will have a positive impact on cost effectiveness, quality and access to the services proposed. Just because an applicant is a new provider, does not mean it should be approved under Criterion (18a). (Smith, Vol. 2, p. 362)

310 Criterion (18a) does not allow an applicant to simply show that "I'm going to be a new provider in this service area or this county and therefore I conform." It requires an applicant to show how enhanced competition will have a positive impact on the factors set forth there. (Smith, Vol. 6, p. 1397)

311. If an applicant is nonconforming under Criterion (3) and as well as under Criterion (5), then it would not be cost effective under Criterion (18a) because it would be a duplication of services. (Smith, Vol. 6, pp. 1313-14)

312. If a new competitor comes into an area and is underutilized, it would foreclose the ability of other providers in the future to get approvals for additional dialysis stations and, in fact, it might actually reduce the utilization of existing providers which would not meet the spirit of Criterion (18a). (Sullivan, Vol. 4, pp. 1055-56)

TRC's Applications to establish a New Facility and expand its Harrisburg Facility

313. TRC already has two facilities in Cabarrus County: the Copperfield facility and the Harrisburg facility. TRC's Copperfield facility is certified and approved to operate 21 dialysis stations, and as of December 31, 2009 it was providing in-center dialysis to 60 patients, all of whom were residents of Cabarrus County. (Jt. Ex. 3, pp. 3, 32) The TRC Harrisburg facility is certified and approved for the operation of 15 dialysis stations, and on December 31, 2009, it was serving 39 in-center dialysis patients, all of whom were residents of Cabarrus County. (Jt. Ex. 4, pp. 3, 32)

314. TRC's current facilities in Cabarrus County serve all 109 of the residents who are documented in the July 2010 SDR as receiving dialysis at a facility in Cabarrus County.

315. TRC submitted three applications: to expand its Copperfield and Harrisburg facilities, and to establish a new Cabarrus County facility located in central Cabarrus County. TRC did not appeal the denial of its Copperfield facility and thus the only TRC applications that remain at issue are TRC's proposal for a new Cabarrus County facility and its proposal to expand its Harrisburg facility.

316. Dr. William K. Halstenberg is a licensed physician specializing in nephrology and practicing with Central Carolina Nephrology in Concord in Cabarrus County. (Halstenberg, Vol. 1, pp. 88-89) He has been practicing medicine in Concord since 1994. (Halstenberg, Vol. 1, p. 90)

317. TRC has an established relationship with Central Carolina Nephrology, which is the only nephrology practice in Cabarrus County. The TRC Cabarrus County Application contained letters from each of the five nephrologists associated with Central Carolina Nephrology. Each of the five physicians' letters specifically stated that the practice "has had a longstanding, solid professional relationship with DaVita for several years." The letters also state support for the Application. (Jt. Ex. 2, pp. 175-79])

318. The TRC Cabarrus County Applications also confirmed that Dr. Halstenberg has established referral relationships with other physicians in Cabarrus County. (Jt. Ex. 2, p. 39) When TRC applied to establish its first facility in Cabarrus County, in 2005, Mr. Hyland asked Dr. Halstenberg to solicit letters of support for the application from referral sources in Cabarrus County, and Dr. Halstenberg was able to gather more than 100 letters. (Hyland, Vol. 4, pp. 1114-17)

319. Northeast Medical Center is the hospital located in Cabarrus County. In order to admit patients to the hospital, a physician must have privileges there. Unlike Dr. Doman, Dr. Halstenberg has privileges at Northeast Medical Center and has admitted patients there. (Halstenberg, Vol. 1, pp. 94-95)

320. As a nephrologist, Dr. Halstenberg regularly treats patients who are candidates for or undergoing dialysis. (Halstenberg, Vol. 1, p. 90) Dr. Halstenberg's practice typically refers between four and six new Cabarrus County patients to dialysis each month. (Halstenberg, Vol. 1, p. 105)

321. Based on the volume of his practice in Cabarrus County versus Dr. Doman's practice, Dr. Halstenberg does not believe there would be sufficient patients for RAI to meets its projections of six new in-center patients per month during the first year of operations. (Halstenberg, Vol. 1, p. 110)

322. Dr. Halstenberg does not support the opening of an RAI clinic in Cabarrus County because he believes it is an overutilization of resources. He does not believe another unit is necessary. (Halstenberg, Vol. 1, p. 125)

323. The TRC Cabarrus County Application proposed to establish a 12-station facility, about half the size of the new facility proposed by RAI, on a site located in the center of the Cabarrus County at the intersection of Highway 601 and Highway 49. (Jt. Ex 2, pp. 2, 62]

324. The TRC Cabarrus County Application proposed to serve exclusively patients who resided in Cabarrus County. (Jt. Ex 2, p. 29)

325. The TRC Cabarrus County Application contained more than a hundred letters of support from patients. (Jt. Ex 2, pp. 180-296)

- Each letter confirmed that the person signing it was a resident of Cabarrus County.

- Each letter confirmed that the person signing it was currently receiving dialysis.

- Each letter confirmed that the patient was receiving dialysis under the care of a nephrologist associated with Central Carolina Nephrology, at a TRC facility.

- Each letter also indicates that the individual signing it has no intention of changing the nephrologist who is providing care for the individual nor any intention of changing the dialysis provider which is furnishing the individual's dialysis treatments.

- Each of the letters states that the individual signing the letter understands that the Cabarrus County facility is proposed to be located near the geographic center of Cabarrus County and confirms that the person signing the letter understands that this would give

that individual and other dialysis patients living in Cabarrus County the option of transferring to the new facility without having to change the provider of their care.

326. Patient support letters like those in the TRC Cabarrus Application are commonly accepted by the CON Section as indications of support for a specific project proposed by the applicant.

327. In the TRC Cabarrus County Application, TRC projected the growth of the patient populations in its Harrisburg and Copperfield facilities. It also presented a detailed computation which forecast the number of Cabarrus County residents who would need in-center dialysis in the future by using the SDR methodology, including applying the average annual change rate of 8.5 per cent identified in the July, 2010 SDR. However, TRC's methodology extended this computation to June 30, 2012, the day before the TRC Cabarrus County facility was projected to open. This computation led to the conclusion that there would be about 212 residents of Cabarrus County who would require in-center dialysis on July 1, 2012. (Jt. Ex 2, p. 30)

328. TRC's application to expand its existing Harrisburg Dialysis Center proposed to add five stations to the facility at a total capital cost of $113,000, and the result of this expansion would be a facility with a total of 20 stations. (Jt. Ex. 4, p. 3, 48)

329. The TRC Harrisburg Application, showed that it had begun operations in 2009 with an initial population of 2 patients and had grown to 49 patients by the end of 2009. (Jt. Ex. 4, p. 32)

330. Like the TRC Cabarrus Application, the TRC-Harrisburg Application proposed to serve exclusively patients who resided in Cabarrus County. (Jt. Ex 4, p. 25)

331. Like the TRC Cabarrus Application, the TRC-Harrisburg Application documented that the nephrologists with Central Carolina Nephrology have admitting privileges at the facility. (Jt. Ex. 4, p. 45)

332. The TRC Harrisburg Application confirmed that its medical Director, Dr. Charles Stoddard, and his partners with Central Carolina Nephrology, have an established referral basis through most of the attending physicians in Cabarrus County. (Jt. Ex. 4, p. 36)

333. The TRC Harrisburg Application also assumed that the population of the facility would continue to grow proportionately with the Cabarrus County five-year average annual change rate of 8.5 per cent that was identified in the July, 2010 SDR. (Jt. Ex. 4, p. 31)

334 The TRC Harrisburg Application presented morbidity and mortality data about its patient population, as requested by the CON application form.

IV. Comparative Analysis

335. When the CON Section has multiple applications whose request totals more than the number of units available, they conduct an analysis to compare each of the applications to

determine which is the least costly or most effective alternative. The comparative analysis is based on some factors that are generally related to the statutory review criteria, or they may also be related to comments that are received in the comment period or at the public hearing. (Smith, Vol. 6, p. 1334)

336. Because the four applicants proposed a greater number of stations than the determinative limit, 23 dialysis stations in the 2010 SMFP and July 2010 SDR, the review was deemed competitive and the Agency conducted a comparative analysis of the applicants. (Jt. Ex. 1, pp. 459, 526-31)

337. Ms. Rupp selected the comparative factors utilized in the review based on both prior competitive ESRD reviews she had conducted and based on guidance from CON Section Chief Craig Smith. (Rupp, Vol. 1, p. 232)

338. Specifically, Ms. Rupp consulted the Brunswick County dialysis review and the Davie County dialysis review. A copy of the comparative portions of each of these findings was included in the Agency File. (Rupp, Vol. 1, p. 232; Jt. Ex. 1, pp. 396-404)

Availability of Home Training

339. The Agency found the RAI Application and TRC Cabarrus Application were equal in terms of their effectiveness with respect to home training because both applicants proposed to offer home training at its facility. However, the TRC Cabarrus Application was not approvable due to its Criterion 20 issue. (Jt. Ex. 1, p. 527; Rupp, Vol. 1, pp. 233-34)

340. The Agency found that the TRC Harrisburg and TRC Copperfield applications were less effective alternatives because patients would be required to travel to another facility for home training. (Jt. Ex. 1, p. 527)

Hours of Availability

341. The Agency found the TRC Cabarrus Application to be the most effective alternative because it proposed to operate two shifts, six days per week and a third shift, three days per week. (Jt. Ex. 1, p. 527; Rupp, Vol. 1, p. 234)

Provision of Services In Rural, Remote Areas

342. The Agency concluded that this factor was not applicable to the applications under review because Cabarrus County is not a rural, remote area. (Jt. Ex. 1, p. 527; Rupp, Vol. 1, p. 234)

Facility Location

343. Since all of the proposed or existing facilities were located along a major road which bisected Cabarrus County, the Agency determined that facility location was not a comparative issue in the review. (Jt. Ex. 1, p. 528)

Access by Underserved Groups

344. With respect to the comparative factor of Access by Underserved Groups, the Agency concluded the TRC Copperfield Application was the most effective alternative because it proposed the highest percentage of patients to have some or all of their services paid by Medicare or Medicaid. (Jt. Ex. 1, p. 528)

Service to Cabarrus County Residents

345. The Agency concluded that the TRC Cabarrus, TRC Harrisburg and TRC Copperfield Applications were the most effective alternatives because the existing TRC Harrisburg and TRC Copperfield facilities currently serve 109 in-center hemodialysis patients and will continue to do so in addition to adding proposed new stations and a new location. (Jt. Ex. 1, p. 528; Rupp, Vol. 1, pp. 235-36)

Access to Alternative Providers

346. The Agency concluded that the RAI Application was the most effective alternative because TRC currently operates two in-center dialysis facilities in Cabarrus County and six additional dialysis facilities in other counties contiguous to Cabarrus County. (Jt. Ex. 1, pp. 236-37) RAI operates two facilities in Mecklenburg County but no facilities in Cabarrus County. Rupp, Vol. 1, p. 236)

Operating Costs and Revenues

347. The Agency compared the applicants with respect to Operating Costs in Year Two and concluded that RAI and TRC Harrisburg had the lowest projected operating costs. (Jt. Ex. 1, p. 529; Rupp, Vol. 1, p. 237-38)

348. The Agency compared the applicants with respect to Revenue per treatment in Year Two and concluded that RAI projected the lowest revenue per treatment. (Jt. Ex. 1, p. 529; Rupp, Vol. 1, p. 237-38) However, since the RAI Application failed to provide reasonable and supported assumptions and methodology to support its need projections, the TRC Harrisburg Application was determined to be the more effective alternative. (Id.)

Direct Salary Staff

349. The Agency compared the applications using the factor of direct care staff salaries and concluded the RAI Application was the more effective alternative because it projected higher registered nurse salaries and higher technician salaries than the other applicants. (Jt. Ex. 1, pp. 530-31; Rupp, Vol. 1, p. 238)

Provision of Quality of Care

350. With respect to the factor of provision of quality of care, the Agency concluded that the RAI Application was the more effective alternative because the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation do not report any issues regarding quality of care at RAI facilities located in counties contiguous to Cabarrus County. Conversely, the Agency noted the January 28, 2010 survey findings at the Copperfield facility and concluded: "the facility [Copperfield] failed to conform to four [sic] Medicare Conditions of Participation, resulting in a finding that the facility was unable to ensure the provision of quality care in a safe environment for its patients. Since Total Renal Care of North Carolina, LLC is also the proposed owner of the Cabarrus County Dialysis Center [TRC Cabarrus], since the facilities are all in or proposed to be in the same county, and since the same nephrology practice is or will be providing nephrology services to facility patients, the quality of care issue is directly relevant to each DaVita, Inc./Total Renal Care of North Carolina, LLC facility." (Jt. Ex. 1, p. 531)

CONCLUSIONS OF LAW

1. To the extent that certain portions of the foregoing Findings of Fact constitute mixed issues of law and fact, such Findings of Fact shall be deemed incorporated herein by reference as Conclusions of Law.

2. A court need not make findings as to every fact which arises from the evidence and need only find those facts which are material to the settlement of the dispute.. Flanders v. Gabriel, 110 N.C. App. 438, 440, 429 S.E.2d 611, 612, aff'd, 335 N.C. 234, 436 S.E.2d 588 (1993).

3. Under North Carolina's Certificate of Need Law, a kidney disease treatment center, also known as a dialysis clinic, is a "health service facility." N.C. Gen. Stat. § 131E-176(9b). The construction, development, or other establishment of a new health service facility is a "new institutional health service." N.C. Gen. Stat. § 131E-176(16)(a).

4. A new institutional health service may not be offered or developed without first obtaining a certificate of need. N.C. Gen. Stat. § 131E-178(a). Therefore a dialysis clinic cannot be offered or developed without first obtaining a certificate of need.

5. In a competitive review, the CON Section must first evaluate each application on its own merits and then perform a comparative review to determine which applicant is the superior applicant and should receive the certificate of need. Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 385, 455 S.E.2d 455, 464 (1995).

6. N.C. Gen. Stat. § 131E-183 provides that the Agency "shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued."

7. The Certificate of Need Law provides that no later than 150 days after the review begins, the Agency shall issue a decision to approve, approve with conditions, or deny an

application for a new institutional health service. Within five (5) business days after it makes a decision on an application, the Agency shall provide written notice of all the findings and conclusions upon which it based its decision, including the criteria used by the Department in making its decision, to the applicant. N.C. Gen. Stat. § 131E-186.

8 Under N.C. Gen. Stat § 131E-183(a), the Agency "shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued."

9. The CON Section must determine whether an application is consistent with, or not in conflict with, each applicable review criterion set forth in N.C. Gen. Stat. § 131E-183 and any applicable standards, plans and criteria which are in effect at the time the review commences. See 10A N.C.A.C. 14C.0207.

10. The subject matter of this contested case is the Agency's decision on the RAI and TRC Applications. See N.C. Gen. Stat. § 131E-188(a) (providing for administrative review of Agency decision to issue, deny or withdraw certificate of need); Presbyterian Hospital v. N.C. Dep't of Health and Human Services, 177 N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006); Britthaven, Inc. v. North Carolina Dep't of Human Resources, 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995) ("The subject matter of a contested case hearing by the ALJ is an agency decision.")

11. N.C. Gen. Stat § 131E-188 provides the statutory grounds for and prerequisites to filing a petition for a contested case hearing regarding certificates of need; it does not provide the framework for deciding the contested case, which is governed by Article 3 of Chapter 150B of the General Statutes. RAI and TRC each is an "affected person," as to the CON Section's decision on each of the applications at issue, and each is authorized to petition for a contested case hearing. See N.C. Gen. Stat. § 131E-188 (2003).

12. RAI, TRC and the CON Section are properly before the Office of Administrative Hearings which has jurisdiction over the parties and the subject matter of this contested case. (Tr. p. 1)

13. A petitioner bears the burden of proof on each and every element of its case. In a contested case, "[u]nder N.C. Gen. Stat. § 150B-23(a), the ALJ is to determine whether the petitioner has met its burden in showing that the agency substantially prejudiced petitioner's rights, and that the agency acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule." Britthaven, 118 N.C. App. at 382, 455 S.E.2d at 459 (emphasis in original). The burden of persuasion placed upon each petitioner is by a "preponderance of the evidence." N.C. Gen. Stat. §150B-29 (stating "the party with the burden of proof in a contested case must establish the facts required by G.S. 150B-23(a) by a preponderance of the evidence. . . .").

14. The CON Section disapproved the application submitted by RAI and the Cabarrus County and Harrisburg Applications submitted by TRC and therefore, RAI and TRC each has demonstrated that it is substantially prejudiced that by the CON Section's decision that is under appeal.

15. In a CON contested case, the court is limited to a review of the information presented to or available to the CON Section at the time of the review. Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995); see also In re Application of Wake Kidney Clinic, 85 N.C. App. 639, 643, 355 S.E.2d 788, 791 (1987) ("The hearing officer is properly limited to consideration of evidence which was before the Section when making its initial decision, but the hearing officer is not limited to that part of the evidence before it that the Section actually relied upon in making its decision.") Information that was unavailable at the time of the CON Section's decision cannot be a basis for finding Agency error in making the decision.

16. In determining these issues, the undersigned only considered evidence that was presented or available to the Agency during the review period. Living Centers-Southeast, Inc. v. N.C. Dep't of Health and Human Servs., 138 N.C. App. 572, 581, 532 S.E.2d 192, 197 (2000); Britthaven, 118 N.C. App. at 382, 455 S.E.2d at 459 (citing In re Application of Wake Kidney Clinic, 85 N.C. App. 639, 355 S.E.2d 788 (1987)).

17. This contested case is not a de novo review of the CON Section's decision. Britthaven, 118 N.C. App. at 382, 455 S.E.2d at 459. This court may not substitute its judgment for that of the Agency, "even though the court could justifiably have reached a different result had the matter been before it de novo." Charter Pines Hosp., Inc. v. N.C. Dep't of Human Resources, 83 N.C. App. 161, 171, 349 S.E.2d 639, 646 (1986) (citations omitted).

18. The appropriate standard of review in this case depends upon the issue being reviewed. When an appellant charges that a state agency erred in interpreting a statutory term, an appellate court may freely substitute its judgment for that of the agency. Britthaven, 118 N.C. App. at 384, 455 S.E.2d at 460. However, when an appellant questions whether the Agency's decision was supported by the evidence or whether it was arbitrary or capricious, the appropriate standard is the whole record test. Id.

19. Under the whole record test, "a court must examine all the record evidence - that which detracts from the agency's findings and conclusions as well as that which tends to support them - to determine whether there is substantial evidence to justify the agency's decision." Good Hope Health Sys. v. N.C. Dep't of Health and Human Servs., 189 N.C. App. 534, 543, 659 S.E.2d 456, 462 (2008) (quoting Watkins v. N.C. State Bd. of Dental Exmn'rs., 358 N.C. 190, 199, 593 S.E.2d 764, 769 (2004)), aff'd, 362 N.C. 504, 666 S.E.2d 749 (2008). Substantial evidence is "relevant evidence a reasonable mind might accept as adequate to support a conclusion." N.C. Gen. Stat § 150B-2(8b). The whole record test merely gives the reviewing court the capability to determine whether the administrative decision has a rational basis in the evidence. Carillon Assisted Living, LLC v. N.C. Dep't of Health and Human Servs., 175 N.C. App. 265, 270, 623 S.E.2d 629, 633 (2006).

20. Under the whole record test, error in the Agency's analysis of an approved applicant does not require the applicant's disapproval if the error does not affect the outcome of the review. See, e.g., Britthaven, 118 N.C. App. at 386, 455 S.E.2d at 461.

21. North Carolina law gives great weight to the Agency's interpretation of a law it administers. Frye Regional Medical Center v. Hunt, 350 N.C. 39, 45, 510 S.E.2d 159, 163 (1999). The Agency's interpretation and application of the statutes and rules it is empowered to enforce are entitled to deference, as long as the Agency's interpretation is reasonable and based on a permissible construction of the statute. Good Hope Health Sys., LLC v. N.C. Dep't of Health and Human Servs., 189 N.C. App. 534, 544, 659 S.E.2d 456, 463 (2008), aff'd, 362 N.C. 504, 666 S.E.2d 749 (2008); Craven Reg. Medical Authority v. N.C. Dep't of Health and Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006); see also Carpenter v. N.C. Dep't of Human Res., 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992) (a reviewing court should defer to the agency's interpretation of a statute it administers "so long as the agency's interpretation is reasonable and based on permissible construction of the statute.")

22. North Carolina law also presumes that the Agency has properly performed its duties, and this presumption is rebutted only by a showing that the Agency was arbitrary or capricious in its decision making. In re Broad and Gales Creek Community Assoc., 300 N.C. 267, 280, 266 S.E.2d 645, 654 (1980); Adams v. N.C. State Bd. of Reg. for Prof. Eng. and Land Surveyors, 129 N.C. App. 292, 297, 501 S.E.2d 660, 663 (1998) (stating, "It is proper to presume that an administrative agency has properly performed its official duties."); In re Land and Mineral Co., 49 N.C. App. 529, 531, 272 S.E.2d 6, 7 (1980) (stating that "the official acts of a public agency . . . are presumed to be made in good faith and in accordance with the law.")

23. Administrative agency decisions may be reversed as arbitrary and capricious only if they are "patently in bad faith" or "whimsical" in the sense that "they indicate a lack of fair and careful consideration," or "fail to indicate 'any course of reasoning and the exercise of judgment'. . . ." ACT-UP Triangle v. Comm'n for Health Services, 345 N.C. 699, 707, 483 S.E.2d 388, 393 (1997) (citations omitted).

24. The "arbitrary and capricious" standard is a difficult one to meet. Blalock v. N.C. Dep't of Health and Human Servs., 143 N.C. App. 470, 475, 546 S.E.2d 177, 181 (2001).

25. The Agency has statutory authority to approve an applicant with conditions that ensure the project conforms with applicable review criteria. N.C. Gen. Stat. § 131E-186; 10A NCAC 14C.0201(a); see also Dialysis Care of North Carolina, LLC v. N.C. Dep't of Health and Human Servs., 137 N.C. App. 638, 648-51, 529 S.E.2d 257, 263-64 (2000), aff'd per curiam, 353 N.C. 258, 538 S.E.2d 566 (2000) (affirming conditional approval of application regarding availability and commitment of portion of funding required for proposed project); In re Humana Hosp. Corp. Inc. v. N.C. Dep't of Human Resources, 81 N.C. App. 628, 632, 345 S.E.2d 235, 237 (1986) ("the law does not require that applications for certificates of need be approved precisely as submitted or not at all, and it would be folly if it did so.")

27. The Certificate of Need Law was enacted to control the proliferation of unnecessary healthcare facilities. Therefore, demonstrating the need for a proposal under review is a critical and integral part of the entire certificate of need process. Criterion 3 and Criterion 6 are instrumental in the CON Section's determination whether to approve a project that is under review.

28. Each of the TRC Applications at issue demonstrated that it had identified a population to be served, had demonstrated the need that the population identified had for the services proposed in each of the TRC Applications, and ensured appropriate access to those services by the population to be served. Therefore, each of the TRC Applications at issue demonstrated conformity with Criterion 3.

29. Each of the TRC Applications at issue in this case demonstrated that it would not unnecessarily duplicate other existing or approved services because the Applications showed that the TRC facilities would be appropriately utilized and therefore would not result in unused, duplicative capacity in Cabarrus County. Therefore, each of the TRC Applications at issue conformed with Criterion 6.

30. The RAI Application failed to present reasonable and supported assumptions and methodology to demonstrate the need that the population RAI identified had for the services proposed. Therefore, the RAI Application did not conform with Criterion 3.

31. Similarly, the RAI Application failed to show that it would not result in the creation of unused and duplicative capacity. Therefore, the RAI Application failed to conform with Criterion 6.

32. The plain statutory language of Criterion 1 provides that a proposed project "shall be consistent with applicant policies and need determinations in the State Medical Facilities Plan". N.C. Gen. Stat. § 131E-183(a)(1). As a result of its non-conformity with Criterion 3, RAI failed to demonstrate that its proposal would maximize healthcare value under Policy GEN-3 and therefore RAI's Application failed to conform with Criterion 1.

33. The statutory language of Criterion 3 requires and applicant to "identify the population to be served by the proposed project and demonstrate the need that this population has for the services proposed" N.C. Gen. Stat. § 131E-183(a)(3).

34. As the North Carolina Court of Appeals has noted regarding CON applications: "A reasonable projection of something that will occur in the future, by its very nature, cannot be established with absolute certainty." Craven Reg. Med. Auth. v. N.C. Dep't of Health and Human Servs., 176 N.C. App. 46, 53, 625 S.E.2d 837, 841 (2006) (holding that uncertainty regarding specific procedure to patient ratio used by applicant to demonstrate need for its proposal was not grounds to find applicant non-conforming with Criterion 3 because ratio used by applicant was reasonable and supported by record evidence).

35. Criterion 4 requires the Agency to determine whether an applicant adequately demonstrated that its application represents the most effective alternative of the different options available to the applicant for the objectives and need the applicant's proposed project is intended to meet. N.C. Gen. Stat. § 131E-183(a)(4). Inasmuch as RAI failed to demonstrate need for its proposal under Criteion 3, the RAI Application is not an effective alternative as required by Crierion 4 and therefore RAI's Application failed to conform with Criterion 4.

36. Criterion 5 requires an applicant to show: (1) the availability of funds for capital and operating needs; and (2) the immediate and long-term financial feasibility of the proposed project. N.C. Gen. Stat. § 131E-183(a)(5). Inasmuch as RAI's patient projections were based upon unreasonable and unsupported assumptions, RAI failed to demonstrate that its proposal was basedupon reasonable costs and charges and therefore is non-conforming to Criterion 5..

37. Criterion 6 addresses whether a proposed project will result in duplication of existing or approved health service capabilities or facilities that is not needed or is unnecessary. N.C. Gen. Stat. § 131E-183(a)(6).

38. Criterion 6 does not prohibit any and all duplication of health services – only that duplication which is unnecessary. If the Agency determines that a project proposed in a CON application would result in necessary duplication of existing or approved health service capabilities or facilities, then the Agency may lawfully conclude that the application conforms with Criterion 6 if the applicant demonstrates the need of its identified population for the proposed project.

39. In determining conformity with Criterion 6, the Agency properly relied upon the same facts upon which it determined conformity with Criterion 3. As discussed above, the Harrisburg and TRC Cabarrus Applications both adequately demonstrated the need for their respective projects.

40. The Agency conducted an independent analysis of the TRC Harrisburg Application and TRC Cabarrus Application under Criterion 6.

41. The Agency conducted an independent analysis of the RAI Application under Criterion 6.

42. There is nothing in the CON Law that prohibits the Agency from relying on the same information in a CON application in determining conformity with more than one criterion.

43. Criterion 18a requires an applicant to demonstrate "the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to services proposed . . . ." N.C. Gen. Stat. § 131E-183(a)(18a).

44. Criterion 18a required the applicant to demonstrate that its proposed project will positively impact competition in the proposed service area. The applicant was not required to demonstrate that its proposal will positively impact, or will not negatively impact, existing providers of similar services in its proposed service area in order to demonstrate that its proposed project conformed with Criterion 18a.

45. Inasmuch as the TRC Harrisburg Application and the TRC Cabarrus Applicaiotn failed to conform with Criterion 20, the applications failed to demonstrate that they would have a positive impact upon quality as required by Criterion 18a and therefore the applications failed to conform with Criterion 18a.

46. Inasmuch as the RAI Application and the TRC Cabarrus Application failed to conform with Criterion 3, RAI failed to demonstrate that its proposal would have a positive impact upon cost effectiveness and quality as required by Criterion 18a and therefore the RAI Applications failed to conform with Criterion 18a.

47. Neither RAI nor TRC challenged or appealed the Agency's findings of conformity with Statutory Review Criteria 3a, 7, 8, 9, 10, 12, 13 and 14. Thus, the Agency correctly and reasonably concluded that the TRC Harrisburg Application, the TRC Cabarrus Application and the RAI Application were conforming with these Statutory Review Criteria and its February 25, 2011 decision was free from error on those criteria.

48. Criterion 20 is a required statutory criterion that examines whether an applicant has demonstrated the provision of quality care in the past. See N.C. Gen. Stat. § 131E-183(a)(20). The Agency's approach to analyzing and investigating applicants with respect to Criterion 20 has been in place for as long as any Agency witness in this hearing could recall. The CON Section works closely with the Licensure and Certification Section to investigate past quality of care issues involving an applicant for new or expanded services.

49. The CON Section looks at the provision of quality of care at the existing facility and any of the applicant's other existing facilities in the same and contiguous counties where a sufficient nexus between those entities exists. The sufficiency of the nexus between facilities depends upon factors such as the ownership, medical directorship, governing body and management.

50. The Agency's investigation of quality of care issues under Criterion 20 looks back at an applicant's past performance over an 18-month time period immediately preceding the date of the relevant Agency decision. The 18-month look back time period has been in place since approximately 1988 and is utilized by the Agency in all Criterion 20 inquiries. The 18-month look back period is fair and reasonable and applicants need only review any set of Agency Findings issued over the last 20 or more years where Criterion 20 was applicable to be on notice of the 18-month look back period.

51. It was undisputed that the Agency properly found the TRC Copperfield Application non-conforming with Criterion 20 as it relates to the provision of quality of care based upon the Licensure and Certification Section survey results dated January 28, 2010 citing that facility for being out of compliance with seven Medicare standards and two Medicare Conditions of Coverage for an incident that resulted in the death of a patient. The survey report showed serious deficiencies in the quality of patient care.

52. The Agency also properly found TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 20 based on the same TRC Copperfield survey report because a sufficient nexus existed between TRC Copperfield and TRC Harrisburg and the proposed TRC Cabarrus and because the January 28, 2010 survey was also within the 18-month look back period for all TRC Applications in this review. The Agency's analysis was thorough and drew on the experience and expertise of the CON Section Chief who has been almost solely

responsible for dialysis reviews for nearly twenty years, the CON Section Assistant Chief who has seventeen years of experience, the Project Analyst who has done multiple dialysis reviews, and a former Team Leader who is a licensed nurse with four years of experience as a surveyor of dialysis facilities in North Carolina.

53. Moreover, the applicant in all three TRC Applications was Total Renal Care of North Carolina. Based on the plain language of Criterion 20 alone, because the "applicant" Total Renal Care of North Carolina was the same for all three applications, the Agency properly found TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 20.

54. Additionally, the Agency correctly concluded that there was a sufficient nexus between TRC Copperfield and the TRC Harrisburg and the TRC Cabarrus projects to find all three non-conforming with Criterion 20. This nexus included common applicants, common ownership and operation by DaVita, Inc., common Medical Directors in Dr. Halstenberg and his partner Dr. Stoddard who provide coverage for each other, common clinical coverage by Central Carolina Nephrology, common governance, and common location (Concord, Cabarrus County). The nexus between these three facilities is shown in the chart below:

	TRC Copperfield	TRC Harrisburg	TRC Cabarrus
Applicant	Total Renal Care of North Carolina	Total Renal Care of North Carolina	Total Renal Care of North Carolina
Owner	DaVita, Inc.	DaVita, Inc.	DaVita, Inc.
Location	Concord, Cabarrus County	Concord, Cabarrus County	Concord, Cabarrus County
Medical Director	Dr. Halstenberg (Central Carolina Nephrology)	Dr. Stoddard (Central Carolina Nephrology)	Dr. Halstenberg (Central Carolina Nephrology)
Governance	Medical Director: Dr. Halstenberg CEO/Regional Operations Director: Jenny Richeson Facility Administrator: Luke Santillo	Medical Director: Dr. Stoddard CEO/Regional Operations Director: Jenny Richeson Facility Administrator: Amanda Herring	Medical Director: Dr. Halstenberg CEO/Regional Operations Director: Jenny Richeson Facility Administrator: to be named
Clinical Coverage	Central Carolina Nephrology	Central Carolina Nephrology	Central Carolina Nephrology
Clinical Services Specialist	Michele Brandt-Becher	Michele Brandt-Becher	Michele Brandt-Becher
Policies/Procedures	DaVita, Inc.	DaVita, Inc.	DaVita, Inc.
Staff	Shared/transferred as needed	Shared/transferred as needed	Shared/transferred as needed

55. The Agency's determination that TRC Cabarrus and TRC Harrisburg were non-conforming with Criterion 20 was also consistent with past Agency decisions, of which TRC had notice.

56. TRC failed to meet its burden that the Agency erred in finding TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 20.

57. The Agency properly found TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 1 because both applications failed to demonstrate the proposals will promote safety and quality of care and were found non-conforming with Criterion 20.

58. TRC failed to meet its burden that the Agency erred in finding TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 1.

59. The Agency properly found TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 4 because both applications failed to demonstrate the applicant has provided quality of care in the past. Moreover, TRC Cabarrus and TRC Harrisburg were also found non-conforming with Criterion 20, Criterion 1, and TRC Harrisburg was non-conforming with the rules at 10A N.C.A.C. 14C.2204(7) and (10).

60. TRC failed to meet its burden that the Agency erred in finding TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 4.

61. The Agency properly found TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 18a because both applications failed to demonstrate the proposals would have a positive impact on the quality of dialysis services proposed and were found non-conforming with Criterion 20, Criterion 1 and Criterion 4.

62. As the North Carolina Court of Appeals held in Total Renal Care of N.C. v. N.C. Dep't of Health and Human Serv., 171 N.C. App. 734, 741, 615 S.E.2d 81, 85 (2005):

We find increased competition and consumer choice to be well within the established criteria in N.C. Gen. Stat. § 131E-183 and not inconsistent with the General Assembly's findings in N.C. Gen. Stat. § 131E-175. . . Also, this Court has approved of "competition" as a rational means of comparing competing applications and awarding a certificate of need.

63. Moreover, TRC is the only existing provider of dialysis services in Cabarrus County. The approval of another TRC facility or additional stations at an existing TRC facility in Cabarrus County will not improve competition or provide patients with a choice of provider in Cabarrus County.

64. TRC failed to meet its burden that the Agency erred in finding TRC Cabarrus and TRC Harrisburg non-conforming with Criterion 18a.

65. The Agency properly found TRC Harrisburg non-conforming with 10A N.C.A.C. 14C.2204(7) and (10) because it failed to provide the information required by the Agency to complete its review and was otherwise not approvable.

66. TRC failed to meet its burden that the Agency erred in finding TRC Harrisburg non-conforming with 10A N.C.A.C. 14C.2204(7) and (10).

67. TRC did not challenge or appeal the Agency's determination with respect to certain Criteria and Standards for End-Stage Renal Disease Services found in 10A N.C.A.C. 14C .2200, et. seq. Specifically TRC did not challenge the Agency's determination on 10A N.C.A.C. 14C .2202, .2203, .2204(1), (2), (3), (4), (5), (6), (8), (9), (11), and (12), or .2205.

68. RAI did not challenge or appeal the Agency's determination with respect to certain Criteria and Standards for End-Stage Renal Disease Services found in 10A N.C.A.C. 14C .2200, et. seq. Specifically RAI did not challenge the Agency's determination on 10A N.C.A.C. 14C .2202(a), .2203(b), .2204 or .2205.

DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, it hereby is recommended that the Director of the Division of Facility Services, Department of Health and Human Services, affirm the CON Section's decision to deny both the Harrisburg Application and TRC Cabarrus Application and affirm the CON Section's decision to deny the RAI Application for a certificate of need.

ORDER

It is hereby ordered that the Agency serve a copy of the Final Decision on the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, NC 27699-6714, in accordance with N.C. Gen. Stat. § 150B-36(b).

NOTICE

The Agency that will make the final decision in this contested case is the North Carolina Department of Health and Human Services.

The Agency is required to give each party an opportunity to file exceptions to the decision and to present written arguments to those in the Agency who will make the final decision. N.C. Gen. Stat. § 150B-36(a). The Agency is required by N.C. Gen. Stat. § 150B-36(b) to serve a copy of the final decision on all parties and to furnish a copy to the parties' attorneys of record and to the Office of Administrative Hearings.

In accordance with N.C. Gen. Stat. § 150B-36 the Agency shall adopt each finding of fact contained in the Administrative Law Judge's decision unless the finding is clearly contrary to the preponderance of the admissible evidence. For each finding of fact not adopted by the agency, the agency shall set forth separately and in detail the reasons for not adopting the finding of fact and the evidence in the record relied upon by the Agency in not adopting the finding of fact. For each new finding of fact made by the Agency that is not contained in the Administrative Law Judge's decision, the Agency shall set forth separately and in detail the evidence in the record relied upon by the Agency in making the finding of fact.

This the 15th day of December, 2011.

Joe J. Webster
Administrative Law Judge

A copy of the foregoing was mailed to:

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This the 15th day of December, 2011

Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6714
(919) 431-3000

CERTIFICATE OF SERVICE

I certify that I have served a copy of the foregoing FINAL AGENCY DECISION on each party, upon each party's counsel of record and upon the Office of Administrative Hearings, at the addresses and by the means indicated below. The address shown for Petitioner is the latest address given to Respondent by Petitioner.

CERTIFIED MAIL

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I certify that a copy of the foregoing Final Decision has been served upon the Office of Administrative Hearings by depositing a copy in an official depository of the United States Postal Service in a first-class, postage prepaid envelope addressed as follows:

U. S. MAIL

Kim Hausen
Chief Hearings Clerk
Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6714

HAND DELIVERY AND INTEROFFICE MAIL

I certify that a copy of the foregoing Final Decision has been served upon the Certificate of Need and the Acute and Home Care Licensure and Certification Sections by Hand Delivery or Interoffice Mail:

Craig Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Azzie Conley, Chief
Acute and Home Care Licensure and Certification Section
Division of Health Service Regulation
2712 Mail Service Center
Raleigh, NC 27699-2712

This the 15th day of March, 2012.

Jeff Horton, Chief Operating Officer
Division of Health Service Regulation
N.C. Department of Health and Human Services

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: November 23, 2011
FINDINGS DATE: December 2, 2011
PROJECT ANALYST: Gregory F. Yakaboski
ASSISTANT CHIEF: Martha J. Frisone

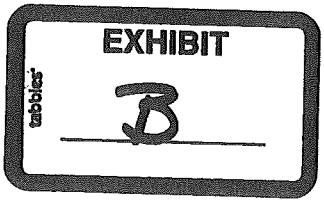
PROJECT I.D. NUMBER: **M-8689-11** / Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center/ Construct a satellite hospital with 65 acute care beds, 7 observation beds, two operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services/Cumberland County

H-8690-11 / FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital / Construct a hospital on US Highway 401 in Raeford with 65 acute care beds, 2 operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services/Hoke County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.



NC

CFV North
FHCH

The 2011 State Medical Facilities Plan (SMFP) includes a need determination for 65 acute care beds for the Cumberland/Hoke County Acute Bed Service Area. The 2011 SMFP states:

> *"Any qualified applicant may apply for a certificate of need to acquire the needed acute care beds. A person is a qualified applicant if he or she proposes to operate the additional acute care beds in a hospital that will provide:*
>
> *(1) a 24-hour emergency services department,*
>
> *(2) inpatient medical services to both surgical and non-surgical patients, and*
>
> *(3) if proposing a new licensed hospital, medical and surgical services on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid services (CMS), as follows:* ... [as listed in the 2011 SFMP]."

Policy GEN-3: Basic Principles is applicable to this review. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities is applicable to this review. This policy states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN 4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control."

Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center ("CFV North") proposes to develop a new 65-bed acute care hospital at 6387 Ramsey Street in Fayetteville in Cumberland County. The applicant proposes to develop all of the 65 acute care beds available for the Cumberland-Hoke Acute Care Bed Service Area in the 2011 SMFP. The applicant does not propose to develop more acute care beds than are determined to be needed in the Cumberland-Hoke Acute Care Bed Service Area. In Section II.1, page 20, the applicant states CFV North will operate a 24-hour emergency services department. In Section II.8, page 71, the applicant provides the projected number of patient days of care by major diagnostic category (MDC) to be provided at CFV North in the first three operating years. The applicant projects the hospital will provide services in all 25 MDCs listed in the 2011 SMFP. Therefore, the applicant adequately demonstrates that it will provide medical and surgical services in at least five MDCs recognized by CMS. CFV North adequately demonstrates that it will provide inpatient medical services to both surgical and non-surgical patients. Thus, CFV North is a qualified applicant and the proposal is consistent with the need determination in the 2011 SMFP for acute care beds in the Cumberland-Hoke Acute Care Bed Service Area.

Policy GEN-4

With regard to Policy GEN-4, in Section III.2, pages 142-143, CFV North states:

The proposed CFV North Hospital will provide energy efficiency and water conservation as outlined in a letter from the architect in Exhibit 43 and listed below.

- *Architecture/General Construction:*
  1. *Glazing systems and insulation in walls, floors and roofs will be designed for optimal thermal values*
  2. *Design will incorporate natural day lighting to as many interior spaces possible in order to reduce necessary lighting levels during the day*

- *Water conservation features:*
  1. *Condensate recovery from all AHU's with the recovered water being used first in the cooling towers and secondly for irrigation.*
  2. *Low flow fixtures.*
  3. *Meters for cooling tower, domestic hot water, boiler make up, and irrigation (if any).*

- *Energy conservation measures:*
  1. *Extensive use of occupancy sensors for lighting.*
  2. *VAV systems in non sensitive areas.*
  3. *Reduction of air flow during unoccupied period in OR's.*
  4. *Full DDC building automation system with individual room thermostats*
  5. *Basic commissioning*
  6. *Leakage test on all ductwork about 2" static pressure*
  7. *Flat plate heat exchanger for free cooling*
  8. *Energy recovery chiller to preheat DHW*
  9. *Extensive use of air flow monitors*
  10. *Power Logic breakers and switchgear to provide enhanced electrical metering*
  11. *Registration of EPA Energy Star Program*

Response for SMFP Policy GEN-4 Paragraph 2: Develop & Implement an Energy Efficiency and Sustainability Plan Consistent with NC State Building Codes

If CFV North is conditionally approved by the CON Section, the Applicant will comply with the above described SMFP Policy GEN-4 condition pertaining to the development and implementation of its Energy Star and Sustainability Plan, which is consistent with the latest edition of the North Carolina Building Codes as noted in SMFP Policy GEN-4.

Response for SMFP Policy GEN-4 Paragraph 3: After CON Approval Submission of Required CFV North Plan for Energy Efficiency & Water Conservation

If CFV North is awarded a CON, the Applicant will comply with SMFP Policy GEN-4 requirement above to submit a Plan for Energy Efficiency and Water

Conservation to the DHSR Construction Section, which Plan will be consistent with the Applicant's representations and pursuant to Paragraph 1 of SMFP Policy GEN-4."

The applicant adequately described the project's plan to assure improved energy efficiency and water conservation. Thus, the application is conforming to Policy GEN-4.

Policy GEN-3

With regard to Policy GEN-3, in Section III.2, pages 139-142, CFV North states:

"The proposed project will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by improving access to health care services to the patient population served by CFV North. In Section VI.14, CFVMC provides documentation regarding the projected level of care provided to residents of the service area as a function of payor category, including Medicare, Medicaid, and Charity Care/Self Pay, which the CON statutory review criteria identify as the "medically underserved." In addition, the CON pro forma projections for this project include a page that shows Net Revenue by payor category, as prescribed by the Agency. The proposed project will result in improved access for all residents of the CFV North Service Area.

Promote Cost Effective Approaches

Please see CFV North's responses to Section II., Questions 6. and 7. and Exhibit 13 for a copy CFVHS's Performance Improvement Plan related to quality care. As discussed in the responses in Section II, Questions 8.(a) and (b), CFV North will establish a focused quality management program dedicated to ongoing quality assessment and improvement to provide high quality, cost-effective health care that meets the needs of all patients and enhances clinical effectiveness and health outcomes for the population.

Expand Health Care Services to the Medically Underserved Encourage Quality Health Care Services

The proposed project will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by providing more efficient health care services to the patient population served by the Applicant. In Section VI.14, CFVMC provides documentation regarding the projected level of care provided to residents of the service area as a function of payor category, including Medicare, Medicaid, and Charity Care/Self Pay, which the CON statutory review criteria identify as the "medically underserved." Many residents from parts of zip

codes in Cumberland County, southwest and southern Harnett County and northwestern Sampson County, as documented in the patient origin information in Section III. and Exhibit 33, receive acute care inpatient services from the Applicant's facilities and affiliated medical staff. The proposed project will result in improved access for all residents of the defined service area. CFVMC has the availability of capacity to provide those services now and in the future.

The responses to Section VI., Questions 2 through 6 and Exhibit 20 include a thorough discussion of CFVHS's policies on Charity Care, Uninsured Discount, Catastrophic Discount & Payment Plan. These four Charity Care policies will apply to services provided at CFV North. All these policies and processes are fully described in CFVHS's Charity Care policies included in Exhibit 20. These are also indicators of CFV North's commitment to accessible care for medically underserved groups.

The proposed project will bring locally-accessible, high quality, and cost-effective, inpatient services in an accessible location close to the homes of residents of the proposed CFV North Service Area, which includes parts of zip codes in Cumberland County, southwest and southern Harnett County and northwestern Sampson County, who select CFV North for their inpatient care. Excellent access to health care services is an important feature of the quality of life in the communities served by CFVHS facilities and physicians.

Quality Healthcare Services Including Patient Safety

CFVHS has a continuing emphasis on cost effective care for residents of the existing CFVHS service area and the proposed CFV North Service Area. In addition, CFVHS is a member of the Premier Alliance purchasing and contracting network. As a Premier member, CFVHS is provided a variety of resources to identify and target areas where cost savings can be realized and has access to the best pricing available.

The following list reflects several ongoing initiatives at CFVHS which will be expanded to include CFV North.

- *Participation in the Premier Quest (Quality) Initiative and Ascend (Supply Chain) initiative.*

- *Participation in the Institute of Healthcare Improvement: 5 Million Lives Campaign, Triple Aim, (recipient of the North Carolina Hospital Association grant for participation), Patient Safety Officer Training.*
- *Reporting of physician quality data to Clinical Performance Improvement Committee (CPIC), to include complications, percentage of normal cases, case volume/clinical mix.*

Summary

Cape Fear Valley Health System is committed to providing care at the community level, where possible, and when needed, state-of-the-art specialty care at CFVHS. The CFV North Service Area was identified by reviewing the population currently serviced by CFVHS in need of improved access to healthcare services. As a result, CFV North's projected utilization is based upon the population of the proposed service area and incorporates the three Basic Principles governing the State Medical Facilities Plan (SMFP)"

CFV North adequately demonstrates how its proposal would maximize value. However, the applicant does not adequately demonstrate how its proposal would promote equitable access or safety and quality of care. See Criterion (13b) and (20) for discussion. Therefore, the application is nonconforming to Policy GEN-3.

In summary, CFV North is conforming to the need determination in the 2011 SMFP and to Policy GEN-4. However, the applicant is not conforming to Policy GEN-3. Therefore, the application is nonconforming to this criterion.

FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital ("FirstHealth") proposes to develop a new 65-bed acute care hospital (FirstHealth Hoke Community Hospital or **FHCH**) along US-401 East (Williams Properties) in Raeford in Hoke County. The applicant proposes to develop all of the 65 acute care beds available for the Cumberland-Hoke Acute Care Bed Service Area in the 2011 SMFP. The applicant does not propose to develop more acute care beds than are determined to be needed in the Cumberland-Hoke Acute Care Bed Service Area. In Section II.1, page 34, the applicant states it will operate a 24-hour emergency services department. In Section II.8, page 117, the applicant provides the projected number of patient days of care by major diagnostic category (MDC) to be provided at FHCH in the first three operating years. The applicant projects the hospital will provide services in all 25 MDCs listed in the 2011 SMFP. Therefore, the applicant adequately demonstrates that it will provide medical and surgical services in at least five MDCs recognized by CMS. FHCH adequately demonstrates that it will provide inpatient medical services to both surgical and non-surgical patients. Thus, FHCH is a qualified applicant and the proposal is consistent with the need determination in the 2011 SMFP for acute care beds in the Cumberland-Hoke Acute Care Bed Service Area.

On September 27, 2010, FHCH was conditionally approved to develop an 8-bed acute care hospital in Raeford (Project ID # N-8497-10). That decision is currently under appeal. In Section I, page 8, FHCH states

"FirstHealth of the Carolinas is not abandoning its previously-approved FirstHealth Hoke Community Hospital CON application, Project ID #N-

8497-10. FirstHealth of the Carolinas also does not intent to build two hospitals in Hoke County. If the Agency approves FirstHealth's 2011 CON application for a Hoke County hospital, FirstHealth will relinquish the approved 2010 CON, Project ID # N-8497-10."

Policy GEN-4

With regard to Policy GEN-4, on page 152, FHCH states:

*"**Architectural Statement***

The design of FHCH will conform to all local, state and federal codes and regulations for energy compliance.

The design will start with appropriate site selection to minimize negative environmental impacts associated with the building and related site development.

The building will be oriented to minimize energy consumption by taking advantage of solar and wind effects. Each façade will be design [sic] *to respond to its orientation and will utilize elements such as sun screens, use of glass as appropriate to its orientation and material selection.*

Design to support the minimization of waste in construction and operation and allocation of adequate space for recycling will be incorporated.

Potable water quality will be evaluated and consumption strategies established in all phases of facility development.

This design will not adversely affect the patient health, safety or infection control.

Building design materials will be chosen to reduce energy consumption and the building will be well insulated to conserve energy. Exterior materials anticipated will be a combination of stone, brick and glass for longevity, protection and safety of occupants and energy conservation.

Building glass will be Low E to reduce solar glare and minimize heat infiltration into the interior of the building.

Mechanical an* [sic] *Electrical Engineering Systems Statement

Efficient mechanical and electrical systems will be selected and sized to meet loads, efficiently utilize space and in consideration of climate characteristics.

Day lighting and building orientation and design will be implemented to reduce energy consumption and shall be incorporated as part of the design.

Energy efficiency goals shall be considered in all phases of facility development.

The design in addition to reducing energy consumption and use will enhance the users' well-being.

Building materials will be selected to reduce the emission of greenhouses gases, wherever possible."

The applicant adequately described the project's plan to assure improved energy efficiency and water conservation. Thus, the application is conforming to Policy GEN-4.

Policy GEN-3

With regard to Policy GEN-3, in Section III.2, page 151, FHCH states:

"The proposed project to develop a hospital in Raeford will promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services by providing more efficient health care services to the patient population served by FirstHealth and FHCH.

In Section V of this CON application, FirstHealth fully discusses the three Basic Principles and how FirstHealth and the FHCH will/have addressed each principle.

In Section VI of this CON application, FirstHealth provides documentation regarding the projected services provided to residents of the service area as a function of payer category, including Medicare, Medicaid, and Charity, which the CON statutory review criteria identify as the "medically underserved." Currently, no patients from Hoke County can receive acute care or emergency services in Hoke County; patients must travel to Pinehurst or to Fayetteville or to another county for these services. This travel is costly because, for the most part, residents rely on either private cars or ambulances. The Hoke Area Transit Service operates Monday-Saturday and provides non-emergency medical transportation to both Pinehurst and Fayetteville for $15.00 round trip and to Chapel Hill and Durham for $30.00 round trip. The Hoke Area Transit Service cannot accommodate medical transportation for either emergencies or acute care needs. The proposed project will result in improved access to all residents of the service area.

Please see FirstHealth's responses to Section VI, Questions 2 through 6 and Exhibit 50 for a copy of the FirstHealth Credit and Collections Policy, which relates to Charity Care.

Please see FirstHealth's responses to Section II Questions 6 and 7 and Exhibit 19 for a copy of the FirstHealth policies and procedures related to quality care.

FirstHealth is committed to providing care at the community level. As a result, FirstHealth's projected utilization is based upon the population of the proposed 4-county service area and incorporates the three Basic Principles governing the State Medical Facilities Plan."

FHCH adequately demonstrates how its proposal would promote safety and quality of care and promote equitable access. However, the applicant does not adequately demonstrate the need for its proposal. See Criterion (3) for discussion. Therefore, the applicant does not adequately demonstrate that its proposal would maximize value. Consequently, the applicant does not adequately demonstrate that its proposal is consistent with Policy GEN-3.

In summary, FHCH is conforming to the need determination in the 2011 SMFP and to Policy GEN-4. However, the application is not conforming to Policy GEN-3. Therefore, the application is not conforming to this criterion.

Conclusion

The application submitted by CFV North is consistent with the need determination, and Policy GEN-4 but is not consistent with Policy GEN-3. The application submitted by FHCH is consistent with the need determination and Policy GEN-4 but is not consistent with Policy GEN-3.

Furthermore, only 65 acute care beds may be approved in this review. Therefore, both of the applications cannot be approved. [See the Comparative Analysis section for the decision regarding the development of 65 acute care beds in Cumberland-Hoke County Acute Care Bed Service Area].

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

CFV North

NC
FHCH

CFV North. Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center ("CFVMC") proposes to construct a satellite hospital with 65 acute care beds, 7 observation beds, two operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services in Fayetteville, Cumberland County. The name of the proposed hospital is Cape Fear Valley North Hospital ("CFV North"). The proposed location is 6387 Ramsey Street, Fayetteville immediately adjacent to Cape Fear Valley Medical Center's Health Pavilion North ("HPN"). CFV North would be licensed under the CFVMC license.

The project and the service components are described in detail in Section II.1, pages 20-29. In Exhibit 32, the applicant provides an itemized list of all medical equipment which is valued at more than $10,000. The proposed capital cost of the project is $87,332,825.

Henceforth, the existing campus, which is located on Owen Drive, may be referred to as the Owen Drive campus. The proposed satellite hospital campus will be referred to as CFV North or the Ramsey Street campus.

POPULATION TO BE SERVED

In Section III.5(a), page 147, the applicant states

> *"The proposed CFV North Service Area includes parts of zip codes in Cumberland County, southwest and southern Harnett County, and northwest Sampson County, as shown in the following table.*

CFV North
Service Area

Zip	*County*
Primary Service Area	
28301	*Cumberland*
28303	*Cumberland*
28311	*Cumberland*
28312	*Cumberland*
28344	*Cumberland/Sampson*
28356	*Cumberland*
28390	*Cumberland/Harnett*
28395	*Cumberland*
Secondary Service Area	
28323	*Harnett*
28326	*Harnett*

Source: CFVHS Planning Section

The proposed service area includes zip codes in northern Cumberland County, the northern part of zip code 28312 in Cumberland County, zip codes in southwest and southern Harnett County and one zip code in northern Cumberland/Sampson County. As reflected in Exhibit 33, Table 8 over 70% of the total population in zip code 28301, 8% of zip code 28303, and 40% of zip code 28312 in Cumberland County are geographically closer to the proposed CFV North based upon travel times and a comparison of Cumberland County census tracts and zip codes [sic] *populations. The proposed CFV North Service Area was defined based upon proximity to the proposed hospital and review of current utilization and patient origin at CFVMC and patient origin of CFVMC's outpatient center, Health Pavilion North, located on the site of the proposed CFV North.*

In Section III.5(d), page 150, the applicant states

> *"Patient origin was projected based upon FY 2010 patient origins and projected volume shifted from CFVHS as reflected in III.1.b. and Exhibit 33 and a review of patient origin for services provided at HPN. For purposes of this Application, CFV North assumed patient origin would be consistent for all services which is a reasonable assumption. Any projected variation by service line would be statistically insignificant."*

In Section III.5(c), pages 149-150 the applicant provides projected patient origin for CFV North in each of the first three operating years, as illustrated in the following tables.

CFV North
Inpatient Days of Care
October 2014 - September 2017

	% of Total
Cumberland	81.7%
Harnett	7.8%
Sampson	0.5%
All Other	10%
Total	100%

Source: Section III, page 149.

CFV North
Outpatient Visits
October 2014 - September 2017

	% of Total
Cumberland	78.2%
Harnett	10.9%
Sampson	0.9%
All Other	10%
Total	100%

Source: Section III, page 149.

CFV North
Emergency Visits
October 2014 - September 2017

	% of Total
Cumberland	78.4%
Harnett	11.2%
Sampson	0.5%
All Other	10%
Total	100%

Source: Section III, page 149.

CFV North
Inpatient Surgery Cases
October 2014 - September 2017

	% of Total
Cumberland	79.3%
Harnett	10.0%
Sampson	0.7%
All Other	10%
Total	100%

Source: Section III, page 150.

CFV North
Outpatient Surgery Cases
October 2014 - September 2017

	% of Total
Cumberland	79.3%
Harnett	9.8%
Sampson	0.9%
All Other	10%
Total	100%

Source: Section III, page 150.

The population projected to be served at CFV North is based on historical patient origin for the Owen Drive Campus, HPN, and geographic proximity. The applicant adequately identifies the population to be served.

NEED FOR THE PROPOSED SERVICES

Project Components

In Section II.1, pages 20-29, the applicant describes the proposed project as follows:

> *"The proposed community hospital will include the four basic service components of a community hospital: inpatient care; emergency care; surgical care; and outpatient services and will be licensed under the CFVMC license. Many of the existing outpatient services currently provided at HPN will be integrated into CFV North. In addition, areas of HPN will be renovated to include support services for the new CFV North Hospital.*
>
> *The scope of services offered under each service component on the CFV North campus includes the following:*
>
> *Acute Inpatient Services including:*
> - *65 acute care beds:*
> - *57 acute medical surgical beds;*
> - *8 intensive care beds;*
> - *7 Observation beds;*
> - *Ancillary/Clinical Services including:*
> - *Mobile and portable imaging necessary to support the standard of care in a modern community hospital* [sic]
> - *Pharmacy, laboratory and pathology services, physical therapy, speech therapy, and a multi-modality, all-digital radiology department including a 64-slice CT scanner, digital x-ray, fluoroscopy, and ultrasound.*

Emergency Services including:

- *A 24 / 7 Emergency Department with 20 treatment areas.*
- *Imaging to support the standard of care in a modern community hospital including portable imaging equipment and 1 Mini C-Arm for use in the ED.*

Surgical Services including:

- *2 shared use inpatient/ambulatory operating rooms;*
- *Portable imaging to support the standard of care in a modern community hospital including a multi-purpose C-arm for use in the operating rooms* [sic]

Outpatient Services including:

- *A multi-modality, all-digital radiology department including a 64-slice CT scanner (currently located in Health Pavilion North to be relocated to CFV North), digital x-ray, and ultrasound;*
- *pharmacy, lab, and pathology services;*
- *physical, occupational & speech therapy services;*
- *respiratory therapy services;*
- *other diagnostic testing and outpatient service capabilities that are standard of care in a modern community hospital and the emergency department, such as treadmills, pulmonary function testing, and ECHO, and EKG/Holter Monitor units.*

...

Acute Inpatient Services

Medical –Surgical Acute Care Beds and Intensive Care Beds

CFVHS and CFV North are proposing to develop 65 CON-approved acute care beds in a newly constructed acute care hospital in northern Fayetteville in zip code 28311. CFV North is proposing that all 65 of the CON-approved acute beds will be medical-surgical inpatient and of these, 8 will be Intensive Care beds. The proposed CFV North will be a satellite of CFVMC and will be operated under the CFVMC hospital license.

The line drawings for the proposed CFV North included in Exhibit 9 show that 57 inpatient medical-surgical acute beds and a 8-bed Intensive Care Unit will be located on the 2nd and 3rd floors. The Intensive Care Unit will be located in a setting that is physically and functionally distinct from the rest of the facility and with controlled access. Note that CFVMC will not be adding any new ICU beds. When the 8-bed Intensive Care Unit at CFV North becomes operational, 8 ICU beds at CFVMC will be converted to general medical surgical beds. The proposed CFV North will include a

7-bed observation unit. The 7 observation beds will be unlicensed beds to be used to observe patients for a period of less than 24 hours.

The project proposed in this CON application will increase the number of acute care beds licensed to Cape Fear Valley Health System at completion of both this project and Hoke Community Medical Center from 645 [sic] *licensed and CON approved beds to 710* [sic] *licensed and CON approved beds.*

In addition, all ancillary and support services necessary to support acute inpatient services will be offered at CFV North.

Emergency Services

CFV North will include a new Emergency Department with 20 treatment areas. From time to time, some of the treatment rooms will be used to observe Emergency Department patients in order to make a determinative clinical decision regarding inpatient admission or discharge from the ED. The Emergency Department is located on the first floor of the proposed hospital and is contiguous to radiology, which is also located on the first floor of the proposed hospital. The Operating Room, Pharmacy and Laboratory are also located in proximity on the first floor of CFV North (see Exhibit 9). It is projected that the CFV North Emergency Department will provide over 28,000 Emergency Department visits annually by project year 3. See Section III of this application for further documentation of anticipated ED visit volumes at CFV North.

CFV North will provide fixed, mobile and portable imaging to support the standard of care in a modern community hospital Emergency Department.

Cape Fear Valley's Emergency Medical Services and LifeLink will be available to provide necessary transport for transfers of patients from CFV North to Cape Fear Valley Medical Center or other tertiary hospitals when clinically necessary. In addition, CFV North will include a helicopter pad and CFVMC will provide helicopter transport as necessary. CFVHS has a contracted helicopter on site at CFVMC in conjunction with UNC helicopter services which provides emergency transfers for patients who need specialized trauma services. Copy of UNC online article and CEO letter of support are included in Exhibit 31.

Surgical Services

CFV North will include two shared operating rooms. The two operating rooms will be relocated from Highsmith Rainey Specialty Hospital. This application does not propose any dedicated inpatient ORs, or dedicated

outpatient ORs at CFV North. The line drawing for the proposed CFV North shows that the surgical suite would be located on the first floor. Additional services in the CFV North surgical suites will include: pre- and postoperative bays necessary to support the ORs and the surgical procedures performed there, an anesthesia office and a work room, equipment storage rooms and alcoves, stretcher alcoves, staff lockers and a lounge, and offices for Operating Room Staff (see Exhibit 9).

Ancillary Services

Imaging Services

Initially, the CFV North Radiology Department will include:

- *One digital routine x-ray unit/room*
- *One digital combination x-ray/fluoro unit/room*
- *One 64-slice digital CT scanner, an existing CT scanner located at Health Pavilion North will be relocated the Radiology Department adjacent to the Emergency Room at CFV North*
- *One digital ultrasound unit*
- *Two portable, digital x-ray units for use on the patient floors, Emergency Department and Operating Rooms*
- *Mini C-Arm for use in the Emergency Department for Post-Reduction studies (x-ray after the fracture is casted)*
- *Multi-purpose C-Arm for use in the Operating Rooms*
- *Picture archiving/PACS system for the storage and transmission of digital radiology images*

The Radiology Department will be located on the first floor at the proposed hospital. The imaging equipment will be available to perform diagnostic studies for Emergency Department patients, other outpatients, and medical-surgical patients at CFV North. The CT scanner currently located at HPN will be relocated to the new radiology department at CFV North. Other limited outpatient diagnostic imaging services currently at HPN will remain intact to continue providing outpatient service for CFV North and the medical clinics currently located on the second floor of HPN which will remain in place.

CFV North will seek to contract with Alliance for mobile MRI scanning/imaging services onsite at CFV North initially for two to three days per week. The expense for this mobile service has been included in the CFV North CON pro forma financial income statement projections. CFV North will seek to secure a contract with a mobile MRI vendor prior to the opening of the new hospital in October 2014. Included in Exhibit 11 is a letter to Alliance indicating an interest in working with them when

CFV North becomes a reality.

Laboratory Services

CFV North will have a laboratory program sufficient to support the needs of a 65 bed community hospital and its Emergency Department. The laboratory will be located on the first floor of the proposed hospital. Laboratory services will include hematology, chemistry, coagulation, limited microbiology and blood bank services. CFV North will have access to the Cape Fear Valley Medical Center (CFVMC) reference laboratory for more esoteric studies. See Exhibit 26 for a letter regarding the availability of reference lab and pathology services at Cape Fear Valley Health System. Laboratory services will be available 24 hours a day 7 days a week.

Pharmacy Services

CFV North will have a pharmacy program sufficient to support the needs of a 65 bed community hospital, with an Intensive Care Unit, and an Emergency Department. The pharmacy will be located on the first floor of the proposed hospital. In addition, the existing outpatient retail pharmacy on the first floor of HPN will remain operational. All clinical areas will have access to Pyxis medication dispensing systems. The pharmacy department will have a dedicated IV room for preparation of intravenous medications.

The Pharmacy will be open 7am to 7pm with a pharmacist on call from 7pm to 7am. During the hours a pharmacist is not physically onsite appropriate services for pharmacy oversight will be provided by pharmacy services at Cape Fear Valley Medical Center.

Respiratory Therapy Services

The CFV North Respiratory Therapy 'RT' staff will provide therapeutic and diagnostic RT services to CFV North inpatients, outpatients, and ED patients as requested or ordered by physician. CFV North respiratory therapists will be registered by the National Board of Respiratory Care and will maintain current certification in Basic Life Support (CPR), ACLS, and PALS. Respiratory therapists will also be part of the hospital's Code Blue resuscitation team.

The CFV North RT staff will be qualified and equipped to provide the following types of services at the proposed 65 bed community hospital in northern Cumberland County:

- *Intervention in ventilator management through interpretation of waveforms, calculation, monitoring PIP, plateau pressures and auto-peep*
- *Management of a patient on all protocols, including invasive and noninvasive weaning protocols*
- *Set-up and management of patients on pressure and volume ventilation*
- *Interpretation and intervention with arterial blood gas studies*
- *Competent performance of all aspects of Respiratory Care outlined in the Respiratory Care Protocol and department policy/procedures*
- *Assistance with bronchoscopes*
- *Set up and maintenance of invasive and noninvasive ventilators for all age groups*
- *Serve as liaison to physicians in all areas of patient concern related to respiratory therapy*

Respiratory Therapy will be available 24 hours a day.

Physical Therapy (P.T.), Occupational Therapy (O.T.,) and Speech Therapy (S.T.) Services

Qualified and credentialed P.T., O.T., and S.T. staff will be available on-site to support the care of patients at CFV North. These are already well-established services at Health Pavilion North and can be easily expanded for inpatient coverage.

The CFV North Speech Therapy staff will be qualified and equipped to provide the following types of services:

- *Speech-Language evaluations*
- *Bedside swallowing evaluations*
- *Meal observations for patients transitioning from NPO to oral nutrition/meals*
- *Patient treatments for speech/language/cognition/swallowing issues*
- *Evaluate and prepare S.T. Plans of care for patients*
- *Review S.T. Plan of care with family*

The CFV North Physical Therapy staff will be qualified and equipped to provide the following types of services:

- *Evaluate patients and prepare P.T. Plans of Care*
- *Perform assessments of patients to include: patient history & living*

situation, patient's level of pain, mental status & goals, range of motion, strength, balance, posture, coordination, sensation, skin/edema and tone, transfers & mobility, gait
- *Assist hospitalized patients with execution P.T. Plan*
- *Review P.T. Plan of Care with family*

The CFV North Occupational Therapy staff will be qualified and equipped to provide the following types of service:

- *Evaluate patients and prepare O.T. Plans of Care*
- *Perform assessments of patients to include: patient history & living situation, patient's level of pain, mental status & goals, range of motion, strength, balance, posture, coordination, sensation, skin/edema and tone, transfers & mobility, gait*
- *Assist hospitalized patients with execution O,T. Plan*
- *Review O.T. Plan of Care with family*

Hospital-Based Outpatient Services

On the first floor at the CFV North there will be a dedicated space for services to outpatients. Hospital-based outpatient services can include such services as: pre-admission or pre-procedure testing and patient education, suture removal, injections, immunizations, nerve blocks, etc. Other outpatient services currently operational at Health Pavilion North will enhance the proposed hospital's continuum of care include an outpatient pharmacy, a family practice clinic and a pediatric clinic. The scope of services offered in the outpatient department will be refined and tailored based on input from the medical staff prior the opening of CFV North.

Other Clinical & Non-Clinical Services

CFV North clinical & non-clinical services will be provided by employed or contracted with qualified professional providers to offer:

- *Laboratory and Pathology Services*
- *Anesthesiology Services*
- *Radiology Services*
- *Hospitalist Coverage*
- *ICU medical direction*
- *ED physician coverage and medical direction*
- *Mobile MRI studies*

See letters in Exhibits 11 and 26 regarding these services.

As discussed above, many of the existing outpatient services currently provided at HPN will be integrated into CFV North. Furthermore, existing areas of HPN will be renovated to accommodate administration and other support services. HPN is an outpatient center operated under the CFVMC license with over 50,000 department square feet. The following table illustrates the current and proposed usage of space within HPN.

...

As shown in the previous table, 10,973 square feet within HPN (sum of green highlighted areas) will be renovated as part of the development of CFV North. The Urgent Care Center at HPN will be integrated into the Emergency Department at CFV North. Space vacated on the first floor of HPN will be converted for administration and support services, pre-admission services, security, public relations and marketing, and lobby and waiting areas. On the second floor, there currently is vacant medical office space and a specialty clinic. The specialty clinic will merge with the family care clinic, also on the second floor, and vacated space will be utilized for human resources, infection control and quality assurance, information systems and hospital services waiting and lobby areas.

CFV North will also provide the following, and have in place contracts as necessary for clinical and non-clinical services:

- *Laundry is contracted with the NC State Division of Correctional Services*
- *Environmental Services*
- *Facility Services*
- *Food and Nutrition (Management Contract)*
- *Medical Records/Coding*
- *Clinical Technology Services (CTS)*

The expenses for these services are included in the CFV North CON financial pro forma income statement projections in the expense line item other indirect expense."

In Section III.1, pages 78-97, the applicant describes the need for the proposed project, each service component and the proposed location within the Cumberland-Hoke County Acute Care Bed Service Area.

In Section III.1, pages 81-82, the applicant states

"The following factors influence the current and future demand for inpatient and outpatient hospital services in the service area and the need for CFV North.

The unmet need for inpatient acute care services in southern Wake County [sic] *is substantiated by a variety of factors including:*

- *2011 State Medical Facilities Plan identification of need for 65 acute care beds in the Cumberland* [sic] *Service Area.*
- *Increasing trends in utilization of inpatient and outpatient hospital services at CFVMC and in the service area.*
- *Population of the zip code service area is sufficient to support a full-service community hospital.*
- *Current utilization of CFVHS inpatient services by the residents of the defined service area is sufficient to support a full-service community hospital.*
- *CFVHS current market share reflects opportunity for growth in the defined service area and substantiates the need for the proposed facility.*
- *Growth of the market as a result of the Federal Base Realignment and Closure Program (BRAC).*
- *Growth and development in the defined zip code service area and the surrounding areas.*

In addition, the need for hospital services at CFV North at the community level for the residents of the defined service area also is supported by:

- *Strong physician support from providers who care for residents of the service area in practice locations in Cumberland County included in Exhibit 26.*
- *Letters of support from the community, schools, businesses, local and state government and other healthcare providers are included in Exhibits 27-29.*

CFV North will provide service area residents with locally-accessible, high quality, and cost-effective, inpatient and outpatient hospital services in a comfortable and convenient location close to home.

'Exceptional healthcare for all our patients. That's what Cape Fear Valley Health System strives to provide. In every moment, we're improving the quality of every life we touch.' The proposed CFV North is consistent with the mission of CFVHS."

In Section III.1, pages 83–86, the applicant states *"Development of the proposed 65 new acute care beds at CFV North, in addition to meeting the primary and secondary acute care needs of the defined service area, will allow the shift of patient day volume out of the existing beds at CFVMC relieving the high utilization at CFVMC and relieving congestion on the CFVMC campus. ..."*

On pages 86 – 87, the applicant states

"Population of the Zip Code Service Area is Sufficient to Support a Full-service Community Hospital

> *The proposed CFV North Service Area includes parts of zip codes in Cumberland County, southwest Harnett County, and northwest Sampson County. Projected population growth for data years 2010 through 2016 is shown in the following table..."*

The applicant discusses the *"Growth of the Market as a Result of the Federal Base Realignment and Closure Program (BRAC)"* on pages 87-91 of the application.

The applicant provides a *"Market Share Analysis"* on pages 91-92 and states, in part, *"As shown in the previous table, CFVHS meets the inpatient needs of 84% of the residents of Cumberland County, 6% of inpatient needs of the residents of Harnett County, 15% of the inpatient needs of the residents of Sampson County.*

> ...
>
> *The proposed location of CFV North will improve access to inpatient services for those residents of northern Cumberland, southwest and southern Harnett and northwestern Sampson currently seeking care at CFVMC. In addition, the new facility also will provide opportunities for growth in the future, including: the potential to recapture market share in northern Cumberland County; and, the opportunity to meet the inpatient needs of the growing population in southwest and southern Harnett County."*

Further, the applicant discusses *"Economic Growth and Development"* on pages 92-96; *"Cumberland County Transportation Development"* on page 96; and *"Cumberland County Residential Development"* on pages 96-97.

In Section III.1(b), pages 97-106, the applicant states

> *"To substantiate the need for the proposed new community facility, CFV North projected future inpatient, surgical and emergency visits for the defined Service Area population. In addition, CFV North projected inpatient, surgical and emergency visits for CFVMC surgical volumes* [sic] *for HRSH in Cumberland County, which projections show that all existing and CON-approved acute care beds and operating rooms in Cumberland County are needed now and in the future. Projected emergency visits demonstrate a need for expanded emergency services at CFVMC.*
>
> *The proposed CFV North will improve geographical access and ease of*

access by locating the new facility where the population lives and growth is occurring -- in northern Cumberland County and southwestern and southern Harnett County and away from the ever-increasing congestion on the existing CFVMC campus.

Projected Utilization of Cape Fear Valley Health System Existing and Proposed Health Service Facilities

1. Projected CFVHS Total Patient Days

Acute care inpatient days at CFVMC have increased substantially during the last several years. As shown in the following table, acute care inpatient days at CFVMC have grown at a 3.3% compound annual rate from FFY 2005 to FFY 2010, and at 8.0% in the first six months of FFY 2011 as discussed in Section III.1.(a).

CFVMC
Acute Care Inpatient Days
October 2004 — September 2010

	FFY 2005	FFY 2006	FFY 2007	FFY 2008	FFY 2009	FFY 2010	CAGR 2005-2010
Acute Care Inpatient Days	132,678	134,128	136,755	145,017	149,828	155,926	3.3%
% Change		1.1%	2.0%	6.0%	3.3%	4.1%	
Operational Acute Care Beds	407	394	397	490	490	490	
Occupancy Rate	89.3%	93.3%	94.4%	80.9%	83.8%	87.1%	

Source. LRAs; CON Applications; CFVMC Internal Data
Note. CFVMC has a CON for 41 additional acute care beds not reflected in the previous table which are to be developed at HCMC.

Please note that acute care beds at HRSH are designated as LTACH beds. Therefore, the 66 beds at HRSH and the utilization of these beds are not included in the aforementioned and following discussion.

As discussed in Section III.1.(a), Cumberland County, CFVMC's primary service area, is experiencing record growth as a result of increased presence of the military and the ongoing BRAC plan. Future patient days at CFVMC will continue to grow at record rates. For purposes of the following projections, CFVMC used FFY 2010 base data and a conservative 2.0% CAGR to determine future inpatient days. Patient days projected to shift to CFV North and HCMC were subtracted from projected volumes to reflect utilization for CFVMC only in the following table.

CFVMC Projected Acute Care Inpatient Days
October 2010— September 2017

	Historical Volume	FFY 2011	FEY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Projected Inpatient Days	155,926	159,045	162,225	165,470	161,316	149,890	149,720	150,600
ADC	427.2	435.7	444.5	453.3	442.0	410.7	410.2	412.6
Licensed Bed Capacity	490	490	490	490	490	490	490	490
Occupancy Rate	87.2%	88.9%	90.7%	92.5%	90.2%	83.8%	83.7%	84.2%

Source: Exhibit 33, Table 39

The previous table shows projected utilization of the proposed 490 acute care beds at CFVMC during the interim timeframe and projected project years for CFV North. These projections assume that the 41 beds at HCMC will become operational in October 2013 (FFY 2014) and the 65 new beds at CFV North become operational in October 2014 (FFY 2015).

The following table combines projected patient days for CFV North, HCMC, and CFVMC to reflect total projected utilization for all 596 licensed, CON-approved and proposed acute care beds at CFVHS in Cumberland and Hoke Counties.

CFVHS
Projected Acute Care Inpatient Days
Cumberland and Hoke Counties
October 2010 — September 2017

	Historical Volume	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
CFVMC	155,926	159,045	162,225	165,470	161,316	149,890	149,720	150,600
CFVMC — CFV North						12,591	14,353	16,986
Hoke Community Medical Center					7,463	9,674	11,524	11,524
Total Combined Projected Acute Care Inpatient Days	155,926	159,045	162,225	165,470	168,779	172,155	175,598	179,110
ADC	427.2	435.7	444.5	453.3	462.4	471.7	481.1	490.7
Licensed Acute Care Bed Capacity	490	490	490	490	531	596	596	596
Occupancy Rate	87.2%	88.9%	90.7%	92.5%	87.1%	79.1%	80.7%	82.3%

Source: Exhibit 33, Table 39
Note: Numbers may not foot due to rounding

As shown in the previous table, utilization of all CFVHS acute care beds in Cumberland and Hoke Counties is projected to exceed the 2011 SMFP planning target of 75.2% for facilities with an average daily census greater than 400 patients per day in FFY 2017, the third operating year of CFV North.

2. Projected CFVHS Surgical Cases

As previously discussed, surgical cases at CFVHS health service facilities increased slightly from FFY 2005 to FFY 2007. Due to the departure of two surgeons in 2007 and the economic downturn in 2008, FFY 2009 surgical utilization decreased slightly. Total surgical volume for FFY 2010, reflects a slight decrease in inpatient surgical cases with 6,309 inpatient surgical cases (excluding C-Section and open heart volumes) and considerable growth in outpatient surgery with 9,374 outpatient surgical cases. The following table shows surgical volumes at CFVHS and support [sic] the need for all 18 existing and CON approved operating rooms at CFVMC and HRSH in FFY 2010.

CFVMC Historical Surgical Volume
October 2008 — September 2010

CFVMC	***FFY 2008***	*FFY 2009*	*FFY 2010*	*2008-2010*
Inpatient Cases excluding C-Section and Open Heart	*6,199*	*6,239*	*6,243*	*0.35%*
Outpatient Cases	*6,210*	*5,804*	*6,606*	*3.14%*
HRSH	***FFY 2008***	***FFY 2009***	***FFY 2010***	*2008-2010*
Inpatient Cases excluding C Section and Open Heart	*156*	*72*	*66*	*34.96%*
Outpatient Cases	*2,844*	*2,511*	*2,768*	*-1.35%*
combined	***FFY 2008***	***FFY 2009***	***FFY 2010***	***2008-2010***
Inpatient Cases	*6,355*	*6,311*	*6,309*	*0.36%*
Outpatient Cases	*9,054*	*8,315*	*9,374*	*1.75%*
Weighted Surgical Hours (Inpt x 3.0 hrs per case + Outpt x 1.5 hrs per case)	*32,646*	*31,406*	*32,988*	
ORs Needed at 1,872 hours per room	*17.4*	*16.8*	*17.6*	
Total Capacity 17 Operational ORs = (17 x 2,340 Hours per OR)	*39,780*	*39,780*	*39,780*	
Utilization of 17 Operational ORs	*82.1%*	*78.9%*	*82.9%*	

Source: Exhibit 33, Tables 44, 45
** Includes surgical volume for 17 existing ORs at CFVMC and HRSH in Cumberland County; One additional OR has been approved for HCMC in Hoke County; Excludes open heart and C-Section rooms and volumes*

As shown in the previous table, in FFY 2010, the existing 17 operational shared operating rooms at CVFMC and HRSH were utilized at 82.9% of capacity as defined by the 2011 SMFP.

As discussed in Section III.1.(a), Cumberland County, which is CFVMC's primary service area [sic] *is experiencing record growth as a result of increased presence of the military and the ongoing BRAC plan. It is anticipated that CFVHS acute care facilities and services will grow at record rates. That expected growth will exacerbate existing high utilization of operating rooms and inpatient acute care beds, and constrain the growth of surgical volume since no additional operating rooms are proposed. Therefore, for purposes of this analysis, CFVMC used very conservative*

growth rates to project future surgical cases at CFVMC, and held constant surgical utilization at HRSH as reflected below.

CFVMC
Projected Surgical Volume
October 2010 — September 2017

Inpatient Surgical Cases	*FFY 2010 – Historical Volume*	*FFY 2011*	*FFY 2012*	*FFY 2013*	*FFY 2014*	*FFY 2015*	*FFV 2016*	*FFV 2017*	*Growth Rate 2008-2010*
Inpatient Surgical Cases	*6,243*	*6,265*	*6,287*	*6,310*	*6,108*	*5,731*	*5,653*	*5,606*	*0.4%*
Outpatient Surgical Cases	*FFY 2010- Historical Volume*	*FFY 2011*	*FFY 2012*	*FFY 2013*	*FFY 2014*	*FFY 2015*	*FFV 2016*	*FFY 2017*	*Weighted Pop Growth Rate 10-17*
Outpatient Surgical Cases	*6,606*	*6,701*	*6,797*	*6,894*	*6,619*	*5,859*	*5,734*	*5,663*	*1.4%*
Weighted Surgical Hours	*28,638*	*28,846*	*29,057*	*29,270*	*28,253*	*25,981*	*25,560*	*25,314*	
ORs Needed at 1,872 Hours per OR	*15.3*	*15.4*	*15.5*	*15.6*	*15.1*	*13.9*	*13.7*	*13.5*	
Licensed ORs excluding C-Sec and OH at CFVMC	*13*	*13*	*13*	*13*	*13*	*13*	*13*	*13*	
Additional OR Need	*2*	*2*	*3*	*3*	*2*	*1*	*1*	*1*	

Source: Exhibit 33, Table 49
**projected volumes are adjusted for surgical volume shifted to CFV North and HCMC, Excludes open heart and C-Section rooms and volumes*

HRSH
Projected Surgical Volume
October 2010 — September 2017

Inpatient Surgical Cases	*FFY 2010— Historical Volume*	*FFY 2011*	*FFY 2012*	*FFY 2013*	*FEY 2014*	*FFY 2015*	*FFY 2016*	*FFY 2017*
Inpatient Surgical Cases	*66*	*66*	*66*	*66*	*66*	*66*	*66*	*66*
Outpatient Surgical Cases	*FY 2010— Historical Volume*	*FFY 2011*	*FFY 2012*	*FFY 2013*	*FFY 2014*	*FFY 2015*	*FFY 2016*	*FFY 2017*
Outpatient Surgical Cases	*2,768*	*2,768*	*2,768*	*2,768*	*2,308*	*1,817*	*1,668*	*1,582*
Weighted Surgical Hours	*3 822*	*3 822*	*3 822*	*4 350*	*3 659*	*2 924*	*2 700*	*2,571*
ORs Needed at 1,872 Hours per OR	*2.0*	*2.0*	*2.0*	*2.3*	*2.0*	*1.6*	*1.4*	*1.4*
Licensed ORs	*4*	*4*	*4*	*4*	*4*	*4*	*4*	*4*
OR Need/Surplus	*-2.0*	*-2.0*	*-2.0*	*-1.7*	*-2.0*	*-2.4*	*-2.6*	*-2.6*

Source: Exhibit 33, Table 50
**projected volumes are adjusted for surgical volume shifted to CFV North and HCMC*

The previous tables assume that two operating rooms are relocated from HRSH and become operational at CFV North in October 2014, and that the two HCMC operating rooms become operational in October 2013. CFVMC surgical volume was projected based on actual FFY 2010 surgical volume. Inpatient surgical growth at CFVMC was projected using the FFY 2008 to FFY 2010 actual CAGR, which was more conservative than the CFVMC inpatient surgical services weighted population growth rates. Outpatient surgical growth at CFVMC was inflated annually based upon the CFVMC outpatient surgical services weighted population growth rates, which was more conservative than the FFY 2008 to FFY 2010 actual CAGR for outpatient surgery. Detailed projections are included in Exhibit 33, Tables 43-52.

Surgical utilization at HRSH was maintained at FFY 2010 volumes in order to be conservative. CFV North surgical volumes and HCMC surgical volumes will be shifted from existing CFVHS surgical locations, and were subtracted from projected volumes as reflected in the previous tables.

Total projected surgical volumes for CFVHS in Cumberland and Hoke Counties for the first three years of operation of CFV North are reflected in the following table.

CFVHS
Projected Surgical Volumes
Cumberland and Hoke Counties
October 2010 — September 2017

Inpatient Surgical Cases	***FFY 2010 - Historical Volume***	***FFY 2011***	***FFY 2012***	***FFY 2013***	***FFY 2014***	***FFY 2015***	***FFY 2016***	***FFY 2017***
CFVMC Inpatient Surgical Cases	6,243	6,265	6,287	6,310	6,108	5,731	5,653	5,606
CFV North Inpatient Surgical Cases						347	393	462
HCMC Inpatient Surgical Cases					224	277	331	331
HRSH Inpatient Surgical Cases	66	66	66	66	66	66	66	66
Total Inpatient Surgical Cases	6,309	6,331	6,353	6,376	6,398	6,420	6,443	6,465
Outpatient Surgical Cases	***FFY2010 - Historical Volume***	***FFY 2011***	***FFY 2012***	***FFY 2013***	***FFY 2014***	***FFY 2015***	***FFY 2016***	***FFY 2017***
CFVMC Outpatient Surgical Cases	6,606	6,701	6,797	6,894	6,619	5,859	5,734	5,663
CFV North Surgical Cases						1,157	1,332	1,592
HCMC Outpatient Surgical Cases					834	1,028	1,227	1,227
HRSH Outpatient Surgical Cases	2,768	2,768	2,768	2,768	2,308	1,817	1,668	1,582
Total Outpatient Surgical Cases	9,374	9,469	9,565	9,662	9,761	9,861	9,961	10,065
Weighted Surgical Hours	32,988	33,196	33,407	33,620	33,835	34,052	34,271	34,493
ORs Needed at 1872 Hours per OR	17.6	17.7	17.8	18.0	18.1	18.2	18.3	18.4
Current Operational and CON Approved Inventory	18	18	18	18	18	18	18	18
OR Surplus (-) / OR Need(+)	-0.4	-0.3	-0.2	0.0	0.1	0.2	0.3	0.4

Source: Exhibit 33, Tables 49, 50
Numbers may not foot due to rounding.

The previous table also shows operating room need based upon 2011 SMFP surgical hour weighting and rounding applied to CFVHS projected surgical utilization.

As reflected in the previous table, utilization of operating rooms at CFVHS in FFY 2017 will be approaching the SMFP planning capacity for the 18 existing and approved operating rooms. Projected volumes for CFV North will be shifted from CFVMC and HRSH, thereby reducing congestion on the current CFVMC campus and improving access for the population of northern Cumberland and southern Harnett Counties who receive surgical care at CFVHS surgical facilities in Cumberland County. This analysis supports the need for the proposed two operating rooms at CFV North.

3. Projected CFVHS Emergency Visits

Emergency services at CFVMC expanded with the completion of the Valley Pavilion in 2007. Emergency volumes have increased more rapidly than projected in the Valley Pavilion CON Application. As a result, emergency services at CFVMC will need to be expanded again in the near future.

As reflected in the following table, emergency services have increased substantially during the last several years, reflecting a CAGR of 7.1% from FFY 2005 to FFY 2010. The following table shows historical emergency room growth at CFVMC.

CFVMC
Emergency Department Utilization
October 2005 — September 2010

	FFY 2006	FFY 2007	FFY 2008	FFY 2009	FFY 2010	CAGR 2006-2010
Emergency Visits	93,343	99,075	116,433	118,290	122,828	7.1%
% Change		6.1%	17.5%	1.6%	3.8%	
Four Yr Avg (Less High and LowYrs)					5.0%	
ED Trmt Spaces Needed @1,350 Visits per Room (ACEP)					91	

Source: CFVMC LR4s; ACEP ED Visits per Treatment Room

The previous table shows considerable growth in emergency department visits from FFY 2006 through FFY 2008 as a result of the opening of the expanded emergency department, and steady and increasing growth from FFY 2008 through FFY 2010.

To date in FFY 2011, emergency room utilization has exploded. CFVMC expects to exceed 130,000 emergency room visits this fiscal year which is more than a 7% increase over FFY 2010. FFY 2011 has been the busiest year on record in the CFVMC emergency department to date. In addition, the number of patients admitted to acute care beds from the Emergency Department has increased from 17% in FFY 2010 to 20.3% in FFY 2011 to date, the highest in history. There has been a marked increase in the number of pneumonia patients admitted, which accounts for one component of the overall increase in medical admissions from the emergency room.

As discussed in Section III.1.(a), Cumberland County, CFVMC's primary service area is experiencing record growth as a result of increased presence of the military and the ongoing BRAC plan. Future emergency visits at CFVMC will continue to grow at record rates. For purposes of this analysis CFVMC averaged the annual growth in emergency room visit [sic], *excluding the high and low year growth rates, over the last four years as reflected in the previous table. The resulting 5.0% growth rate was used to project future emergency visits reflected in the following table.*

CFVMC
Projected Emergency Visits
October 2010 — September 2017

	FFY 2010— Historical Volume	*FFY 2011*	*FFY 2012*	*FFY 2013*	*FFY 2014*	*FFY 2015*	*FFY 2016*	*FFY 2017*
CFVMC Projected ED Visits	*122,828*	*128,955*	*135,388*	*142,142*	*149,233*	*156,678*	*164,494*	*172,700*
ED Treatment Spaces Needed	*Visits per trmt space (ACEP) - 1350*	*95.5*	*100.3*	*105.3*	*110.5*	*116.1*	*121.8*	*127.9*
Existing/CON Approved ED Treatment Spaces (Includes CFVMC and HCMC)		*76*	*76*	*76*	*92*	*92*	*92*	*92*
Additional Need		*19.5*	*24.3*	*29.3*	*18.5*	*24.1*	*29.8*	*35.9*
ED Treatment Spaces Needed	*Visits per trmt space (AIA)- 1,500*	*86.0*	*90.3*	*94.8*	*99.5*	*104.5*	*109.7*	*115.1*
Existing/CON Approved ED Treatment Spaces (includes CFVMC and HCMC)		*76*	*76*	*76*	*92*	*92*	*92*	*92*
Additional Treatment Spaces Needed		*10.0*	*14.3*	*18.8*	*7.5*	*12.5*	*17.7*	*23.1*

Source: Exhibit 33, Table 30

The previous analysis supports the need for the 20 additional treatment spaces in the proposed emergency department at CFV North using either the ACEP planning target of 1,350 emergency visits per room which results in a

need for 36 additional ED treatment areas, or using the AIA planning target of 1,500 emergency visits per room which results in a need for 23 additional ED treatment areas. The previous table assumes that the additional 16 ED treatment beds at HCMC become operational in October 2013. Projected volumes for CFV North will be shifted from CFVMC to reduce congestion on the current campus, and improve access for the population of northern Cumberland County and southern Harnett County."

Proposed Location

In Section III.1(c), page 137, the applicant sets forth its rationale for situating the proposed facility at the proposed site in northern Cumberland County as follows:

"The need determination in the 2011 SMFP is for 65 beds for Cumberland and Hoke Counties. The identified bed need is the result of the increasing utilization of CFVMC by residents of Cumberland and surrounding counties. In 2010, HCMC in Hoke County was approved for 41 acute care beds to meet the needs of those patients from Hoke County that received care at CFVMC. Therefore, the most reasonable location for the 65 beds identified as needed in the 2011 SMFP is in Cumberland County.

The proposed CFV North will be located near the intersection of Ramsey Street and Andrews Road, easily accessible from I-95 via the new I-295 interchange. The continued expansion of I-295, the next portion of which is under construction, from Murchison Rd. to Bragg Blvd. will be completed in July 2012, which will result in continued growth in northern Cumberland County and southwest and southern Harnett County. In addition, CFVHS determined that the success of Health Pavilion North in northern Cumberland County supported the need for expanding services in northern Cumberland County to include acute inpatient services at the same location. For residents of northern Cumberland County, CFV North will be the perfect destination for almost all health care needs."

Projected Utilization

In Section III.1(b), pages 107-109, the applicant describes the assumptions and methodologies used to project utilization at CFV North as follows:

"CFV North used two basic methodologies to project future utilization for the proposed project.

1. Projected Growth Rate Methodology

Future Utilization = (CY 2010 Utilization x Growth Rate) + In-migration was used to project:

- *Acute care medical surgical inpatient days, discharges, and bed need;*
- *ICU days and bed need;*
- *Observation bed days and bed need;*
- *Inpatient and outpatient surgical procedures and operating room need;*
- *Emergency Department visits and treatment rooms; and,*
- *Outpatient case volume.*

Growth rates utilized in the projection of future utilization for CFV North were based upon historical utilization and population growth.

2. Ancillary Utilization Projections

Ancillary projections were calculated based upon existing ancillary utilization patterns at CFVMC for patients from the defined zip code Service Area, and projected acuity adjusted patient days and outpatient and emergency volumes were used to project future ancillary volume at the proposed community hospital. CFVMC assumes that projected ancillary utilization at CFV North will be consistent with current ancillary utilization patterns.

Assumptions Consistent Throughout Projections

CFV North utilized the following assumptions throughout the projections.

1. Zip Code Population Projections

The proposed service area consists of zip codes in Cumberland, southwestern and southern Harnett, and northwest Sampson Counties. Population growth in the defined Service Area is expected to continue into the next decade. Therefore, population is expected to grow at the same rate through 2016 as reflected in the following table.

CFV North
Service Area Population
2010 - 2016

Zip	*County*	*2010*	*2016*	*CAGR*
Primary Service Area				
28301	*Cumberland*	*16,376*	*15,530*	*-0.9%*
28303	*Cumberland*	*29,463*	*28,211*	*-0.7%*
28311	*Cumberland*	*33,028*	*33,144*	*0.1%*
28312	*Cumberland*	*18,784*	*19,846*	*0.9%*
28344	*Cumberland/Sampson*	*3,425*	*3,553*	*0.6%*
28356	*Cumberland*	*4,600*	*4,843*	*0.9%*
28390	*Cumberland/Harnett*	*19,789*	*20,422*	*0.5%*
28395	*Cumberland*	*2,233*	*2,309*	*0.6%*
Subtotal PSA		*127,698*	*127,858*	*0.0%*
Secondary Service Area				
28323	*Harnett*	*3,316*	*3,724*	*2.0%*
28326	*Harnett*	*14,899*	*17,137*	*2.4%*
Subtotal SSA		*18,215*	*20,862*	*2.3%*
Total		*145,913*	*148,720*	*0.3%*

Source: Exhibit 33, Table 9

As reflected in the previous table, the total population of the zip code service area for the proposed CFV North is expected to increase slightly from 2010 through 2017 as a result of the projected growth in southwestern and southern Harnett County. Note that the Claritas zip level population data has not been updated to reflect any impact of the 2010 Census. Also, as previously discussed, county population projections from the North Carolina Office of State Budget and Management and the zip code population projections from Thomson Reuters' Claritas Workplace do not include the projected growth in military population, nor the impact on the projected growth in the civilian population related to increases in the military population. Therefore, volumes projected in this Application are based upon very conservative population growth rates.

2. Other Cumberland County Zips and Other County — In-migration Assumption

While not part of the defined Service Area, CFV North recognizes that patients from other Cumberland County zip codes and other North Carolina counties may choose to travel across service areas to receive services at CFV North. As a result, 10% of the total projected utilization in each of the project years has been allocated to the category of "other" or "in-migration"[17]. In FFY 2010, over 80% of total discharges from CFVMC were residents of Cumberland and Harnett County which reflects a 20% in-migration as shown in the following table.

CFVMC
Patient Origin Inpatient Service

County	*Percent*
Cumberland	*77.9%*
Robeson	*6.4%*
Hoke	*4.6%*
Sampson	*3.6%*
Harnett	*2.2%*
Bladen	*2.0%*
All Others	*3.2%*
Total	*100.0%*

Source: 2011 LRA

In a footnote to this section on page 108 the applicant states

> *"In-migration" reflects utilization of a facility over and above the historically defined "Primary and Secondary Service Area." A facility's primary and secondary service area is customarily defined as the markets from which 80% to 90% of patient days or utilization originate. This also is known as those markets upon which the hospital depends for its success. Therefore, "in-migration" is historically between 10% to 20% of total utilization. Consistent with the approach taken in previously approved CON acute care hospital applications, CFVHS has used 10% in-migration in this Application."*

On page 109, the applicant states

> *"CFVMC is a major referral center for tertiary care and received patients from throughout central North Carolina.*
>
> *In addition to reviewing CFVMC's geographic service area and considering the proposed geographic location of CFV North to determine patient origin and in-migration, CFV North also reviewed the HPN Urgent Care Center's patient origin from Cumberland and Harnett Counties which reflects that nearly 90% of total patients receiving care from HPN were from Cumberland and Harnett Counties.*
>
> *Considering the fact that HPN realizes a 10% in-migration from counties other than Cumberland and Hoke* [sic], *and CFVMC experiences 20% in-migration, in addition to historical definitions of in-migration as used for planning purposes, it is reasonable for CFV North to assume a 10% in-migration to CFV North, which would include patients from other zip codes in Cumberland County, and on occasion from patients historically served by CFVMC as reflected in the CFVMC Patient Origin Table included above and in Section III.4.(a)."*

Acute Care Beds

In Section III, page 116, and Section IV.1, page 157, the applicant provides projected utilization of the 65 acute care beds, as illustrated in the table below.

CFV North
Acute Care Beds- Projected Utilization for First Three Project Years

Acute Care Beds	PY1: Oct 2014 – Sept 2015	PY2: Oct 2015 – Sept 2016	PY3: Oct 2016 – Sept 2017
# of Beds	65	65	65
# of Admissions	2,709	3,088	3,655
# of Patient Days	12,591	14,353	16,986
Percent Increase in Patient Days	na	14.0%	18.3%

In Section III.1(b), pages 109-116, the applicant provides the assumptions and methodology used to project utilization of the 65 acute care beds at the proposed CFV North as set forth below.

"1. Projected Total Inpatient Discharges, Days, and Bed Need

CFV North projected acute care medical surgical inpatient days for the first three years of operation using the following methodology.

Projected Acuity Adjusted Patient Day Utilization = (Current CY 2010 Acuity Adjusted Patient Days x Average of Historical Growth Rates and Population Growth for Zip SA) + In-migration

Step 1. Determine Acuity Adjusted Patient Days from CFV North Zip Code Service Area

As previously discussed, the proposed CFV North will be a community hospital; therefore, cardiac surgery, neurosurgery and other tertiary level services will not be provided. In addition, CFV North will not provide obstetrical services. To determine total medical surgical discharges and patient days at CFV North, zip code level acuity adjusted inpatient days were determined using the CFVMC inpatient database. The term, 'acuity adjusted' as used in this application reflects all exclusions referenced in the following table, made from the CFVMC inpatient database of discharges and patient days from the defined service area.

CFVMC Inpatient Database Exclusions
October 2009 - September 2010

Medical Surgical Exclusions
Mental Health and Drug Abuse DRG5
Rehab DRG5
OB and Normal Newborns
NICU
Diag Cardiac Cath
DRG5 with FFY2010 Relative Weight > = 2.0

Source: CFVHS Planning Section

CFV North analyzed CY2010 zip code level CFVMC inpatient data to determine the acuity adjusted acute care medical surgical inpatient volumes at CFVMC appropriate for CFV North. The following table shows calendar year base data, acuity adjusted, from service area zip codes.

CFVMC
Zip Code Acuity Adjusted Patient Days
CFV North Service Area
January 2008 — December 2010

Zip	County	CY 2008 Admissions	CY 2008 Pt Days	CY 2009 Admissions	CY2009 Pt Days	CY2010 Admissions	CY2010 Pt Days
Primary Service Area							
28301	Cumberland	1,965	9,472	1,688	8,023	1,828	8,766
28303	Cumberland	1,676	7,384	1,473	6,732	1,618	7,437
28311	Cumberland	1,515	6,486	1,418	6,161	1,553	7,334
28312	Cumberland	984	4,166	1,065	4,879	1,092	5,114
28344	Cumberland/Sampson	53	183	62	248	50	166
28356	Cumberland	163	644	137	533	161	738
28390	Cumberland/Harnett	719	3,071	657	2,835	707	3,085
28395	Cumberland	146	590	129	670	145	695
Secondary Service Area							
28323	Harnett	32	110	29	217	37	130
28326	Harnett	61	187	83	323	72	290
Combined Primary and Secondary Service Areas							
Total		7,314	32,293	6,741	30,621	7,263	33,755

Source: CFVHS DSS Data System; Exhibit 33, Table 7

As previously discussed, areas of zip codes 28301, 28303 and 28312 are closer to CFVMC. Therefore, total acuity adjusted patient days were adjusted to reflect geographic proximity to CFV North, and to determine total acuity adjusted patient days provided at CFVMC to residents of the CFV North Service Area as reflected in the following table.

CFVMC
Zip Code Acuity Adjusted Patient Days
Geographically Closer to CFV North Service Area
January 2010 — December 2010

Zip	*County*	*CY 2010 Pt Days*	*Percent of Zip Closer to CFV-North*	*Estimated 2010 Patient Days Closer to CFV-North*
Primary Service Area				
28301	*Cumberland*	*8,766*	*70%*	*6,136*
28303	*Cumberland*	*7,437*	*5%*	*372*
28311	*Cumberland*	*7,334*	*100%*	*7,334*
28312	*Cumberland*	*5,114*	*40%*	*2,046*
28344	*Cumberland/Sampson*	*166*	*100%*	*166*
28356	*Cumberland*	*738*	*100%*	*738*
28390	*Cumberland/Harnett*	*3,085*	*100%*	*3,085*
28395	*Cumberland*	*695*	*100%*	*695*
Secondary Service Area				
28323	*Harnett*	*130*	*100%*	*130*
28326	*Harnett*	*290*	*100%*	*290*
Total PSA and SSA		*33,755*		*20,992*

Source: CFVHS DSS Data System: Exhibit 33, Table 7

As shown in the previous table, CFV North estimated that 20,992 patient days from the defined Service Area are geographically closer to the proposed location for the new CFV North community hospital. As discussed above, if all 20,992 patient days shifted a community hospital with 86 beds would be needed at 66.7% utilization, the SMFP target for hospitals with less than 100 patients per day.

Step 2. Determine Baseline Acuity Adjusted Patient Days

While 100% of the acuity adjusted patient days reflected in Step 1. are appropriate for care at CFV North, CFV North realizes that some patients will continue to choose to drive to CFVMC for inpatient care. Therefore, for the purposes of projecting utilization, CFV North assumes that 70% of current CFVMC patients will shift to CFV North.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from CFVMC to the new

CFV North:

- *Current medical/surgical services at CFVMC are at capacity.*
- *Physician support for the project is overwhelming.*
- *Community support for the project is overwhelming (please see Exhibits 27 to 29).*
- *Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.*
- *CFVMC's emergency room is experiencing record volumes and is at capacity.*
- *CFV North offers a choice for inpatient and outpatient care closer to home.*
- *The proposed location of CFV North on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.*
- *Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to CFV North.*

Baseline CY 2010 patient days are reflected in the following table.

CFV North
Baseline Acuity Adjusted Patient Days from Zip Code Service Area
January 2010 - December 2010

Zip	*County*	*Estimated CY 2010 Patient Days Closer to CFV-North*	*70% Percent of CY 2010 Patient Days Shifted to CFV-North*	*Baseline CY 2010 Patient Days Shifted to CFV-North*
Primary Service Area				
28301	*Cumberland*	*6,136*		
28303	*Cumberland*	*372*		
28311	*Cumberland*	*7,334*		
28312	*Cumberland*	*2,046*		
28344	*Cumberland/Sampson*	*166*		
28356	*Cumberland*	*738*		
28390	*Cumberland/Harnett*	*3,085*		
28395	*Cumberland*	*695*		
Secondary Service Area				
28323	*Harnett*	*130*		
28326	*Harnett*	*290*		
Total PSA and SSA		*20,992*	*70%*	*14,694*

Source: CFVHS DSS Data System; Exhibit 33, Table 7

As shown in the previous table, CFV North utilized 14,694 acuity adjusted patient days as a baseline for projecting future inpatient utilization for the new community hospital located in northern Cumberland County.

Step 3. Determine Patient Day Growth Rate

CFV North reviewed the growth in admissions, patient days and population from the defined service area, and changes in inpatient use rates, to determine the most reasonable growth rate to use for projecting inpatient days. As previously discussed, overall growth in patient days at CFVMC is at an all time high. CFVMC is operating at over 90% capacity and may be losing patients to other inpatient facilities as a result.

CFV North Service Area
Combined Primary and Secondary Zip Service Areas — Growth Rate Variables
January 2008 — December 2010

Growth Variables	*CY 2008*	*CY 2009*	*CY 2010*	*CAGR 2008-2010*
Admissions	*7,314*	*6,741*	*7,263*	
% Change		*-7.8%*	*9.2%*	*-0.3%*
Patient Days	*32,293*	*30,621*	*33,755*	
% Change		*-5.1%*	*10.2%*	*2.2%*
Weighted Population Growth Rate – 2010				*-0.1%*
Average of Three Growth Rate Variables				*0.6%*

Source: CFVHS DSS Data System; Exhibit 33, Table 7
AGR = Annual Growth Rate

As reflected in the previous table, the CAGR for inpatient admissions is negative from CY 2008 to CY 2010 for residents of the CFV North Service Area as a result of decreased admissions in CY 2009. The growth from CY 2009 to CY 2010 was over 9%. Patient days from the CFV North Service Area also decreased from CY 2008 to CY 2009, but recovered significantly in CY 2010 resulting in a positive CAGR for patient days of 2.2%

Population growth for some of the zip codes in the CFV North Service Area is negative or just shy of 1%, resulting in a weighted population growth rate for the Service Area of -0.1%. The increase in patient days at CFVMC is a result of increased medical admissions, many from the emergency room, with longer lengths of stay as reflected in Exhibit 33, Table 7, and slight decreases in elective surgery, with shorter lengths of stay. CFVHS recently hired a Director of Care Management to direct the medical management process.

As reflected in the following table, the acuity adjusted admission use rate per

1,000 and the acuity adjusted patient days use rate per 1,000 population decreased from 2008 to 2009, and increased from 2009 to 2010 for residents of the CFV North Service Area.

CFV North Service Area
Acuity Adjusted Admission and Acute Care Inpatient Day Use Rates
October 2006 — September 2010

	FFY 2008	*FFY 2009*	*FFY 2010*
Total Cases	*10,018*	*9,627*	*249,907*
Total Patient Days	*46,860*	*44,942*	*46,299*
Total Zip Population	*139,478*	*143,635*	*145,913*
Admission Use Rate	*71.82*	*67.02*	*67.90*
Acute Care Inpatient Day Use Rate	*335.97*	*312.89*	*317.31*

Source: Exhibit 33, Table 17

CFV North decided not to use the higher 2.2% patient day growth rate to project future utilization at CFV North despite the fact that growth in patient day use rates supports use of that variable. CFV North decided to average the three growth rates, and grow the baseline acuity adjusted patient days by 0.6% annually to project future inpatient utilization.

Step 4. Project CFV North Acute Care Inpatient Days

Projected CFV North inpatient days for the first three years of operation were calculated using FFY 2010 baseline patient days from Step 2. and projected growth rates determined in Step 3. CFV North assumed the new facility would grow at a reasonable rate, achieving 75% of the market shift from CFVMC in Project Year 1, 85% of the market shift from CFVMC in Project Year 2, and 100% of the proposed 70% market shift from CFVMC by the end of Project Year 3. Projected acute care inpatient patient days are reflected in the following table. Projected in-migration also is reflected in the following table.

CFV North
Projected Acute Care Inpatient Days
October 2010 – September 2017

	Baseline Pt Days CY 2010 Patient Days Shifted to CFV-North = 705 of Volume Geographically Closer	***CAGR***	***CY 2014***	***CY 2015***	***CY 2016***	***CY 2017***
CFV North Projected Patient Days Primary and Secondary Service Areas	*14,694*	*0.6%*	*15,043*	*15,131*	*15,220*	*15,309*
In-Migration (10%)	*10%*		*1,671*	*1,681*	*1,691*	*1,701*
Total CFV North Projected Pt Days			*16,714*	*16,812*	*16,911*	*17,011*
Convert to Project Years				*FFY 2015*	*FFY 2016*	*FFY 2017*
Projected Pt Days				*16,788*	*16,886*	*16,986*
Ramp Up Utilization				*75%*	*85%*	*100%*
Total CFV North Projected Pt Days				*12,591*	*14,353*	*16,986*

Source: Exhibit 33, Table 2
Calculation example: FFY 2015 = 25% x CY 2014 + 75% x CY 2015

Utilization at CFV North is projected to approach 17,000 patient days in Project Year 3 as shown in the previous table. The following table summarizes the previous projections and reflects projected bed need for CFV North and projected occupancy levels for the proposed 65 acute care beds at CFV North for the first three project years.

CFV North
Projected Acute Care Inpatient Days
October 2014 — September 2017

	FEY 2015	*FFY 2016*	*FFY 2017*
Total CFV North Projected Pt Days	*12,591*	*14,353*	*16,986*
ADC	*34.5*	*39.3*	*46.5*
Beds Needed at 66.7% Planning Target Occupancy Rate	*52*	*59*	*70*
Occupancy Rate with 65 Beds	*53.1%*	*60.5%*	*71.6%*

Source: Exhibit 33, Table 2

The previous table reflects projected acute care bed need based upon the 2011 State Medical Facilities Plan Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients, which results in a acute care bed need at CFV North of 70 acute care beds in PY 3. The proposed 65 acute care beds at CFV North are projected to achieve an occupancy level of 71.6% in PY 3.

Step 5. Project Acute Care Discharges

Acuity adjusted FFY 2010 CFVMC acute care inpatient discharge and inpatient day data specific to the CFV North Service Area were analyzed to determine an average length of stay of 4.65 days for the proposed CFV North. Actual data is included in Exhibit 33, Table 7.

As discussed above, ALOS has increased as a result of increased medical patients and the resulting lack of capacity for elective short stay surgical cases. CFVHS has hired a new Director of Care Management who is tasked with implementing programmatic efforts to address the increase in ALOS. As a result, ALOS for CFV North is projected to remain constant at 4.65 days per patient. Projected acute care inpatient days were divided by average length of stay to project acute care discharges for each of the three project years shown in the following table.

CFV North
Projected Acute Care Inpatient Discharges
October 2014 — September 2017

	FFY 2015	*FFY 2016*	*FFY 2017*
Total CFV North Projected Acute Care Inpatient Days	*12,591*	*14,353*	*16,986*
ALOS	*4.65*	*4.65*	*4.65*
Total CFV North Projected Discharges	*2,709*	*3,088*	*3,655*

Source: Exhibit 33, Table 2

The previous table reflects projected acute care discharges for the proposed facility. CFV North is projected to have 3,655 medical surgical discharges by the third year of operation."

The tables below illustrate historical acute care utilization and projected utilization at Owen Drive and Ramsey Street during the first three years following completion of the proposed satellite community hospital.

CFVMC (Owen Drive)
Acute Care Inpatient Days
October 2004 — September 2010

	FFY 2005	**FFY 2006**	**FFY 2007**	**FFY 2008**	**FFY 2009**	**FFY 2010**	**CAGR 2005-2010**
# of Operational Acute Care Beds	407	394	397	490	490	490	
Acute Care Days	132,678	134,128	136,755	145,017	149,828	155,926	3.3%
% Change in Patient Days		1.1%	2.0%	6.0%	3.3%	4.1%	

CFVHS
Projected Acute Care Days
Cumberland and Hoke Counties
October 2010 — September 2017

	FFY 2010 Historical Volume	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
# of Licensed Acute Care Beds	490	490	490	490	531	596	596	596
CFVMC (Owen Dr)	155,926	159,045	162,225	165,470	161,316	149,890	149,720	150,600
CFV North (Ramsey St)						12,591	14,353	16,986
Hoke Community Medical Center					7,463	9,674	11,524	11,524
Total Combined Projected Acute Care Inpatient Days	155,926	159,045	162,225	165,470	168,779	172,155	175,598	179,110
% Change in Patient Days	-na-	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
ADC	427.2	435.7	444.5	453.3	462.4	471.7	481.1	490.7
% Occupancy	87.2%	88.9%	90.7%	92.5%	87.1%	79.1%	80.7%	82.3%

As shown in the table above, occupancy of the existing acute care beds at Owen Drive was 87.2% during FFY 2010. Furthermore, as shown in the table above, acute care patient days increased at a Compound Annual Growth Rate (CAGR) of 3.3% between FFY 2005 and FFY 2010. The applicant projects acute care patient days will increase 2% per year through FFY 2017.

Projected utilization of the 65 acute care beds at CFV North is based on reasonable, credible and supported assumptions regarding historical and continued growth in acute care patient days. The applicant adequately demonstrated the need for 65 acute care beds at the proposed CFV North (Ramsey Street).

Intensive Care Unit Beds

The applicant proposes that 8 of the 65 acute care beds at CFV North be designated as intensive care unit (ICU) beds. In Section IV.1, page 157, the applicant provides projected utilization of the 8 ICU beds at CFV North in the first three years of operation, which is illustrated in the table below.

ICU Beds	PY 1: Oct 2014 – Sept 2015	PY 2: Oct 2015 – Sept 2016	PY 3: Oct 2016 – Sept 2017
# of Beds	8	8	8
# of Admissions	669	763	903
# of Patient Days	1,339	1,526	1,806

On page 117, the applicant describes its assumptions and methodology for projecting utilization of the proposed ICU beds as follows:

" Projected ICU Days and Bed Need

CFVHS reviewed historical ICU utilization for all hospitals in North Carolina reporting ICU utilization. That data is included in Exhibit 33, Table 19. ICU patient days as a percent of Total Acute Inpatient Patient Days (less neonatal days) for all North Carolina hospitals reporting ICU data had a mean value of 10.8% in FFY 2008. Acuity adjusted data specific to CFV North Service Area reflected a three year average ICU patient days as a percent of total patient days of 10.6%

Projected ICU beds were determined using total projected inpatient days at CFV North, and acuity adjusted ICU utilization data from the CFV North Service Area. That data is included in Exhibit 33, Table 4. The following table shows projected ICU patient days and the resulting ICU bed need for CFV North.

CFV North
Projected ICU Patient Days and Bed Need
October 2014 — September 2017

	FFY 2015	*FFY 2016*	*FFY 2017*
Total CFV North Projected Pt Days	*12,591*	*14,353*	*16,986*
Percent ICU	*10.6%*	*10.6%*	*10.6%*
Projected ICU Days	*1,339*	*1,526*	*1,806*

Based upon the ICU CON Criteria and Standards planning occupancy target of 60% for small ICUs, CFV North needs an 8-bed ICU unit in PY 3 (FFY 2017). The proposed 8-bed ICU unit is projected to achieve an occupancy level of 61.8% in PY 3 as reflected in Exhibit 33, Table 3."

In Exhibit 33, Table 4, the applicant provides the Acuity Adjusted Patient Days and the Acuity Adjusted ICU Days for the last three calendar years for patients admitted to CFVMC from the proposed service area for CFV North and determined the number of ICU days as a percentage of total days, as illustrated in the table below.

CFV North Zip Service Area- Historical Acuity Adjusted Volumes

	CY 2008	CY 2009	CY 2010	3 Year Average
Acuity Adjusted Patient Days	32,293	30,621	33,755	
Acuity Adjusted ICU Days	4,223	4,259	3,997	
Percent of Total Days	10.8%	11.4%	9.7%	10.6%

Source: Exhibit 33, Table 4.

The applicant then applied the historical 3 year average to the projected patient days for CFV North to project ICU days, average daily census ("ADC"), ICU bed need and projected utilization of the 8 ICU beds for the first three years of operation following project completion, as illustrated in the table below.

CFV North
Projected ICU Patient Days and Bed Need
October 2014 — September 2017

	FFY 2015	FFY 2016	FFY 2017
Total CFV North Projected Pt Days	12,591	14,353	16,986
Percent ICU	10.6%	10.6%	10.6%
Projected ICU Days	1,339	1,526	1,806
ADC	3.7	4.2	4.9
ICU Bed Need	6.1	7.0	8
Projected Utilization of 8 ICU beds	45.8%	52.3%	61.8%

Projected utilization of the 8 ICU beds at CFV North is based on reasonable, credible and supported assumptions regarding historical utilization at CFVMC by the population proposed to be served (acuity adjusted). The applicant adequately demonstrated the need to develop 8 ICU beds at CFV North.

Observation Beds

The applicant proposes to develop 7 observation beds (unlicensed) at CFV North. In Section IV.1, page 158, the applicant provides projected utilization of the observation beds at CFV North in the first three years of operation, which is illustrated in the table below.

Observation Beds	PY 1: Oct 2014 – Sept 2015	PY 2: Oct 2015 – Sept 2016	PY 3: Oct 2016 – Sept 2017
# of Beds (unlicensed)	7	7	7
# of Patients	1,211	1,380	1,633
Average Length of Stay	23 hours or less	23 hours or less	23 hours or less

On pages 117-118, the applicant describes the assumptions and methodology used to project utilization of the proposed observation beds as follows:

> "*Internal observation utilization at CFVMC is deflated due to the use of observation beds for inpatients who are admitted and waiting for an inpatient bed. Therefore, CFV North determined projected observation patient days based upon a review of historical utilization of designated observation units in North Carolina hospitals.*
>
> *Historical data is included in Exhibit 33, Table 6. That historical data shows*

that observation days average 1 observation day for every 10.4 inpatient days. The North Carolina hospitals with dedicated observation beds vary in size and utilization. Charles A. Cannon Memorial Hospital and Rowan Regional Medical Center, the facilities representing the median are community hospitals with ratios of 1 observation day to 10.3 inpatient days and 10.4 inpatient days respectively. As a result, CFV North believes the 10.4 average is a reasonable estimate to project future observation days. Furthermore, in 2008, prior to the current capacity issues being experienced at CFVMC, the use of observation services was higher than the state rate for the Hoke County and southwestern Cumberland County population. Based upon actual utilization data in 2008, the use of observation beds averaged 1 observation day for every 5.3 inpatient days. By the end of 2009 the rate averaged 1 observation day for every 5.8 inpatient days. This illustrates the significance of clinical observation services at CFVMC when beds are available. Therefore, the use of the statewide rate of 1 observation day to 10. 4 inpatient days to project future observation days for CFV North is reasonable in comparison. The following table shows projected observation bed need for CFV North.

CFV North
Projected Observation Patient Days and Bed Need
October 2014 — September 2017

	FFY 2015	*FFY 2016*	*FFY 2017*
Total CFV North Projected Pt Days	*12,591*	*14,353*	*16,986*
Ratio Observation Days: Total Days	*1:10.4*	*1:10.4*	*1:10.4*
Projected Observation Days	*1,211*	*1,380*	*1,633*
Observation ADC	*3.3*	*3.8*	*4.5*
Observation Bed Need @ 66.7%	*5*	*6*	*7*
Projected Target Utilization	*66.7%*	*66.7%*	*66.7%*

Source: Exhibit 33, Tables 2, 5, 6

The previous table reflects projected observation patient days and bed need based upon the 2011 State Medical Facilities Plan Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients, which results in a need for 7 observation beds at CFV North in PY 3."

Projected utilization of the seven observation beds (unlicensed) at CFV North is based on reasonable, credible and supported assumptions regarding ratios of observation days to acute care patient days in NC hospitals. The applicant adequately demonstrated the need for 7 observation beds at CFV North.

Operating Rooms

The applicant proposes to relocate two existing shared operating rooms to CFV North from Highsmith Rainey Specialty Hospital ("HRSH").

In Section IV.1, page 158, the applicant provides projected utilization of the two shared operating rooms at CFV North in the first three years of operation following completion of the proposed project, which is illustrated in the table below.

Surgical Suite	PY 1: Oct 2014 – Sept 2015	PY 2: Oct 2015 – Sept 2016	PY 3: Oct 2016 – Sept 2017
# of Shared ORs	2	2	2
# of IP Surgical Cases	347	393	462
# of OP Surgical Cases	1,157	1,332	1,592

In Section III.1, page 124, the applicant provides the following table:

CFV North
Projected Shared Inpatient/Ambulatory Operating Room Need
October 2013 — September 2016

	FFY 2015	*FFY 2015*	*FFY 2016*	*FFY 2016*	*FFY 2017*	*FFY 2017*
	In	*Out*	*In*	*Out*	*In*	*Out*
Projected Surgical Volume	*347*	*1,157*	*393*	*1,332*	*462*	*1,592*
Weighted Surgical Hours	*1,040*	*1,735*	*1,179*	*1,998*	*1,387*	*2,388*
Weighted Inpt + Outpt Surgical Hours	*2,775*		*3,177*		*3,775*	
ORs Needed at 1872 Surgical Hrs per OR	*1.5*		*1.7*		*2.0*	
Utilization of 2 ORs @ 2,340 hrs/OR	*59%*		*68%*		*81%*	

Source: Exhibit 33, Table 22

On pages 118-125, the applicant describes the assumptions and methodology used to project utilization of the two operating rooms at CFV North as follows:

> "*CFV North projected inpatient and outpatient surgical volume for the first three years of operation using the following methodology.*
>
> *Projected Inpatient Surgery = (CY2010 Acuity Adjusted Inpatient Surgical Utilization Held Constant) + In-migration*
>
> *Projected Outpatient Surgery = (Current Outpatient Surgical Utilization x Average of CAGR and Weighted Population Growth Rates) + In-migration*
>
> *Step 1. Determine Baseline Surgical Volume from CFV North Service Area*
>
> *a. Historical Surgical Utilization at CFVHS Surgical Facilities from Service Area*

The following table reflects the total acuity adjusted inpatient surgical volume and outpatient surgical volume by zip code provided at existing CFVHS surgical facilities, CFVMC and HRSH, to residents of the proposed service area from FFY 2008 through FFY 2010.

CFVHS
Zip Code Acuity Adjusted Inpatient and Outpatient Surgical Volumes
CFV North Service Area

Zip	County	CY 2008	CY 2008	CY 2009	CY 2099	CY 2010	CY 2010
		In	Out	In	Out	In	Out
Primary Service Area							
28301	*Cumberland*	*301*	*515*	*224*	*465*	*221*	*492*
28303	*Cumberland*	*322*	*675*	*197*	*625*	*216*	*753*
28311	*Cumberland*	*264*	*667*	*217*	*589*	*203*	*767*
28312	*Cumberland*	*183*	*403*	*135*	*356*	*137*	*424*
28344	*Cumberland/Sampson*	*14*	*19*	*12*	*26*	*7*	*27*
28356	*Cumberland*	*40*	*56*	*27*	*63*	*23*	*83*
28390	*Cumberland/Harnett*	*143*	*306*	*96*	*256*	*100*	*279*
28395	*Cumberland*	*42*	*69*	*18*	*60*	*20*	*58*
	Subtotal	*1,309*	*2,710*	*926*	*2,440*	*927*	*2,883*
Secondary Service Area							
28323	*Harnett*	*5*	*26*	*4*	*22*	*6*	*24*
28326	*Harnett*	*17*	*38*	*13*	*63*	*15*	*50*
	Subtotal	*22*	*64*	*17*	*85*	*21*	*74*
Combined Primary and Secondary Service Area							
Total		*1,331*	*2,774*	*943*	*2,525*	*948*	*2,957*
Growth Rates						*0.5%*	*17.1%*

Source: Exhibit 33, Table 23
Note: Inpatient excludes c-section volumes

As previously discussed, areas of zip codes 28301, 28303 and 28312 are closer to CFVMC. Therefore, total acuity adjusted inpatient surgical cases and outpatient surgical cases were adjusted to reflect geographic proximity to CFV North, and to determine total surgical cases performed in CY2010 at CFVHS surgical facilities for the CFV North Service Area as reflected in the following table.

CFVMC
Zip Code Acuity Adjusted Inpatient Surgery Cases and Outpatient Surgical Cases Geographically Closer to CFV North Service Area
January 2010 — December 2010

Zip	*County*	*In*	*Out*	*Percent of Zip Closer to CFV-North*	*Estimated 2010 Inpt Surgery Closer to CFV-North*	*Estimated 2010 Outpt Surgery Closer to CFV-North*
Primary Service Area						
28301	*Cumberland*	*221*	*492*	*70%*	*155*	*344*
28303	*Cumberland*	*216*	*753*	*5%*	*11*	*38*
28311	*Cumberland*	*203*	*767*	*100%*	*203*	*767*
28312	*Cumberland*	*137*	*424*	*40%*	*55*	*170*
28344	*Cumberland/Sampson*	*7*	*27*	*100%*	*7*	*27*
28356	*Cumberland*	*23*	*83*	*100%*	*23*	*83*
28390	*Cumberland/Harnett*	*100*	*279*	*100%*	*100*	*279*
28395	*Cumberland*	*20*	*58*	*100%*	*20*	*58*
Secondary Service Area						
28323	*Harnett*	*6*	*24*	*100%*	*6*	*24*
28326	*Harnett*	*15*	*50*	*100%*	*15*	*50*
Combined Primary and Secondary Service Area						
Total		*948*	*2,957*		*594*	*1,840*

Source: Exhibit 33, Table 23

As shown in the previous table, CFV North estimated that 594 acuity adjusted inpatient surgical cases and 1,840 outpatient surgical cases from the defined Service Area in CY 2010 were performed on residents of the zip code area geographically closer to the proposed location for the new CFV North community hospital.

b. Calculate Baseline CY 2010 Acuity Adjusted Inpatient and Outpatient Surgical Volume

While 100% of the acuity adjusted inpatient surgical cases and 100% of the outpatient cases reflected above are appropriate for care at CFV North, CFV North realizes that some patients will continue to choose to drive to CFVMC for surgical care. Therefore, for the purposes of projecting utilization, CFV North assumes that 70% of current CFVMC surgical patients will shift to CFV North.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from CFVMC to the new CFV North:

- *Current medical/surgical services at CFVMC are at capacity.*
- *Physician support for the project is overwhelming.*
- *Community support for the project is overwhelming (please see Exhibits 27 to 30).*
- *Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.*
- *High utilization of CFVMC emergency services.*
- *CFV North offers a choice for inpatient and outpatient care closer to home.*
- *The proposed location of CFV North on Hwy 401* [aka Ramsey Street] *will result in ease of access to the existing population in the defined zip code service area.*
- *Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to CFV North.*

Baseline CY 2010 surgical cases used to project future surgical volumes at CFV North are reflected in the following table.

CFV North
Baseline Acuity Adjusted Inpatient Surgery Cases and Outpatient Surgical Cases from Zip Code Service Area
January 2010 — December 2010

Zip	*County*	*Estimated 2010 Inpt Surgery Closer to CFV-North*	*Estimated 2010 Outpt Surgery Closer to CFV-North*	*Percent of 2010 Surgical Cases Shifted to CFV-North*	*Baseline 2010 Inpt Surg Shifted to CFV-North*	*Baseline 2010 Outpt Surg to CFV-North*
Primary Service Area						
28301	*Cumberland*	*155*	*344*			
28303	*Cumberland*	*11*	*38*			
28311	*Cumberland*	*203*	*767*			
28312	*Cumberland*	*55*	*170*			
28344	*Cumberland/Sampson*	*7*	*27*			
28356	*Cumberland*	*23*	*83*			
28390	*Cumberland/Harnett*	*100*	*279*			
28395	*Cumberland*	*20*	*58*			
Secondary Service Area						
28323	*Harnett*	*6*	*24*			
28326	*Harnett*	*15*	*50*			
Combined Primary and Secondary Service Area						
Total		*594*	*1,840*	*70%*	*416*	*1,288*

Source: Exhibit 33, Table 23

Step 2. Determine Inpatient and Outpatient Surgical Growth Rates

CFV North reviewed the growth in surgical utilization and population from the defined service area to determine the most reasonable growth rate to use for projecting inpatient and outpatient surgical volume for CFV North.

CFV North Service Area
Combined Primary and Secondary Zip Service Areas – Growth Rate Variables
January 2008 – December 2010

Growth Variables	CY 2008	CY 2009	CY 2010	CAGR 2008-2010
Inpatient Surgery	1,331	943	948	
% Change		-29.2%	0.5%	-15.6%
Outpatient Surgery	2,774	2,525	2,957	
% Change		-9.0%	17.1%	3.2%
Weighted Population Growth Rate – 2010				-0.1%
Inpt Surgical Growth Rate				0.0%
Outpt Surgical Growth Rate Average of CAGR and Population Growth Rate				1.6%

Source: CFVHS DSS Data System; Exhibit 33, Table 7 AGR=Annual Growth Rate

As reflected in the previous table, acuity adjusted inpatient surgical cases from the defined Service Area dropped significantly from FFY 2008 to FFY 2009. However, inpatient surgical volumes recovered slightly from FFY 2009 to FFY 2010. Outpatient surgical volumes also decreased from FFY 2008 to FY 2009 but recovered in FFY 2010 resulting in a positive 3.2% CAGR.

Population growth for some of the zip codes in the CFV North Service Area is negative or just shy of 1%, resulting in a weighted population growth rate for the Service Area of -0.1% as reflected in the previous table.

Total inpatient and outpatient surgical data is not available to calculate surgical use rates for the combined zip code Service Area. CFV North reviewed county and regional surgical use rates, reflected in the following table, to determine trends in surgical utilization in the proposed market.

CFVHS Service Area
Surgical Use Rates
October 2007 — September 2010

	2008	2009	2010
Cumberland County			
Inpatient Surgical Use Rate per 1000 Population	*25.6*	*25.2*	*25.0*
Outpatient Surgical Use Rate per 1000 Population	*69.6*	*54.7*	*57.7*
Harnett County			
Inpatient Surgical Use Rate per 1000 Population	*27.2*	*27.3*	*25.8*
Outpatient Surgical Use Rate per 1000 Population	*56.6*	*53.0*	*50.3*
Total CFVHS Six County Service Area			
Inpatient Surgical Use Rate per 1000 Population	*27.64*	*27.41*	*27.87*
Outpatient Surgical Use Rate per 1000 Population	*65.17*	*55.73*	*57.48*

Source. Exhibit 33, Table 25

As reflected in the previous table, Cumberland County inpatient surgical use rates and outpatient use rates decreased from FFY 2008 to FFY 2009 and outpatient surgical use rates increased in FFY 2010. Overall for the six county CFVHS Service Area, inpatient surgical use rates have increased from FFY 2008 to FFY 2009 and outpatient use rates dipped from FFY 2008 to FFY 2009 and increased in FFY 2010. Harnett County surgical use rates have decreased during this timeframe.

To project future surgical utilization CFV North decided to hold current inpatient volumes constant even though the most current utilization data from FFY 2009 to FFY 2010 showed positive growth. To project future outpatient surgical volume CFV North decided to be conservative and not use the FFY 2008 to FFY 2010 CAGR of 3.2% reflected above. Outpatient surgical volume was projected using the 1.6% average in the above table, which is the average of the outpatient CAGR and the weighted population growth rate.

Step 3. Project Surgical Cases for CFV North

CFV North projected surgical cases are reflected in the following table. Projected inmigration and total surgical cases also are included.

Surgical Projections for CFV North
January 2013 through December 2017

	2014	2014	2015	2015	2016	2016	2017	2017
	In	Out	In	Out	In	Out	In	Out
Projected PSA and SSA Surgical Volume	416	1,372	416	1,394	416	1,416	416	1,438
Immigration (10%)	46	152	46	155	46	157	46	160
Projected Surgical Volume	462	1,524	462	1,549	462	1,573	462	1,598
Converted to Project Years			FY 2015	FY 2015	FY 2016	FY 2016	FY 2017	FY 2017
			In	Out	In	Out	In	Out
Ramp Up Utilization			75%	75%	85%	85%	100%	100%
Projected Surgical Volume			347	1,157	393	1,332	462	1,592

Source, Exhibit 33, Table 22
Calculation example: FFY 2015 = 25% x CY2014 + 75% x CY2015

Total projected surgical cases reflected in the previous table for January 2013 to December 2017 were calculated using the baseline surgical volumes determined in Step 1. and the growth rate determined in Step 2. The resulting calendar year projections were converted to FFY years in the previous table.

Step 4. Project Shared Operating Room Need for CFV North

Projected inpatient and outpatient surgical cases were used to project shared operating rooms needed at CFV North using the case weighting and operating room capacity assumptions used in the State Medical Facilities Plan Operating Room Need Methodology. The following table reflects the operating rooms needed at CFV North.

CFV North
Projected Shared Inpatient/Ambulatory Operating Room Need
October 2013 — September 2016

	FFY 2015	FFY 2015	FFY 2016	FFY 2016	FFY 2017	FFY 2017
	In	Out	In	Out	In	Out
Projected Surgical Volume	347	1,157	393	1,332	462	1,592
Weighted Surgical Hours	1,040	1,735	1,179	1,998	1,387	2,388
Weighted Inpt + Outpt Surgical Hours	2,775		3,177		3,775	
ORs Needed at 1872 Surgical Hrs per OR	1.5		1.7		2.0	
Utilization of 2 ORs @ 2,340 hrs/OR	59%		68%		81%	

Source: Exhibit 33, Table 22

The previous table shows projected inpatient and outpatient surgical cases and the resulting shared operating rooms needed based upon the State Medical Facilities Plan Operating Room Need Methodology, inpatient surgical case weighting of 3.0 hours per case, outpatient surgical case weighting of 1,5 hours per case, and a planning target of 1,872 operating hours per year which results in a need at CFV North for two shared surgical operating rooms in Project Year 3. The previous table shows projected surgery volume sufficient to support 2.0 operating rooms or a need for two shared operating rooms at CFV North."

As indicated in the above table, the applicant projects it will perform 1,592 outpatient surgical cases and 462 inpatient surgical cases in the two shared operating rooms to be developed at CFV North in the third year of the proposed project (FFY 2017). Based on the performance standards promulgated in 10A NCAC 14C .2103 (b)(1), the applicant demonstrates a need for two operating rooms [1,592 x 1.5 hours) + (462 x 3.0 hours) = 3,775 hours; 3,775 hours / 1,872 hours = 2.02 operating rooms] at CFV North.

The tables below illustrate the historical, interim and projected utilization of operating rooms at all locations in the CFVHS.

CFVMC Historical Surgical Utilization
October 2008 — September 2010

CFVMC	FFY 2008	FFY 2009	FFY 2010	2008-2010 CAGR
Inpatient Cases (excluding C-Section and Open Heart)	6,199	6,239	6,243	0.35%
Outpatient Cases	6,210	5,804	6,606	3.14%
HRSH	**FFY 2008**	**FFY 2009**	**FFY 2010**	**2008-2010 CAGR**
Inpatient Cases (excluding C-Section and Open Heart)	156	72	66	-34.96%
Outpatient Cases	2,844	2,511	2,768	-1.35%
Combined	**FFY 2008**	**FFY 2009**	**FFY 2010**	**2008-2010 CAGR**
Inpatient Cases (excluding C-Section and Open Heart)	6,355	6,311	6,309	-0.36%
Outpatient Cases	9,054	8,315	9,374	1.75%
Weighted Surgical Hours (Inpt x 3.0 hrs per case + Outpatient x 1.5 hrs per case)	32,646	31,406	32,988	
ORs Needed at 1,872 hours per OR per year	17.4	16.8	17.6	
Total Capacity 17 Shared ORs = (17 x 2,340 Hours per OR)	39,780	39,780	39,780	
Utilization of 17 Shared ORs	82.1%	78.9%	82.9%	
Total Cases – Inpatient and Outpatient	15,409	14,626	15,683	
Percent Increase Year to Year	-na-	-5.1%	7.2%	

Source: Section III, page 100.
* Includes surgical volume for 17 existing ORs at CFVMC and HRSH in Cumberland County; One additional C-Section OR has been approved for HCMC in Hoke County; Excludes open heart and C-Section operating rooms and volumes.

In Section III.1(b), page 99, the applicant addressed the decrease in total surgical cases in FFY 2009 as follows:

> *"As previously discussed, surgical cases at CFVHS health service facilities increased slightly from FFY 2005 to FFY 2007. Due to the departure of two surgeons in 2007 and the economic downturn in 2008, FFY 2009 surgical utilization decreased slightly. Total surgical volume for FFY 2010, reflects a slight decrease in inpatient surgical cases with 6,309 inpatient surgical cases (excluding C-Section and open heart volumes) and considerable growth in outpatient surgery with 9,374 outpatient surgical cases."*

CFVHS
Projected Surgical Volumes
Cumberland and Hoke Counties
October 2010 — September 2017

Inpatient Surgical Cases	FFY 2010— Historical Volume	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
CFVMC Inpatient Surgical Cases	6,243	6,265	6,287	6,310	6,108	5,731	5,653	5,606
CFV North Inpatient Surgical Cases						347	393	462
HCMC Inpatient Surgical Cases					224	277	331	331
HRSH Inpatient Surgical Cases	66	66	66	66	66	66	66	66
Total Inpatient Surgical Cases	6,309	6,331	6,353	6,376	6,398	6,420	6,443	6,465
Outpatient Surgical Cases	**FFY2010 - Historical Volume**	**FFY 2011**	**FFY 2012**	**FFY 2013**	**FFY 2014**	**FFY 2015**	**FFY 2016**	**FFY 2017**
CFVMC Outpatient Surgical Cases	6,606	6,701	6,797	6,894	6,619	5,859	5,734	5,663
CFV North Surgical Cases						1,157	1,332	1,592
HCMC Outpatient Surgical Cases					834	1,028	1,227	1,227
HRSH Outpatient Surgical Cases	2,768	2,768	2,768	2,768	2,308	1,817	1,668	1,582
Total Outpatient Surgical Cases	9,374	9,469	9,565	9,662	9,761	9,861	9,961	10,065
Weighted Surgical Hours	32,988	33,196	33,407	33,620	33,835	34,052	34,271	34,493
ORs Needed at 1872 Hours per OR	17.6	17.7	17.8	18.0	18.1	18.2	18.3	18.4
Current Operational and CON Approved Inventory	18	18	18	18	18	18	18	18
OR Surplus (-) / OR Need(+)	-0.4	-0.3	-0.2	0.0	0.1	0.2	0.3	0.4
Total Cases – Inpatient and Outpatient	15,683	15,800	15,918	16,038	16,159	16,281	16,404	16,530
Percent Increase Year to Year	-na-	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%

Source: Section III, page 102.
Numbers may not foot due to rounding.

As shown in the table above, the applicant projects total surgical cases performed at all CFVHS facilities (CFVMC, HRSH and HCMC) will increase from 15,583 in FFY 2010 to 16,530 in FFY 2017 in the third year following completion of the proposed project, or by 5.4% over a 7-year period.

Projected utilization of operating rooms in the CFVHS is based on reasonable, credible and supported assumptions regarding historical and continuous growth and the number of cases expected to shift from the Owen campus or HRSH to CFV North. Exhibit 26 of the application contains letters from physicians expressing support for the proposed project. The applicant adequately demonstrated the need for the two shared operating rooms at CFV North.

Emergency Department

The applicant proposes to develop an emergency department with 20 treatment bays at CFV North. In Section III.1(b), pages 129-134, the applicant describes the assumptions and methodology used to project utilization of the proposed emergency department at CFV North as follows:

" *The proposed CFV North will be a community hospital which will provide emergency services. CFV North projected emergency visits for the first three years of operation using the following methodology.*

Projected Emergency Visits = (Current Emergency Visits x Annual Growth Rate) + In-migration

Step 1. Determine Baseline Emergency Visits from CFV North Zip Code Service Area

To determine total emergency visits at CFV North, zip code level data from CFVMC emergency department was analyzed.

a. Historical Emergency Utilization from CFV North Service Area

The following table reflects the total emergency visit volume by zip code provided at CFVMC to residents of the proposed service area from FFY 2008 through FFY 2010.

CFVMC
Emergency Visits
CFV North Service Area

Zip	*County*	*CY 2008*	*CY 2009*	*CY 2010*
Primary Service Area				
28301	*Cumberland*	*10,016*	*9,467*	*8,739*
28303	*Cumberland*	*8,650*	*8,315*	*8,559*
28311	*Cumberland*	*7,341*	*7,371*	*7,344*
28312	*Cumberland*	*4,453*	*5,016*	*4,765*
28344	*Cumberland/Sampson*	*209*	*190*	*170*
28356	*Cumberland*	*574*	*572*	*643*
28390	*Cumberland/Harnett*	*4,816*	*4,373*	*4,092*
28395	*Cumberland*	*554*	*476*	*449*
Secondary Service Area				
28323	*Harnett*	*174*	*189*	*221*
28326	*Harnett*	*429*	*593*	*670*
Combined Primary and Secondary Service Area				
Total		*37,216*	*36,562*	*35,652*

Source: Exhibit 33, Table 28

Note: Emergency data reflected above does not include the HPN urgent care volumes or patients that 'leave without being seen' (LWBS), both of which should be included to determine future utilization; LWBS data is not available by zip code

As previously discussed, areas of zip codes 28301, 28303 and 28312 are closer to CFVMC. Therefore, total emergency visits were adjusted to reflect geographic proximity to CFV North as shown in the following table.

Zip	County	CY 2010	Percent of Zip Closer to CFV-North	Estimated 2010 Outpt Volume Closer to CFV-North
Primary Service Area				
28301	Cumberland	8,739	70%	6,117
28303	Cumberland	8,559	5%	428
28311	Cumberland	7,344	100%	7,344
28312	Cumberland	4,765	40%	1,906
28344	Cumberland/Sampson	170	100%	170
28356	Cumberland	643	100%	643
28390	Cumberland/Harnett	4,092	100%	4,092
28395	Cumberland	449	100%	449
Secondary Service Area				
28323	Harnett	221	100%	221
28326	Harnett	670	100%	670
Combined Primary and Secondary Service Area				
Total		35,652		22,040

Source: Exhibit 33, Table 28
Note: Emergency data reflected above does not include the HPN urgent care volumes or patients that 'leave without being seen' (LWBS), both of which should be included to determine future utilization; LWBS data is not available by zip code

As shown in the previous table, CFV North estimated that 22,040 emergency visits from the defined Service Area in CV 2010 were geographically closer to the proposed location for the new CFV North community hospital.

b. Calculate Baseline CY2010 Emergency Visits

While almost 100% of the emergency visits reflected above are appropriate for care at CFV North, CFV North realizes that some trauma and Level III patients will be taken directly to CFVMC and some patients will continue to choose to drive to CFVMC for emergency care, Therefore, for the purposes of projecting utilization, CFV North assumes that 85% of current emergency volume will shift to CFV North. A higher volume was shifted for emergency visits since HPN, an existing outpatient center providing urgent care services, currently is located at the proposed site with an established presence in the market. In addition, emergency services by definition are an emergency such that patients are seeking appropriate care rapidly and are not specific to physician. This takes physician choice out of the equation when seeking emergency services, resulting in the greater potential those residents of the CFV North Service Area will seek emergency services closer to home at the new CFV North Emergency Department.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from CFVMC to the new CFV North:

- *HPN is an active, busy urgent care center located at the proposed location.*
- *CFVMC emergency department is operating at capacity.*
- *Current medical/surgical services at CFVMC are at capacity.*
- *Physician support for the project is overwhelming.*
- *Community support for the project is overwhelming (please see Exhibits 27 to 29).*
- *Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.*
- *CFV North offers a choice for inpatient and outpatient care closer to home.*
- *The proposed location of CFV North on Hwy 401* [aka Ramsey Street] *will result in ease of access to the existing population in the defined zip code service area.*
- *Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for emergency services in the service area will not shift to CFV North.*

Baseline CY 2010 emergency visits calculated below were used to project future emergency volumes at CFV North.

CFV North
Baseline Emergency Visits Cases [sic] *from Zip Code Service Area*
January 2010 — December 2010

Zip	*County*	*Estimated 2010 Outpt Volume Closer to CFV-North*	*Percent of 2010 ED Volume Shifted to CFV-North*	*Baseline 2010 ED Visits Shifted to CFV-North*
Primary Service Area				
28301	*Cumberland*	*6,117*		
28303	*Cumberland*	*428*		
28311	*Cumberland*	*7,344*		
28312	*Cumberland*	*1,906*		
28344	*Cumberland/Sampson*	*170*		
28356	*Cumberland*	*643*		
28390	*Cumberland/Harnett*	*4,092*		
28395	*Cumberland*	*449*		
Secondary Service Area				
28323	*Harnett*	*221*		
28326	*Harnett*	*670*		
Combined Primary and Secondary Service Area				
Total		*22,040*	*85%*	*18,734*

Source: Exhibit 33, Table 28

Step 2. Determine Emergency Visit Growth Rate

CFV North reviewed the growth in emergency utilization and population from the defined service area and growth in emergency visits at CFVMC to determine the most reasonable growth rate to use for projecting future emergency visits for CFV North.

CFV North Service Area
Combined Primary and Secondary Zip Service Areas Growth Rate Variables
January 2008 December 2010

		CY 2008	*CY 2009*	*CY 2010*	*CAGR 2008-2010*
*CFV North SA Emergency Visits**		*37,216*	*36,562*	*35,652*	
% Change			*-1.8%*	*-2.5%*	*-2.1%*
	FFY 2007	*FFY 2008*	*FFY 2009*	*FFY 2010*	*CAGR 2007 – 2010*
CFVMC Emergency Visits	*99,075*	*116,433*	*118,290*	*122,828*	
% Change		*17.5%*	*1.6%*	*3.8%*	*7.1%*

Source: CFVHS DSS Data System; Exhibit 33, Table 28,30
**Does not include HPN volumes or the LWBS patient volume for the defined Service Area*

As reflected in the previous table, emergency visits from the CFV North Service Areas have decreased since CY 2008. However, these volumes do not include the HPN urgent care volume or patients that sought care at CFVMC and left without being seen. As utilization has increased at the CFVMC emergency room the LWBS rate has also increased as patients become frustrated with having to wait. Both variables would impact the growth of emergency volumes for this population. CFVMC emergency volumes have increased annually since FFY 2007 resulting in a positive 7.1% CAGR. In addition, as discussed in response to Section III.1.a. emergency room utilization at CFVMC has increased an additional 7% in 2011. CFV North took into consideration all these variables and utilized the same emergency services growth rate previously used to project future CFVMC ED visits to project future emergency room utilization. For purposes of this analysis CFV North averaged the annual CFVMC growth in emergency room visits, excluding the high and low year growth rates, over the last four years reflected in the previous table. The resulting 5.0% growth rate was used to project future emergency visits at CFV North.

Step 3. Project Emergency Visits Cases [sic] *for CFV North,*

CFV North projected emergency visits are reflected in the following table. Projected in-migration and total surgical [sic] *cases also are included.*

Emergency Visits Projections for CFV North
January 2014 through December 2017

	CY 2014	CY 2015	CY 2016	CY 2017
CFV North PSA and SSA Emergency Visits	22,762	23,897	25,089	26,341
In-migration	2,529	2,655	2,788	2,927
Projected CFV North Emergency Visits	25,291	26,552	27,877	29,268
Convert to Project Years		FFY 2015	FFY 2016	FFY 2017
Ramp Up Utilization		75%	85%	100%
Projected CFV North Emergency Visits		19,678	23,414	28,920

Source. Exhibit 33, Table 31
Calculation example. FFY 2015 = 25% x CY 2014 + 75% x CY 2015

Total projected emergency visits, reflected [sic] *the previous table for January 2013 to December 2017, were calculated using the baseline surgical volumes determined in Step 1. And the growth rate determined in Step 2. The resulting calendar year projections were converted to FFY years in the*

previous table.

The previous table reflects projected emergency visits for CFV North based upon historical volumes and historical growth rates.

Step 4. Project Emergency Treatment Rooms Needed for CFV North

CFV North utilized projections from Step 3. to determine the number of emergency treatment rooms needed at the new community hospital using a combination of the ACEP estimated emergency visits per room and the AIA estimated emergency visits per room as reflected in the following table.

CFV North Emergency Treatment Rooms
October 2014 through September 2017

	FFY 2015	*FFY 2016*	*FFY 2017*
Projected CFV North ED Volume	*19,678*	*23,414*	*28,920*
ED Treatment Spaces (1,330 Visits per Space) ACEP	*14.8*	*17.6*	*21.7*
ED Treatment Spaces (1,500 Visits per Space) AIA	*13.1*	*15.6*	*19.3*
Avg of Two Standards			*20*

Source: Exhibit 33, Table 27

As reflected in the previous table, projected emergency volume at CFV North results in a need for 20 emergency treatment spaces."

Projected utilization of the emergency department at CFV North is based on reasonable, credible and supported assumptions regarding utilization of CFVHS's existing emergency services by residents of the proposed service area, the percentage of CFVMC patients in the proposed service area that will choose to seek emergency services at CFV North rather than CFVMC's existing Fayetteville facility. Therefore, the applicant adequately demonstrated the need for the proposed Emergency Department at CFV North.

Ancillary Services

The applicant proposes to offer several ancillary services at CFV North. In Section III.1(b), pages 134-135, the applicant describes the assumptions and methodology used to project utilization of the proposed ancillary services at CFV North as follows:

> *"As previously discussed, CFV North will be a community hospital with a full range of inpatient and outpatient services. Equipment planning for the proposed CFV North was completed by CFVMC's internal management staff. CFV North will have a comprehensive array of diagnostic equipment as reflected in Section II.1.*

Ancillary utilization projections were calculated based upon actual ancillary utilization patterns for the defined service area reflected in Exhibit 33, Table 37. Admissions, outpatient visits, and emergency visits at CFVHS facilities were analyzed to determine the actual volume of ancillary services utilized. CFV North assumes that projected ancillary utilization at CFV North will imitate current ancillary utilization patterns determined from CFVMC and HPN.

Relevant data was acquired from internal hospital systems for FFY 2008 through FFY 2010 and a three-year average was determined. Inpatient ancillary volumes for CFV North were projected using the three-year average percent of total inpatient discharges. Outpatient ancillary volumes were projected using the three-year average percent of total outpatient and ED visits as shown in the following table. Historical data and relevant percentages used to project future ancillary volume are included in Exhibit 33, Table 37. Data was analyzed to determine the relationship between ancillary volumes and inpatient, outpatient, and ED volumes. The following table reflects projected ancillary utilization for CFV North.

CFV North
Projected Ancillary Service Utilization
October 2014 – September 2017

	PY 1 Oct 2014 – Sep 2015	*PY 2 Oct 2015 – Sep 2016*	*PY 3 Oct 2016 – Sep 2017*
MRI (mobile)	*1,276*	*1,488*	*1,803*
CT	*6,363*	*7,428*	*9,005*
Ultrasound	*3,492*	*4,077*	*4,943*
Xray	*13,871*	*16,151*	*19,528*
Other Radiology	*3,449*	*4,028*	*4,884*
Pharmacy Units	*1,237,118*	*1,423,778*	*1,701,425*
Lab Units	*324,657*	*375,012*	*449,810*
Speech Therapy	*1,777*	*2,059*	*2,476*
Respiratory Therapy	*30,988*	*35,447*	*42,097*
Physical Therapy	*18,951*	*22,126*	*26,826*
Occupational Therapy	*2,449*	*2,854*	*3,454*

Source: Exhibit 33, Table 35, 36

The previous table reflects projected ancillary services utilization at CFV North in the defined service area for the first three years of the proposed project. These services are routine services provided at a community hospital and will be needed to meet the current standards of care required for inpatients, outpatient and emergency patients seeking care at CFV North."

Projected utilization for all of the proposed ancillary services is based on

reasonable, credible and supported assumptions regarding historical use rates at CFVMC, projected population growth in the proposed service area and historical ratios of ancillary volumes to inpatient, outpatient, and ED volumes for CFVMC patients residing in the proposed service area.

In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the proposed services. Therefore, the application is conforming to this criterion.

FHCH. FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital ("FirstHealth") proposes to construct a new, separately licensed, four story acute care hospital in Hoke County on US Highway 401 in Raeford with 65 acute care beds, two operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services. The name of the proposed hospital is FirstHealth Hoke Community Hospital ("FHCH"). FirstHealth is a 297-bed acute care hospital located in Pinehurst in Moore County. In this application, FHCH proposes relocating two existing operating rooms from FMRH to FHCH. According to the 2011 SMFP (p. 70), Hoke County and Moore County belong to the same multi-county operating room service area.

The project and the service components are described in detail in Section II.1, pages 34-59. In Exhibit O, the applicant provides an itemized list of all medical equipment. The proposed capital cost of the project is $81,397,816.

On September 27, 2010, the applicant was conditionally approved to develop an 8-bed acute care hospital in Raeford (Project ID # N-8497-10). That decision is currently under appeal. In Section I, page 8, FHCH states

> *"FirstHealth of the Carolinas is not abandoning its previously-approved FirstHealth Hoke Community Hospital CON application, Project ID #N-8497-10. FirstHealth of the Carolinas also does not intent to build two hospitals in Hoke County. If the Agency approves FirstHealth's 2011 CON application for a Hoke County hospital, FirstHealth will relinquish the approved 2010 CON, Project ID # N-8497-10."*

POPULATION TO BE SERVED

In Section III.5(c), page 169, the applicant provides projected patient origin for the services to be provided at FHCH during each of the first two operating years, as illustrated in the following table.

Inpatient Services

County	2016	2017
Hoke	61.1%	60.8%
Cumberland	26.1%	28.1%
Robeson	8.1%	7.1%
Scotland	4.7%	4.1%
Total	100.0%	100.0%

Totals may not foot due to rounding

Emergency Department Services

County	2016	2017
Hoke	66.8%	67.1%
Cumberland	13.6%	15.2%
Robeson	12.4%	11.2%
Scotland	7.2%	6.4%
Total	100.0%	100.0%

Totals may not foot due to rounding

In Section III.5(a), page 168, the applicant states

> *"The service area is Hoke, Cumberland, Robeson, and Scotland counties. However, it is important to note that the proposed facility will serve any clinically appropriate patient regardless of their place of resident* [sic]."

In Section III.5(d), page 169, the applicant states "*FirstHealth expects its patient origin to be based on the need methodology and assumptions identified in Section IV. FHCH may have patients from outside the service area receive care at FHCH, but the numbers will be insignificant to the financial feasibility of the project.*"

The applicant adequately identified the population it proposes to serve. However, see following discussion regarding the reasonableness of its assumptions which impact projected utilization.

NEED FOR THE PROPOSED SERVICES

Project Components

In Section II.1(a), pages 34-59, the applicant describes the project components as follows:

> *"FirstHealth proposes to construct the first acute care hospital in Hoke County. FirstHealth will accomplish the development of the new hospital through the following:*
>
> - *Developing twelve (12) emergency treatment rooms*
> - *Developing sixty-five (65) acute care beds (pursuant to the*

acute care bed need determination on page 59 of the 2011 SMFP)

- *Fifty-four (54) Medical/Surgical Beds*
  - *Forty-eight (48) General Medical/Surgical Beds*
  - *Four (4) Pediatric Beds*
  - *Two (2) Gynecology Beds*
- *Eight (8) Intensive Care Beds*
- *Three (3) LDRP Beds*

- *Relocating two (2) operating rooms from FMRH to FHCH*
- *Acquiring one (1) fixed general radiography unit*
- *Acquiring one (1) fixed fluoroscopy unit*
- *Acquiring one (1) CT scanner*
- *Acquiring one (1) mammography unit*
- *Acquiring one (1) ultrasound unit*
- *Acquiring one (1) nuclear medicine system*
- *Acquiring one (1) mobile fluoroscopic c-arm*
- *Acquiring one (1) mobile general radiography unit*
- *Providing mobile MRI scanner services*
- *Providing routine and stat laboratory services*
- *Providing IP physical and respiratory therapies*
- *Providing pharmaceutical services*
- *Providing ancillary services, as required by licensure requirements*
- *Hospitalist services*

...

The key components of FHCH include:

- *Emergency Services*

Emergency services will be available 24 hours per day/7 days per week and staffed by board-certified, emergency care physicians the same physicians that provide care at FMRH. The Emergency Department will be designed with twelve (12) treatment rooms, including a fully-equipped resuscitation/trauma room....

- *Inpatient Acute Care Services*

Sixty-five (65) acute care beds will be developed to meet the needs of Hoke County and surrounding counties as identified in the CON application.

The acute care beds will be developed as follows:

- *Forty-eight (48) private, acute care beds will be utilized for general medical and surgical patients.*
- *Four (4) private, acute care beds will be utilized for pediatric medical and surgical patients.*
- *Two (2) private, acute care beds will be utilized for gynecology medical and surgical patients.*
- *Eight (8) private, acute care beds will be utilized for intensive care patients.*
- *Three (3) private, acute care beds will be utilized for labor/delivery/recovery/post-partum (LDRP) patients.*

...

- *Surgical Services*

Surgical services will be available through two (2) operating rooms equipped for the surgical cases expected to be performed by the surgeons on the medical staff. The operating rooms will be relocated from Moore Regional Hospital in Moore County. Moore County and Hoke County are part of a multi-county operating room service area pursuant to page 70 of the 2011 SMFP. Surgical services will be designed to accommodate inpatient and outpatient surgical cases from several specialties, but not limited to general surgery, ophthalmology, orthopedics, otolaryngology, vascular, neurosurgery, and dentistry/oral surgery. Pre- and post-operative anesthesia care will occur in (7) pre-op/post-op rooms that are equipped for preparing patients for surgery and recovering patients from general anesthesia, as well as 4 recovery bay spaces for recovering patients from conscious sedation.. Anesthesiologists and certified nurse anesthetists will provide anesthesia services, including general, regional and local blocks. Central sterile supply, as well as a sub-sterile room will be located within Surgical Services. A mobile c-arm fluoroscope will be available to surgical patients from the Radiology Department.

...

- *Diagnostic Services*

The Radiology Department, including general radiography, ultrasound, and CT scanning, as well as diagnostic testing, including cardiopulmonary and neurology testing will be provided 24 hours per day/7 days per week, with outpatient diagnostic testing, primarily fluoroscopy and mammography, scheduled Monday-Friday from 9:00AM — 5:00PM. A mobile general radiography unit will be available for inpatients and to Emergency Department patients. Mobile MRI services will be available two (2) days per week.

...

Routine and urgent laboratory services will be available on-site to support the diagnosis and treatment of disease. Tests such as general chemistry, limited toxicology and therapeutic drug monitoring, hematology, limited coagulation, transfusion service, limited microbiology and serology, urinalysis and blood gas studies will be provided 24 hours per day/7 days per week. A services arrangement will be established with FMRH to perform tests not available on-site. Body storage will be provided in a dedicated room in the Material Management area....

- *Other Clinical Services*

Inpatient Physical Therapy services will be available on-site Monday-Friday from 9:00AM - 5:00PM. Patients in the inpatient settings will have access to physical therapy services based on the patient's need.

Routine and emergency respiratory therapy services will be available for inpatients, outpatients, and emergency patients. Respiratory services for inpatients, outpatients, and emergency patients will be available 24 hours per day/7 days per week. Services include inhalation therapies, pulmonary function studies, airway management, oxygen therapy, and wellness education. Respiratory therapy will also provide support for obtaining cardiopulmonary and neurology testing, and arterial blood gas tests in either the Cardio/Pulmonary area or at the patient's bedside.

Pharmacy Services - A registered Pharmacist will be available on-site to provide services Monday-Friday from 8:00AM — 3:00PM and Saturday-Sunday from 8:00AM — 1:00PM. An on-call system will be maintained to assure 24-hour access to these services. Automated medication dispensing units (e.g., Omni cell) will be used to provide accurate and timely drug dispensing for the patient care areas...

- *Clinical Staff*

Attending physicians will supervise all patient care, including completing initial assessments, monitoring changes in the patient's medical status, providing consultation or treatment, prescribing new therapy as needed, ordering patient's transfer to another level of care when necessary, and conducting routine visits or delegating and supervising follow-up visits by physician assistants and/or nurse practitioners. FHCH will utilize the services of hospitalists to expedite the admission of patients who do not have an admitting physician and to assist the attending physicians during the course of inpatient treatment...

Registered nurses and certified nursing assistants will provide 24-hour nursing care to patients in FHCH. The nursing staff, in collaboration with the ancillary and support staff will be responsible for carrying out the specific plan of care for patients. The patient care areas will use an interdisciplinary team approach to develop and implement the patient's care. Nursing services will provide direct care to patients utilizing current standards of care.

- *Ancillary Services*

The following ancillary services will also be available at FHCH:

Administrative Services - On-site staff will manage payroll, time and attendance, licensure/certification, and staff scheduling.

Business office, admitting and registration - Services will be provided on-site, including: receptionist, switchboard, cashier functions, and data processing. Clinical staff will be cross-trained to provide admitting/registration services for ED and inpatient admissions. Billing, accounts payable, general accounting and collection functions will be provided by a services arrangement with FMRH.

Dietary Services - Meal preparation will occur at FHCH by cooks and dietary assistants, who will also make nutritious meal options available for staff and patient family members. Dietary consultation for special diets and nutritional assessments will be provided by a dietitian.

Housekeeping - Housekeeping staff will be responsible for daily and discharge room cleaning, maintaining linen inventory at reasonable levels, and providing cleaning services for all public areas and offices.

Information Management – First Health's approach with technology in the FHCH will be patient-centered. The goal is to ensure all clinicians can provide care, documentation and monitoring from the bedside. Medication administration, phlebotomy services and alerting capabilities will be a component of the technology to further promote safety and patient-centered care.

From home or other setting a comprehensive web site will enable patients to find physicians, request certain appointments, communicate with clinicians, and pay a bill. If a visit is required, the use of mobile registration tools and electronic signatures will allow the registration process to occur at patient locations across the facility. When an admission is required, each patient room and all clinical areas will have computers allowing full access to all data for all caregivers, including digital (PACS) images, the electronic chart and laboratory data.

Diagnostic and clinical areas of the FHCH will provide state-of-the-art solution for the management of cardiac patients including cardiology imaging and interventional capabilities. Other diagnostic services planned include imaging modalities such as x-ray, nuclear medicine, CT, ultrasound, and angiography which will provide digital images that can be viewed by the caregiver at any computer.

Medical Records - Services such as transcription, coding and abstracting, assembling, and processing charts and credentialing and medical staff support functions will be provided on-site and through a services arrangement with FMRH.

Plant Management - Plant Management will assure routine maintenance of buildings, heating and A/C, plumbing, electrical and outside maintenance of grounds, plan, organize, and direct the maintenance and engineering functions related to building, grounds, and equipment; and manage new projects and construction.

Purchasing and material management - On-site staff will maintain inventory, order supplies and equipment, issue purchase orders, and submit invoices to accounts payable. Routine supplies will be maintained through an exchange cart system. Biomedical support will be available through a services arrangement with FMRH.

Quality Management and Infection Control - On-site staff will facilitate the implementation of the Quality First Quality Management Program and the Infection Control Plan with back-up through a services arrangement with FMRH.

Risk Management services such as loss prevention and liability control will be provided by on-site staff with back-up through a services arrangement with FMRH.

Utilization Review and Social Services - The following services will be available on-site: discharge planning, home health and nursing home referrals, high risk social assessments and interventions, case management support, concurrent review, and patient satisfaction monitoring. The on-site Social Worker will also support community health promotion projects.

Additional support services such as medical staff support, human resources/personnel/wage and benefits, purchasing, planning and marketing, staff education and legal will be provided through a services agreement with FMRH."

In Section III.1, pages 128-149, the applicant describes the need for the proposed project, each service component and the proposed location within the Cumberland/Hoke County Acute Care Bed Service Area.

In Section III.1(a), pages 128-138, the applicant states the following regarding the need for the proposed 65-bed hospital in Hoke County.

"Although it is one of the fastest growing counties in North Carolina, there is no hospital in Hoke County at the present time. However, FirstHealth has been approved to construct an eight (8) bed acute care hospital, Project ID # N-8497-10. The development of the approved CON project is under appeal. This means that all Hoke County residents who need inpatient, outpatient or emergency department care must travel outside of Hoke County to receive care."

"An unmet need for a new hospital in Hoke County exists because every Hoke County resident must leave the county and travel to another county for acute care and outpatient services."

"Because no emergency care is offered in Hoke County, residents must travel outside of Hoke County for services..."

"A 2007 study, published in the Emergency Medicine Journal, concluded that for every 6-mile increase in straight-line distance to a hospital increases the risk of death by 1 percent. The distance from most locations in Hoke County to either Pinehurst or Fayetteville is between 6- and 24- miles resulting in a 1 to 4 percent increase in the risk of death for Hoke County residents."

"While the lack of a hospital in a growing county is an obvious problem, FirstHealth does not rely solely on the lack of a hospital to demonstrate the need for a hospital in Hoke County."

"Based on counties of similar size with a hospital that offers emergency care, most county residents would seek treatment at the local emergency department, rather than travel outside of the county for care."

"Hoke County shows evidence of all of the factors that contribute to a barrier to health care access. The following tables identify county population, uninsured adults, primary care providers, high school graduates, unemployment, and children in poverty for five North Carolina counties for comparison purposes. These social and economic measures were chosen to be studied because they represent characteristics of a community that will lead to poorer health and act as barriers to accessing healthcare. The counties selected by FirstHealth to compare are Hoke County (location of hospital proposed in this CON application), Pender County (similar in population size with a hospital and adjacent to a county with a tertiary care hospital), Richmond County (similar in population size with a FirstHealth owned hospital), Caswell County (second largest county in NC without a hospital and adjacent to a county with a tertiary care

hospital), and Scotland County (adjacent to and smaller than Hoke County with a hospital)."

...

"The following statements are validated by the previous two tables:

- *Hoke County has the second highest percentage of uninsured adults.*
- *Hoke County has the second highest population per primary care physician.*
- *Hoke County has the second lowest percentage of 9th graders that graduate in four years.*
- *Hoke County has the second lowest ED utilization rate, behind Caswell County.*
- *The two counties that lack a local community hospital, Hoke and Caswell counties, have Emergency Department utilization rate* [sic] *that are close to or more than 50 percent less than each of the counties with hospitals.*

These disparities in care patterns indicate that counties without hospitals have less access to emergency services which results in impediments to access to other health care services, thus supporting a need for an acute care hospital in Hoke County."

In Section III.1(b), pages 139-146, the applicant states the following regarding the need for the proposed 65 bed hospital in Hoke County.

"The need that necessitates the development of FHCH is based on the following factors:

- *Hoke County is one of the fastest growing counties in North Carolina*
- *McLauchlin and Raeford townships are the most populated townships in Hoke County*
- *McLauchlin Township is projected to have a greater school age population growth due to the impact of BRAC*
- *Comprehensive Regional Growth Plan for the Fort Bragg*

Region, September 2008, identifies a need for a community hospital in Hoke County

- *Hoke County is the largest county in North Carolina without a hospital*
- *Hoke County residents utilize healthcare services at a lower rate as compared to similar counties*

...

The 2011 population of Hoke County is larger than the county populations of 30 North Carolina counties that have an acute care hospital within its borders. The following table identifies the North Carolina counties that do not have a hospital with the associated 2011 population and state rank.

This table clearly indicates that Hoke County is not just the largest county without a hospital, but Hoke County is more than double the size of the next county's population without a hospital, Caswell County."

In Section III.1(c), pages 147-149, the applicant explains why it selected the proposed location.

"The following key points led FirstHealth to conclude that the location for FHCH, along Route 401, near the border of McLauchlin Township and Raeford Township is the most reasonable location for the proposed hospital.

McLauchlin and Raeford townships are the most populated townships in Hoke County

Combined, McLauchlin and Raeford townships represent 69.3 percent of the county's 2011 population and 70.1 percent of the county's 2016 population. McLauchlin Township where FHCH will be located is also the most rapidly growing township in the county.

...

In its approved land Use Plan, Hake County has taken the initiative to develop four commercial nodes within an urban service area, McLauchlin Township. The commercial nodes were established to coordinate the development of commercial, retail, and services to the fastest growing portions of Hake County. FirstHealth proposes to locate the FHCH in one of these four commercial nodes, the East Hake commercial node."

In Section III.1(a), page 128, the applicant states

> *"Since Hoke County has no hospital, while Cumberland County is well served with nearly five hundred (500) acute care beds, the appropriate and logical place to have the sixty-five (65) beds is Hoke County."*

Section III.1 of the application requests that the applicant:

> *"(a) Describe, in specific terms, the unmet need that necessitated the inclusion of each of the proposed project components (i.e., beds, services, and medical equipment), as set forth in the description of the scope of services in Section II.1;*
>
> *(b) Provide statistical data that substantiates the existence of an unmet need for each project component and proposed services identified in Section II.1; and*
>
> *(c) Document that the facility is needed at the proposed site as opposed to another area of the service area."*

Throughout Section III.1, pages 128-149, the applicant continually states there is no hospital in Hoke County.

On September 27, 2011, prior to the submittal of this application, the Certificate of Need Section approved two separate applications for hospitals in Hoke County, both approved to be located in McLauchlin Township in Hoke County.

FirstHealth in Project ID # N-8497-10 was conditionally approved to construct a hospital on US Highway 401 in Raeford with 8 acute care beds, 4 observation beds, one operating room, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services. That conditional approval is currently under appeal. In the current application, the applicant proposes to develop a 65-bed hospital on the site where it received approval in 2010 to develop the 8-bed hospital. FHCH has stated that if the current application for a 65-bed hospital is approved it would relinquish the CON approval for the 8-bed hospital. See Section I, page 8.

In addition, Hoke Healthcare, LLC, Project ID N-8499-10 was conditionally approved to construct a hospital on US Highway 401 in Raeford with 41 acute care beds, 9 observation beds, two operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services. The conditional approval for the 41-bed hospital is also currently under appeal. Hoke Healthcare, LLC is a subsidiary of CFVHS.

Thus, FHCH's statements that there is no hospital in Hoke County are correct with respect to the lack of an existing operational hospital. The statements fail to disclose that there are two approved hospitals in Hoke County.

The following table compares the two proposals submitted by FirstHealth.

SERVICE OR DEPARTMENT	FHCH #1 8 beds	FHCH #2 65 beds	Difference
ACUTE CARE BEDS			
# of Medical/Surgical Beds (breakdown further)	8	54	+46
# of Intensive Care Unit Beds	0	8	+8
# of Obstetrical Beds	0	0	0
# of LDRP Beds	0	3	+3
Total Licensed Acute Care Beds	8	65	+57
# OF LEVEL I BASSINETS (unlicensed)	0	0	0
OBSERVATION BEDS (unlicensed)	4	0	-4
SURGERY			
# of Shared Operating Rooms	1	2	+1
# of C-Section Operating Rooms	0	0	0
RADIOLOGY			
CT Scanner	1	1	0
Radiography/Fluoroscopy units-Fixed			0
mobile	2	2	
Nuclear Medicine Camera	1	1	0
Ultrasound Units	1	1	0
Mammography Units	1	1	0
MRI-mobile	yes	yes	Same
EMERGENCY SERVICES			
# of Treatment Rooms	8	12	+4
LABORATORY SERVICES	yes	yes	Same
PHARMACY SERVICES	yes	yes	Same
CARDIOPULMONARY SERVICES (includes Respiratory Therapy)	yes	yes	Same
PHYSICAL THERAPY SERVICES	yes	yes	Same

The table below summarizes what has already received conditional approval for development in McLauchlin Township, Hoke County.

SERVICE OR DEPARTMENT	FHCH 8-beds	HCMC 41-beds	Total
ACUTE CARE BEDS			
# of Medical/Surgical Beds	8	21	29
# of Intensive Care Unit Beds	0	4	4
# of Obstetrical Beds	0	16	16
# of LDRP Beds	0	0	0
Total Licensed Acute Care Beds	8	41	49
# OF LEVEL I BASSINETS (unlicensed)	0	16	16
OBSERVATION BEDS (unlicensed)	4	9	13
SURGERY			
# of Shared Operating Rooms	1	2	3
# of C-Section Operating Rooms	0	1	1
RADIOLOGY			
CT Scanner	1	1	2
Radiography/Fluoroscopy units (fixed and mobile)	4	4	8
Nuclear Medicine Camera	1	0	1
Ultrasound Units	1	2	3
Mammography Units	1	0	1
MRI-mobile	yes	yes	yes
EMERGENCY SERVICES			
# of Treatment Rooms	8	16	24
LABORATORY SERVICES	yes	yes	yes
PHARMACY SERVICES	yes	yes	yes
CARDIOPULMONARY SERVICES	yes	yes	yes
PHYSICAL THERAPY SERVICES	yes	yes	yes
SPEECH THERAPY SERVICES	no	yes	yes

As noted in the discussion above, FHCH predicates the need for its proposed 65-bed hospital in McLauchlin Township, Hoke County on Hoke County not having a hospital. However, two hospitals have already been approved to be developed in McLauchlin Township, Hoke County.

If both of the 2010 conditional approvals are upheld on appeal and the hospitals constructed, Hoke County would have 2 hospitals, both located in McLauchlin Township, with a combined total of 49 acute care beds (including 4 ICU beds and 16 obstetrical beds), 3 shared operating rooms and a dedicated C-Section OR and 2 emergency departments with a total of 24 treatment rooms. In addition, both hospitals would offer diagnostic imaging, laboratory, pharmacy and rehabilitation services.

In Section IV.1, pages 174-209, FHCH describes the three separate methodologies used to project utilization. They are: 1) Emergency Department Need Methodology; 2) Direct Inpatient Admission Need Methodology; and 3) Outpatient Department

Need Methodology. Each methodology is described below. On page 174, the applicant states

"Emergency Department Need Methodology

- *The Hoke County population generates Emergency Department visits*
- *Each Emergency Department visit is categorized by level (Level I through V).*
- *Each Emergency Department visit categorized by level results in a discharge, an observation stay, or an inpatient stay.*
- *Each Emergency Department visits that results in a discharge, an observation stay, or an inpatient stay will utilize ancillary services at different rates.*
- *These different service rates result in utilization for ancillary services including lab, pharmacy, ultrasound, general radiography, CT scan, MRI scan, nuclear medicine, and surgery.*

Direct Inpatient Admission Need Methodology

- *Direct Inpatient Admissions are supported by physician referrals.*
- *Each Inpatient Admission results in utilization of ancillary services including lab, pharmacy, ultrasound, general radiography, CT scan, MRI scan, nuclear medicine, and surgery,*

Outpatient Department Need Methodology

- *The Hoke County population by age and sex group generates outpatient visits at different rates.*
- *These different outpatient rates result in utilization for outpatient services including ultrasound, general radiography, fluoroscopy, CT scan, MRI scan, surgery, and mammography."*

In Section IV.1, pages 174-209, the applicant applies the three methodologies sequentially: first the Emergency Department Need Methodology; second the Direct Inpatient Admission Need Methodology; and third the Outpatient Department Need Methodology. The second methodology builds off of and relies on the projected utilizations derived from the Emergency Department Need Methodology. The third methodology builds off and relies on the projected utilization in both the Emergency Department Need Methodology and the Direct Inpatient Admission Need Methodology.

Emergency Department Services

The applicant proposes to develop an emergency department with 12 treatment rooms at the 65-bed hospital. In Section IV.1, page 184, the applicant provides projected emergency department visits during each of the first three operating years, as shown in the table below.

Emergency Department Visits

	2016	2017	2018
Hoke	7,332	9,201	10,734
Cumberland	1,496	2,085	2,683
Robeson	1,356	1,540	1,727
Scotland	788	882	976
Total Visits	**10,972**	**13,708**	**16,121**

In Section IV.1, pages 176-192, the applicant describes the assumptions and methodology used to project utilization of the proposed emergency department as follows

"Emergency Department Need Methodology

FirstHealth used the following need methodology to project FHCH Emergency Department visits. The projected FHCH Emergency Department visits then generated observation days, inpatient days, inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes.

Please refer to Exhibit A for population and need methodology sources.

Step 1.

The following table presents actual 2008 through 2010 ED visits and population for the 4-County Service Area. FirstHealth calculated the ED utilization rates by dividing the number of ED visits by (population/100). Using the 2008 and 2010 County ED utilization rates, FirstHealth calculated the 2-year growth rate for each county.

Emergency Department
County Utilization Rate per 100 Population

	ED Visits	*ED Visits*	*ED Visits*	*County Population*	*County Population*	*County Population*
	2008	***2009***	***2010***	***2008***	***2009***	***2010***
Hoke	*10,148*	*11,349*	*13,602*	*44,529*	*46,134*	*47,298*
Cumberland	*75,189*	*78,471*	*94,052*	*306,885*	*321,071*	*321,018*
Robeson	*64,671*	*74,494*	*88,710*	*131,704*	*131,080*	*134,502*
Scotland	*15,832*	*18,163*	*21,868*	*36,488*	*36,926*	*36,098*
Total	*165,840*	*182,477*	*218,232*	*519,606*	*535,211*	*538,916*

Source: ED Visits- NCHA ED Data Reports, 2008-2010
Population- North Carolina Office of State Budget and Management, April 2011.

	ED Utilization Rates	ED Utilization Rates	ED Utilization Rates	2-yr Growth
	2008	2009	2010	
Hoke	22.8	24.6	28.8	26.2%
Cumberland	24.5	24.4	29.3	19.6%
Robeson	49.1	56.8	66.0	34.3%
Scotland	43.4	49.2	60.6	39.6%

Step 2.

FirstHealth used actual 2008 through 2010 Emergency Department visits (from all hospitals), as reported by Thomson Reuters and included in Exhibit A, to conservatively calculate Emergency Department utilization rates for the 4-County Service Area. FirstHealth assumes no annual growth in the utilization rate from 2010 to project future ED volumes, which strengthens FirstHealth's conservative projections since an additional new hospital in Hoke County would most surely increase the utilization rate of emergency services.

4-County Service Area
Emergency Department
Projected ED Utilization Rate

	2011	2016	2017	2018
Hoke	28.8	28.8	28.8	28.8
Cumberland	29.3	29.3	29.3	29.3
Robeson	66.0	66.0	66.0	66.0
Scotland	60.6	60.6	60.6	60.6

Step 3.

FirstHealth projected the number of Emergency Department visits that the residents of the 4-County Service Area would generate.

FirstHealth multiplied the 4-County Service Area population projections by the 2016-2018 Projected ED Use Rates, shown in Step 2, to project 4-County Service Area Emergency Department visits.

4-County Service Area
Emergency Department
Projected Population

	2016	2017	2018
Hoke	56,749	58,325	59,898
Cumberland	350,949	354,494	357,722
Robeson	142,662	144,021	145,381
Scotland	35,224	35,075	34,930
Total	585,584	591,915	597,931

Source: Population- North Carolina Office of State Budget and Management, April 2011

4-County Service Area
Emergency Department
ED Projections

	2016	2017	2018
Hoke	16,320	16,773	17,226
Cumberland	102,821	103,860	104,806
Robeson	94,092	94,988	95,885
Scotland	21,339	21,248	21,160
Total	234,572	236,869	239,077

Source: Projected ED Use Rate x (Projected Population/100)

Step 4.

FirstHealth projected the number of Emergency Department visits that would receive care at FirstHealth. FirstHealth used FY2010 Emergency Department visits reported by Thomson Reuters to determine the FirstHealth market share of emergency services in the service area population.

Market Share
Actual FirstHealth
FY2010

	ED Visit Total	FirstHealth Visits	Market Share
Hoke	13,602	6,701	49.3%
Cumberland	94,052	1,098	1.2%
Robeson	88,710	3,195	3.6%
Scotland	21,868	2,018	9.2%

Source: *Market Share= (FirstHealth Visits/ County Total) x 100*

In projecting conservative Emergency Department volumes, FirstHealth used its FY2010 market share of Emergency Department visits to project the number of Emergency Department visits that would be treated by FirstHealth in FY2016 through FY2018.

Emergency Department
FirstHealth ED Projected Market Share

	2016	2017	2018
Hoke	49.3%	49.3%	49.3%
Cumberland	1.2%	1.2%	1.2%
Robeson	3.6%	3.6%	3.6%
Scotland	9.2%	9.2%	9.2%

Emergency Department
FirstHealth ED Projected Market Visits

	2016	2017	2018
Hoke	8,040	8,263	8,486
Cumberland	1,200	1,213	1,224
Robeson	3,389	3,421	3,453
Scotland	1,969	1,961	1,953
Total	14,598	14,858	15,116

Source: Projected -County Service Area ED Visits x FirstHealth Projected Market Share

Step 5.

FirstHealth projected the number of Emergency Department visits that would receive care at FHCH, rather than at FMRH. FirstHealth made the assumption that patients seeking Emergency Department care at FirstHealth are more likely to seek care at a closer FirstHealth Emergency Department that has fewer patients and a shorter wait time. Using the experience of its administrative and outreach teams, FirstHealth assumes that 75.0 percent of ED visits from Hoke County residents who would have gone to FMRH for care will instead receive care at FHCH; however, this percentage will ramp-up over a three year period. FirstHealth also assumes that 50.0 percent of the ED visits from Cumberland, Robeson, and Scotland counties who would have gone to FMRH for care will instead receive care at FHCH; again, this percentage will ramp-up over a three year period. This projected 'shift' in existing patients is lower than most 'shift' rates in previously approved CON applications associated with Freestanding Emergency Departments; those applications assumed patient 'shift' rates of between 75.0 and 80.0 percent over the first three years of operation.

Emergency Department
FirstHealth ED Projected "Shift" Rates

	2016	2017	2018
Hoke	50.00%	65.00%	75.00%
Cumberland	40.00%	45.00%	50.00%
Robeson	40.00%	45.00%	50.00%
Scotland	40.00%	45.00%	50.00%

Emergency Department
FHCH ED Projections
FirstHealth ED Visits

	2016	2017	2018
Hoke	4,020	5,371	6,365
Cumberland	480	546	612
Robeson	1,356	1,540	1,727
Scotland	788	882	976
Total	6,643	8,339	9,679

Source: Projected FirstHealth ED Visits x FirstHealth Projected "Shift" Rate

Step 6.

FirstHealth subtracted the FirstHealth ED Visits, calculated in Step 5, from the total Projected ED Visits, calculated in Step 3, to identify the Emergency Department visits that would NOT typically be treated at FirstHealth.

Non-FMRH ED Visit Projection

	2016	2017	2018
Hoke	8,280	8,510	8,739
Cumberland	101,621	102,647	103,582
Robeson	90,703	91,567	92,432
Scotland	19,369	19,287	19,208
Total	219,973	222,012	223,961

Source: Projected FirstHealth ED Visits x FirstHealth Projected "Shift" Rate

Step 7.

FirstHealth applied the following FHCH percentages, based on the experience of its administrative and outreach teams; FirstHealth assumes the following percentages of ED visits from the 4-County Service Area who would NOT have gone to FMRH for care will instead receive care at FHCH.

Other Hoke County residents will seek care at FHCH because it is within the county borders and closer to their home than either FMRH or CFVMC. Additional Cumberland County residents will seek care at FHCH because currently no alternative exists to the Emergency Department at CFVMC that is within a 20 minute drive of Fayetteville. Additional ED patients from Scotland and Robeson counties will be limited because of the distance to FHCH and their existing treatment care patterns.

FHCH ED Projections
Non-FMRH ED Visit % to FHCH

	2016	2017	2018
Hoke	40.0%	45.0%	50.0%
Cumberland	1.0%	1.5%	2.0%
Robeson	0.0%	0.0%	0.0%
Scotland	0.0%	0.0%	0.0%

Source: Projected ED Visit %

Emergency Department
FHCH ED Projections
Non-FMRH ED Visits to FHCH

	2016	2017	2018
Hoke	3,312	3,829	4,370
Cumberland	1,016	1,540	2,072
Robeson	-	-	-
Scotland	-	-	-
Total	4,328	5,369	6,441

Source: Projected Non-FirstHealth ED Visits x Projected ED Visit %

As the following map shows, nearly 90% of the Hoke County and a large percentage of population in Cumberland County are located within 12 miles of the proposed FHCH. This decrease in the distance to emergency care is enough to change emergency care patterns of travel.

[See page 183 for the FHCH Emergency Department 12-Mile Ring map.]

Step 8.

FirstHealth added the projected FHCH Emergency Department visits from FMRH visits, calculated in Step 5, to the FHCH Emergency Department visits from non-FMRH visits, calculated in Step 7, to identify the total number of projected Emergency Department visits for 2016 through 2018.

Emergency Department
FHCH ED Projections

	2016	2017	2018
Hoke	7,332	9,201	10,734
Cumberland	1,496	2,085	2,683
Robeson	1,356	1,540	1,727
Scotland	788	882	976
Total	10,972	13,708	16,121

Source: Projected FHCH Visits + Projected Non-FirstHealth FHCH Visits

Step 9.

Next, FirstHealth calculated the effective market share that the FHCH will achieve. The effective market share was calculated by dividing the projected Total FHCH Emergency Department visits calculated in Step 8 by the Projected 4-County ED Demand calculated in Step 3.

Emergency Department
FHCH Effective Market Share

	2016	2017	2018
Hoke	44.9%	54.9%	62.3%
Cumberland	1.5%	2.0%	2.6%
Robeson	1.4%	1.6%	1.8%
Scotland	3.7%	4.2%	4.6%
Total	4.7%	5.8%	6.7%

Source: Projected Total FHCH Visits /Projected Total 4-County ED Visits

As shown in Section III.1(a), the Hoke County ED market share that FirstHealth projects is conservative as compared to other hospital ED market share's in similarly sized counties.

Step 10.

FirstHealth projected the number of Level I through Level V Emergency Department visits that would be generated by the number of FHCH Emergency Department visits calculated in Step 8. Using a sample data pull for FY2008 through FY2010 of 4-County Service Area residents treated at the FMRH Emergency Department, FirstHealth calculated a 1-year rate to apply to future projections. The following table shows the 3-year experience. Service Levels are based on resources billed during the patient encounter in the Emergency Department with Level I having the lowest utilization of resources and Level V having the highest utilization of resources.

FMRH Emergency Department
4-County Service Level
FY2008 — FY2010

	2008	2009	2010	1-YR Exp.
Level I	812	696	118	
Level II	1,845	1,810	385	
Level III	4,038	4,702	4,743	
Level IV	4,297	4,894	5,388	
Level V	367	647	2,563	
ED Visits	11,359	12,749	13,197	
Level I	7.1%	5.5%	0.9%	0.9%
Level II	16.2%	14.2%	2.9%	2.9%
Level III	35.5%	36.9%	35.9%	35.9%
Level IV	37.8%	38.4%	40.8%	40.8%
Level V	3.2%	5.1%	19.4%	19.4%
Total	100.0%	100.0%	100.0%	100.0%

FirstHealth then multiplied the FHCH Emergency Department visits calculated in Step 8 by the most recent 1-year Service Level percentages as previously above.

FMRH Emergency Department
4-County Service Level
FY2016 — FY2018

	1-YR Exp.	*2016*	*2017*	*2018*
Level I	*0.9%*	*98*	*123*	*144*
Level II	*2.9%*	*320*	*400*	*470*
Level III	*35.9%*	*3,943*	*4,927*	*5,794*
Level IV	*40.8%*	*4,479*	*5,597*	*6,582*
Level V	*19.4%*	*2,131*	*2,662*	*3,131*
ED Visits	***100.0%***	***10,972***	***13,708***	***16,121***

Step 11.

Using the sample data pull for FY2008 through FY2010 of 4-County Service Area residents treated at the FMRH Emergency Department used in Step 10, FirstHealth calculated the percent of observation patients, inpatients, and discharged patients by Service Level to identify the 1-year experience to apply to future projections.

Table 1 shows the number, percentage, and 3-year total and 1-year experience of observation, inpatients, and discharge patients for FY2008 through FY2010.

Table 2 shows the projected number of observation, inpatients, and discharge patients for FY2016 through FY2018 using the 1-year experience observation, inpatient, and discharge patient percentages shown in Step 10.

Table 1
FMRH Emergency Department
1-Year Experience
Observation, Inpatient, and Discharge Percent by Service Level
FY2008-FY2010

	2007	2008	2009	3-YR Tot		2007	2008	2009	1-YR EXP
Level I	812	696	118	812		7.1%	5.5%	0.9%	0.9%
Level II	1,845	1,810	385	1,845		16.2%	14.2%	2.9%	2.9%
Level III	4,038	4,702	4,743	4,038		35.5%	36.9%	35.9%	35.9%
Level IV	4,297	4,894	5,388	4,297		37.8%	38.4%	40.8%	40.8%
Level V	367	647	2,563	367		3.2%	5.1%	19.4%	19.4%
ED Visits	11,359	12,749	13,197	11,359		100.0%	100.0%	100.0%	100.0%
Observation Patient Volume and Percentage									
Level I	1	-	-	1		0.1%	0.0%	0.0%	0.0%
Level II	2	1	-	3		0.1%	0.1%	0.0%	0.0%
Level III	2	1	-	3		0.0%	0.0%	0.0%	0.0%
Level IV	354	221	6	581		8.2%	4.5%	0.1%	0.1%
Level V	12	36	220	268		3.3%	5.6%	8.6%	8.6%
ED Observation Patients	371	259	226	856					
Inpatient Volume and Percentage									
Level I	-	-	-	-		0.0%	0.0%	0.0%	0.0%
Level II	29	27	1	57		1.6%	1.5%	0.3%	0.3%
Level III	50	50	16	116		1.2%	1.1%	0.3%	0.3%
Level IV	1,516	1,491	213	3,220		35.3%	30.5%	4.0%	4.0%
Level V	260	510	2,071	2,841		70.8%	78.8%	80.8%	80.8%
ED Inpatient Patients	1,855	2,078	2,301	6,234					
Discharge Volume and Percentage									
Level I	811	696	118	1,625		99.9%	100.0%	100.0%	100.0%
Level II	1,814	1,782	384	3,980		98.3%	98.5%	99.7%	99.7%
Level III	3,986	4,651	4,727	13,364		98.7%	98.9%	99.7%	99.7%
Level IV	2,427	3,182	5,169	10,778		56.5%	65.0%	95.9%	95.9%
Level V	95	101	272	468		25.9%	15.6%	10.6%	10.6%
ED Discharge Patients	9,133	10,412	10,670	30,215					

[Note: the applicant uses the wrong years in the first row of the table.]

Table 2
FHCH Emergency Department
Observation, Inpatient, and Discharge Volume by Service Level
FY2016- FY2018

	1-YR EXP		2016	2017	2018
Level I	0.9%		98	123	144
Level II	2.9%		320	400	470
Level III	35.9%		3,943	4,927	5,794
Level IV	40.8%		4,479	5,597	6,582
Level V	19.4%		2,131	2,662	3,131
ED Visits	100.0%		10,972	13,708	16,121
Projected Observation Patient Volume					
Level I	0.0%		-	-	-
Level II	0.0%		-	-	-
Level III	0.0%		-	-	-
Level IV	0.1%		5	6	7
Level V	8.6%		183	229	269
ED Observation Patient Volume			188	235	276
Projected Inpatient Volume					
Level I	0.0%		-	-	-
Level II	0.3%		1	1	1
Level III	0.3%		13	17	20
Level IV	4.0%		177	221	260
Level V	80.8%		1,722	2,151	2,530
ED Inpatients Patients			1,913	2,390	2,811
Projected Discharge Volume					
Level I	100.0%		98	123	144
Level II	99.7%		319	399	469
Level III	99.7%		3,930	4,910	5,774
Level IV	95.9%		4,297	5,369	6,314
Level V	10.6%		226	283	332
ED Discharge Patients	100.0%		8,871	11,083	13,034

Step 12.

The following table summarizes Table 2 from Step 11:

FHCH Emergency Department
Observation, Inpatient, and Discharge Volumes Summary
FY2016 — FY2018

	2016	2017	2018
Total ED Visits	10,972	13,708	16,121
ED Observation Patients	188	235	276
ED Inpatients	1,913	2,390	2,811
ED Discharges	8,871	11,083	13,034

FirstHealth has determined that it can develop twelve (12) ED treatment rooms at the proposed FHCH to accommodate the projected Emergency Department visit volume.

Step 13.

Using the sample data pull for FY2008 through FY2010 of 4-County Service Area residents treated at the FMRH Emergency Department used in Step 10, FirstHealth calculated the percent of inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes by observation patient, inpatient, and discharged patient to identify the 3-year average to apply to future projections.

Please refer to Exhibit A, for Table 3, which shows the number, percentage, and 3-year average of inpatient surgical hours, imaging procedures, laboratory tests, and other ancillary volumes associated with the Emergency Department observation, inpatients, and discharge patients for FY2008 through FY2010 from the 4-County Service Area.

Table 4 shows the projected number of inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes associated with the Emergency Department observation, inpatients, and discharge patients for FY2016 through FY2018 using the 3-year average observation, inpatient, and discharge patient utilization rates per 100 patients shown in Step 13, Table 3, Exhibit A. For example, Table 3 shows the 3-year average laboratory tests for discharge patients to be 175 laboratory tests per 100 discharged ED patients; this can be further simplified to 1.7 laboratory tests per discharged ED patient. FirstHealth multiplied the 3-year average ancillary volume per 100 patients by the number of projected Emergency Department patients by observation, inpatient, or discharge divided by 100.

Table 4
FHCH Emergency Department
Ancillary Volumes by Observation, Inpatient, and Discharge Patient
FY2016 - FY2018

	Units	*3-YR AVG*	*2016*	*2017*	*2018*
Projected Ancillary Volumes by Discharge Patient					
ED Discharge Patients			*8,871*	*11,083*	*13,034*
Laboratory	*Tests*	*175.3*	*15,554*	*19,433*	*22,853*
Pharmacy	*Units*	*212.2*	*18,828*	*23,523*	*27,664*
General Radiology	*Procedures*	*20.4*	*1,813*	*2,265*	*2,664*
CT Scanner	*Scans*	*21.9*	*1,944*	*2,428*	*2,856*
MRI Scanner	*Scans*	*1.1*	*94*	*117*	*138*
Ultrasound	*Procedures*	*8.4*	*750*	*936*	*1,101*
Nuclear Medicine	*Procedures*	*0.3*	*24*	*30*	*35*
Operating Room	*Hours*	*0.0*	*4*	*5*	*6*
Projected Ancillary Volumes by Observation Patient					
ED Discharge Patients			*188*	*235*	*276*
Laboratory	*Tests*	*1,494.5*	*2,808*	*3,508*	*4,126*
Pharmacy	*Units*	*2,439.3*	*4,583*	*5,726*	*6,734*
General Radiology	*Procedures*	*110.4*	*207*	*259*	*305*
CT Scanner	*Scans*	*47.2*	*89*	*111*	*130*
MRI Scanner	*Scans*	*7.2*	*14*	*17*	*20*
Ultrasound	*Procedures*	*15.2*	*29*	*36*	*42*
Nuclear Medicine	*Procedures*	*261.1*	*491*	*613*	*721*
Operating Room	*Hours*	*5.9*	*11*	*14*	*16*
Projected Ancillary Volumes by Inpatient					
ED Discharge Patients			*1,913*	*2,390*	*2,811*
Laboratory	*Tests*	*3,407.0*	*65,176*	*81,430*	*95,764*
Pharmacy	*Units*	*9,665.6*	*184,900*	*231,013*	*271,679*
General Radiology	*Procedures*	*394.7*	*7,551*	*9,434*	*11,095*
CT Scanner	*Scans*	*86.7*	*1,658*	*2,071*	*2,436*
MRI Scanner	*Scans*	*16.4*	*315*	*393*	*462*
Ultrasound	*Procedures*	*43.9*	*840*	*1,050*	*1,235*
Nuclear Medicine	*Procedures*	*61.2*	*1,170*	*1,462*	*1,720*
Operating Room	*Hours*	*16.7*	*319*	*398*	*468*

Step 14.

FirstHealth summed the projected FHCH ancillary service volumes for observation, inpatients, and discharge patients, calculated in Step 13, to identify the FHCH ancillary service volumes generated by Emergency Department patients for FY2016 through FY2018.

FHCH Emergency Department
Total Ancillary Volumes
FY2016 — FY2018

	Units	*2016*	*2017*	*2018*
Total Ancillary Service Volumes				
Patients	*Visits*	*10,972*	*13,708*	*16,121*
Inpatients	*Admissions*	*1,913*	*2,390*	*2,811*
Laboratory	*Tests*	*83,537*	*104,371*	*122,744*
Pharmacy	*Units*	*208,311*	*260,263*	*306,077*
General Radiology	*Procedures*	*9,572*	*11,959*	*14,064*
CT Scanner	*Scans*	*3,690*	*4,610*	*5,422*
MRI Scanner	*Scans*	*422*	*527*	*620*
Ultrasound	*Procedures*	*1,618*	*2,022*	*2,378*
Nuclear Medicine	*Procedures*	*1,685*	*2,105*	*2,476*
Operating Room	*Hours*	*334*	*417*	*491*

Even without considering the clear need for ancillary services given the Emergency Department utilization projections, every Emergency Department needs to have these services readily available as part of the basic standard of care for patients presenting to an Emergency Department. In the American College of Emergency Physicians publication, Emergency ***Department Design*** *(pages 163 and 164); imaging, laboratory, and pharmacy services are detailed in their inclusion in the design for Emergency Departments. Furthermore, to be licensed as a hospital in North Carolina, a facility must have at least two acute care beds and ancillary services such as lab, imaging and pharmacy. See 10A NCAC 13B .3201.*

Please refer to Exhibit B for copies of the Emergency Department Design pages."

Projected utilization of the emergency department at FHCH is not based on reasonable, credible and supported assumptions as set forth below:

In Step 4 of the Emergency Department Need Methodology, the applicant calculates its market share (based on FMRH) during FY2010. The applicant then projects FirstHealth ED visits (for FMRH and the proposed FHCH) for Project Years 2016-2018 based on that same market share with no growth. However, the applicant did not adequately account for the effect the development of an emergency department with 16 treatment rooms as part of the approved 41-bed hospital would have on projected market share.

In Step 5 of the Emergency Department Need Methodology, the applicant makes assumptions about the percentage of FMRH ED visits generated from the proposed 4-County Service Area who will "shift" to the proposed FHCH. The applicant states *"FirstHealth made the assumption that patients seeking Emergency Department care at FirstHealth are more likely to seek care at a*

closer FirstHealth Emergency Department that has fewer patients and a shorter wait time." These assumptions are reasonable for residents of Hoke and Robeson counties. However, for residents of Cumberland and Scotland counties the applicant did not adequately document that the proposed emergency department at FHCH, located just to the east of Raeford on US 401, would be closer for residents of Cumberland and Scotland counties than the existing emergency department at FMRH. Based on: 1) the physical shape and location of Cumberland and Scotland counties in relation to Hoke County; 2) the location of the Fort Bragg Military Reservation and Pope Air Force Base; and 3) transportation corridors and traffic patterns/congestion it is very likely that a substantial portion of the residents of Scotland and Cumberland counties currently utilizing the emergency department at FirstHealth would still live closer to FMRH's emergency department than to the proposed emergency department at FHCH. Moreover, the two hospitals (FMRH and FHCH) are not comparable with regard to the types of services offered. FMRH offers cardiac services, including cardiac catheritization and open heart; services that are not proposed to be available at FHCH. Thus, some residents would likely drive farther because of the type of services available at FMRH.

In Steps 7-9 of the Emergency Department Need Methodology, the applicant projects how many emergency department visits currently originating from the 4 county service area but not going to FMRH will "shift" over to FHCH once the proposed project is completed. As support for the "shift rate percentages" cited in the table on page 182, the applicant states *"based on the experience of its administrative and outreach teams" ... "Other Hoke County residents will seek care at FHCH because it is within the county borders and closer to their home than either FMRH or CFVMC. Additional Cumberland County residents will seek care at FHCH because currently no alternative exists to the Emergency Department at CFVMC that is within a 20 minute drive of Fayetteville."* However, the approved 41-bed hospital in Hoke County would be both *"within the county borders and closer to home than either FMRH or CFVMC."* In addition, the emergency department at the approved 41-bed hospital would be an alternative for Cumberland County residents and closer than the emergency department at the proposed 65-bed hospital. The applicant failed to account for the effect the emergency room at the approved 41-bed hospital would have on FHCH projected market share for emergency services.

The table below illustrates FHCH's projected market share for emergency department visits generated from the proposed 4-county service area in 2018, which is the third project year following completion of the proposed project.

A	B	C	D	E	F	G
County	Total Projected ED Visits in 2018 (see Step #3- page 178)	2018- Projected ED Visits at FHCH (without market share increase)	2018- FirstHealth ED Visits	"Shift" of non-FirstHealth ED visits to FHCH	C + E = total ED Visits at FHCH	F/B = % of Total ED Visits (i.e. market share)
Hoke	17,226	8,492	8,734	50%= 4,367	12,859	74.6%
Cumberland	104,806	1,258	103,548	2% =2,071	3,329	3.17%
Robeson	95,885	3,452	92,433	-na-	-na-	-na-
Scotland	21,160	1,947	19,213	-na-	-na-	-na-

Thus, in 2018, FHCH projects its Hoke County market share will be 74.6%, up from 49.3% and its Cumberland County Market share will be 3.17%, up from 1.2%. In projecting this market share increase, FHCH failed to account for the effect the emergency department in the approved 41-bed hospital would have on its projected market share for emergency department services.

In Steps 10-14 of the Emergency Department Need Methodology, the applicant, based on its experience at FMRH, determines the number of projected ED visits at FHCH by level, where Level I visits have the lowest utilization of resources and Level V visits have the highest utilization of resources. The applicant, again relying on the experience at FMRH, determines the projected number of observation patients, acute care patients and patients discharged from the Emergency Department (discharge patients) by level. In Step 13, the applicant relies on its experience at FMRH to determine the percent of inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes by observation patients, acute care patients and discharge patients. These percentages were then used to project utilization for these service components for the three project years. In Step 14, this data was used to generate ancillary service volumes from the emergency department utilization projections.

However, FMRH is a tertiary facility offering services not proposed to be offered at FHCH, such as cardiac catheterizations and open heart surgery. The acuity level of the patients at FMRH would also be greater than the acuity level of patients at FHCH. The applicant did not adequately demonstrate that it accounted for those differences when it relied on the experience of FMRH. Furthermore, each step of the methodology is dependent on the previous step. Thus, because the assumptions in Step 10 of the Emergency Department Need Methodology are not reasonable or credible, projections in the subsequent steps of the methodology which depend on the projections in Step 10, are also not reasonable or credible.

Therefore, the applicant does not adequately demonstrate the need for an emergency department with 12 treatment rooms.

Acute Care Beds

The applicant proposes to develop 65 acute care beds in the proposed hospital. In Section IV.1, page 201, the applicant provides projected utilization of the acute care beds, including the eight ICU beds, during each of the first three operating years as shown in the table below.

Fiscal Year	Licensed Acute Care Beds	Patient Days of Care	Average Daily Census	Percent Change	Average Occupancy Rate
2016 (Year 1)	65	10,059	27.5	—	42.3%
2017 (Year 2)	65	13,068	35.8	29.9%	55.1%
2018 (Year 3)	65	15,879	43.5	21.5%	66.9%

In Section IV.1, pages 193 - 201, the applicant describes the assumptions and methodology used to project utilization of the acute care beds as follows:

*"**Direct Inpatient Admission Need Methodology***

FirstHealth used the following need methodology to project FHCH direct inpatient admissions. The projected FHCH direct inpatient admissions then generated inpatient days, inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes.

Please refer to Exhibit A for population sources and for need methodology sources.

Step 1.

The following table presents actual FY2010 inpatient admissions for the 4-County Service Area with projections that assume no growth into the future. FirstHealth identified the number of inpatient admissions generated by ED visits to FHCH, calculated in Step 12 of the Emergency Department Need Methodology, and the projected direct inpatient admissions based on physician referrals as identified in Exhibit U and the experience of its' administrative and outreach teams.

	2010	2016	2017	2018
Hoke	3,981	3,981	3,981	3,981
Cumberland	30,629	30,629	30,629	30,629
Robeson	21,951	21,951	21,951	21,951
Scotland	5,949	5,949	5,949	5,949
Total	62,510	62,510	62,510	62,510
ED IP Admissions	Step 12	1,913	2,390	2,811
Direct IP Admissions	Referral Projections	1,000	1,400	1,800
Total Admissions		2,913	3,790	4,611
4-County Service Area Market Share		4.7%	6.1%	7.4%

Please refer to Exhibit U for copies of physician referral letters.

Step 2.

To begin the calculation of overall market share found in Step 5 of the Direct Inpatient Admission need methodology, FirstHealth calculated FHCH's projected ED patient origin for each county by utilizing the ED patient county volumes calculated in Step 8 of the Emergency Department Need Methodology.

FirstHealth calculated its patient origin by dividing the county ED visits by the total ED visits for 2016 through 2018. The increase in market share is based on the FirstHealth assumption of no increase in the ED use rate in Step 2 of the Emergency Department Need Methodology.

Emergency Department
Total FHCH ED Projections

	2016	2017	2018
Hoke	7,332	9,201	10,734
Cumberland	1,496	2,085	2,683
Robeson	1,356	1,540	1,727
Scotland	788	882	976
Total	10,972	13,708	16,121
Hoke	66.8%	67.1%	66.6%
Cumberland	13.6%	15.2%	16.6%
Robeson	12.4%	11.2%	10.7%
Scotland	7.2%	6.4%	6.1%
Total	100.0%	100.0%	100.0%
ED IP Admissions	1,913	2,390	2,811
Hoke	1,278	1,604	1,872
Cumberland	261	364	468
Robeson	236	268	301
Scotland	137	154	170

Step 3.

FirstHealth projected direct inpatient admission patient origin percentages based on FirstHealth's historical patient origin and the projected FirstHealth physician market share growth based on their presence in Hoke County and the availability of an alternative to Cape Fear Valley Medical Center. FirstHealth assumes no direct inpatient admissions from either Scotland or Robeson counties.

FHCH
Direct Inpatient Admissions

		2016	2017	2018
Direct IP Admissions		1,000	1,400	1,800
Hoke	50.0%	500	700	900
Cumberland	50.0%	500	700	900
Robeson	0.0%	-	-	-
Scotland	0.0%	-	-	-
Total	100.0%	1,000	1,400	1,800

Step 4.

FirstHealth calculated the overall patient origin by adding the ED patients by county identified in Step 2 to the direct inpatient admissions calculated in Step 3.

FHCH

Overall Inpatient Patient Origin

	2016	2017	2018
Total Admissions	*2,913*	*3,790*	*4,611*
Hoke	*1,778*	*2,304*	*2,772*
Cumberland	*761*	*1,064*	*1,386*
Robeson	*236*	*268*	*301*
Scotland	*137*	*154*	*170*
Total	*2,913*	*3,790*	*4,611*
Overall IP Patient Origin			
Hoke	*61.1%*	*60.8%*	*60.1%*
Cumberland	*26.1%*	*28.1%*	*29.7%*
Robeson	*8.1%*	*7.1%*	*6.5%*
Scotland	*4.7%*	*4.1%*	*3.7%*
Total	*100.0%*	*100.0%*	*100.0%*

Step 5.

Using the overall FHCH patient origin calculated in Step 4, FirstHealth can calculate the projected market share for inpatient admissions for the 4-County Service Area by dividing the total admissions in Step 4 by the no-growth inpatient county admissions identified in Step 1. Even assuming no growth in demand, which is very conservative given the rapid population growth in the service area, FHCH projects to capture less than 70 percent market share in its home county, Hoke County, and less than 5 percent market share in each remaining counties in the service area.

FHCH

Overall Inpatient County Market Share

	2016	2017	2018
Total IP Admissions	2,913	3,790	4,611
Hoke	1,778	2,304	2,772
Cumberland	761	1,064	1,368
Robeson	236	268	301
Scotland	137	154	170
Total	2,913	3,790	4,611
Projected IP Admissions*	62,510	62,510	62,510
Hoke	3,981	3,981	3,981
Cumberland	30,629	30,629	30,629
Robeson	21,951	21,951	21,951
Scotland	5,949	5,949	5,949
Total	62,510	62,510	62,510
Overall IP Market Share			
Hoke	44.7%	57.9%	69.6%
Cumberland	2.5%	3.5%	4.5%
Robeson	1.1%	1.2%	1.4%
Scotland	2.3%	2.6%	2.9%
Total	4.7%	6.1%	7.4%

**Projected IP Admissions are assumed to be equal to FY2010 admissions.*

As noted in Step 5, FirstHealth assumes no growth in the number of Hoke County inpatients from its FY2010 total of 3,981 inpatients to determine IP Market Share, This converts to approximately 15,924 days of care, based on an average length of stay of 4.0 days and results in a Hoke County rate of 33.7 days of care per 100 population [15,925 days of care / (47,298 / 100) 33.7].

As reported in the 2011 SMFP, the State of North Carolina had a days of care rate in 2010 of 46.7 days of care per 100 population [4,452,438 days of care / (9,535,438 / 100) 46.7]. Hoke County is currently experiencing a days of care per 100 population rate that is 27.8 percent lower than the North Carolina rate.

If through the development of both the approved 41-bed CFVHS hospital and the proposed 65-bed FHCH hospital, Hoke County can achieve a days of care rate equal to the North Carolina average, both hospitals will have an adequate number of inpatients available to meet the level of inpatients projected in their respective CON applications. But even assuming it doesn't increase its Hoke County rate of 33.7 days of care per 100 population, both hospitals will have an adequate number of inpatients available to meet the level of inpatient case projected in their respective CON applications.

*In its 2010 CON application, CFVHS projected 11,524 days of care and 3,152 IP cases in FY2016 (page 170) and a Hoke County patient origin of 36.5% (page 183). This results in 1,149 Hoke County inpatients [(11,524 * 36.5%) / (11,524 / 3,152) = (4,206 / 3.66) = 1,149].*

On the previous page, FirstHealth proposes to treat 2,772 Hoke County inpatients and by adding this projection to the CFVHS projection of 1,149 inpatients results in 3,921 Hoke County inpatients between the two applications.

- *Assuming Hoke County reaches the North Carolina rate of 46.7 inpatients per 100 population, 6,993 inpatients would make up the projected Hoke County inpatient market [((59,898/100) * 46.7) / 4.0 = 6,993].*

- *Assuming Hoke County maintains its current rate of 33.7 inpatients per 100 population, 4,970 inpatients would make up the projected Hoke County inpatient market [((59,898 / 100) * 33.7)/4.0 = 4,970].*

As a result, the service area and specifically, Hoke County can support the projected volumes proposed by the approved 41-bed CFVHS hospital and the proposed 65-bed FHCH hospital.

...

[Note: Step 6 was not set forth here because it is not related to projected utilization of the acute care beds but to imaging and other ancillary services.]

Step 7.

FirstHealth converted the number of inpatients into "days of care" to determine the utilization rate for inpatient services. The inpatient percentages and days of care by service area are based on FirstHealth's experience in providing these services at three acute care hospitals.

FHCH
Inpatient Bed Utilization

		2016	2017	2018
Inpatients	%			
Medical/Surgical Patients (includes Pediatrics and GYN)	83.0%	2,433	3.153	3.823
LDRP Patients	7.0%	188	258	.326
ICU Patients	10.0%	291	379	461
Total Inpatients		2,913	3,790	4,611
IP Days of Care	Days			
Medical/Surgical Days of Care (includes Pediatrics and GYN)	3.5	8,517	11,036	13,382
LDRP Days of Care	2.0	377	516	652
ICU Days of Care	4.0	1,165	1,516	1,844
Total Days of Care		10,059	13,068	15,879
IP Capacity	Beds			
Medical/Surgical Days of Care (includes Pediatrics and GYN)	54	19,764	19,710	19,710
LDRP Days of Care	3	1,098	1,095	1,095
ICU Days of Care	8	2,928	2,920	2,920
Medical/Surgical Days of Care (includes Pediatrics and GYN)	65	23,790	23,725	23,725
IP Utilization	Beds			
Medical/Surgical % (includes Pediatrics and GYN)	54	43.1%	56.0%	67.9%
LDRP %	3	34.3%	47.1%	59.6%
ICU %	8	39.8%	51.9%	63.2%
Total %	65	42.3%	55.1%	66.9%

Projected utilization of the acute care beds is not based on reasonable, credible and supported assumptions, as set forth below.

In Steps 1-8 of the need methodology used to project FHCH direct inpatient admissions, the applicant first projects direct inpatient admissions and, based on those projections, projects inpatient days, inpatient surgical cases, imaging procedures, laboratory tests and other ancillary volumes. However, the projected direct inpatient admissions are not based on reasonable, credible and supported assumptions because they are based, in part, on the projected inpatient admissions from ED visits (see page 193 of the application).

In Step 7, page 201, the applicant converts the number of inpatients into "days of care" to determine the number of LDRP days of care, the number of ICU days of care and the occupancy rate for the acute care beds. The applicant states *"The inpatient percentages and days of care by service area* [i.e., LDRP or ICU] *are based on FirstHealth's experience in providing these services at three acute care hospitals."* One of those hospitals is FMRH, which is a

tertiary hospital offering additional services which will not be offered at FHCH. For ICU patients, the applicant made no discernable adjustment for the likely differences in acuity level between ICU patients at FMRH and ICU patients at FHCH. With no adjustment for the difference in acuity levels these assumptions on page 201 with respect to inpatient percentages are not reasonable, credible or supported.

The applicant proposes to offer obstetrical services. However, the assumptions and methodology used to project deliveries are not reasonable, credible and supported. The applicant assumes that obstetrical discharges will equal a certain percent (utilization rate) based on *"FirstHealth's experience in providing these services at three acute care hospitals."* However, the methodology used by the applicant does not take into account the relative size of the female population of child-bearing age in the proposed service area. Further, the applicant assumes obstetrical discharges will increase 37.23% in Project Year 2 and 26.35% in Project Year 3 or 31.79% on average over the first three years following completion of the project. However, the applicant did not provide data to show that the birth rate in the proposed service area is reasonably projected to increase at the same rate as the service areas of the three referenced acute care hospitals. The applicant provided no documents or statements that the three referenced hospitals are experiencing an increase in obstetrical discharges at the percentages stated on page 201 of the application. Therefore, the applicant did not adequately demonstrate that projected utilization of the proposed obstetrical beds is based on reasonable and supported assumptions. Consequently, the applicant did not adequately demonstrate the need to develop three LDRP beds.

Operating Rooms

The applicant proposes to relocate two shared operating rooms from FMRH in Moore County to the proposed 65-bed hospital in Hoke County. In Section IV.1, page 202, the applicant describes the assumptions and methodology used to project inpatient surgical cases as follows:

> ***"Step 8.***
>
> *Using the SMFP standard of 3.0 hours per inpatient case, FirstHealth calculated the number of inpatient surgical cases by adding the Emergency Department IP surgical hours calculated in Step 13, Table 4 of the Emergency Department need methodology for ED inpatients to the Direct IP Admission surgical hours calculated in Step 6.*

FHCH
Inpatient Surgical Cases

	2016	2017	2018
ED IP Surgical Hours	319	398	468
Direct IP Admission Surgical Hours	1,449	2,028	2,608
Total Inpatient Surgical Hours	1,767	2,426	3,076
Inpatient Surgical Hours per Case	3.0	3.0	3.0
Total Inpatient Surgical Cases	589	809	1,025

In Section IV.1, pages 203-204, the applicant describes the assumptions and methodology used to project outpatient surgical cases, as follows:

"Step 1.

Outpatient surgical cases were projected by identifying the total number of outpatient surgical cases performed on Hoke County residents in FY2010, as highlighted in the following table:

FY2010
Hoke County Patients
Outpatient Surgical Cases and Market Share

OP Surgical Cases	2010	MS %
Fayetteville ASC	465	26.2%
CFVMC	294	16.5%
Surgery Center of Pinehurst	284	16.0%
FMRH	275	15.5%
Eye Center of Carolinas	163	9.2%
UNC Hospitals	110	6.2%
Highsmith-Rainey	101	5.7%
Duke	41	2.3%
Scotland Memorial	29	1.6%
SRMC	11	0.6%
Sandhills Regional	5	0.3%
Totals	**1,778**	**100.0%**

Source: 2011 Hospital and ASC License Renewal Applications

FirstHealth identified the counties of similar size to identify the average percentage of outpatient surgical cases that remain at the local county hospital. The six counties closest in size were Watauga, Beaufort, Stokes, Richmond, Vance, and McDowell counties, With the exception of Richmond County, each county only has one hospital performing surgical cases, no ambulatory surgery centers, and each county has more than 3 operating rooms.

The following table shows the county hospitals comparison and their percentage of the FY2010 outpatient surgical market for county patients:

County	Hospital	Operating Rooms	Market Share % of County Outpatient Surgical Cases
Watauga	Watauga Medical Center	6	67.9%
Beaufort	Beaufort County Hospital	5	63.5%
Stokes	Stokes-Reynolds	4	3.8%
Richmond	Richmond Memorial	3	20.2%
Richmond	Sandhills Regional	3	12.1%
	Richmond County Total	6	32.3%
Vance	Maria Parham	5	38.1%
McDowell	McDowell Hospital	3	30.4%
Average		4.8	39.1%

FirstHealth assumes that with two (2) operating rooms with no patient waitlist and immediate surgical case scheduling that it will achieve a market share below the six-county average calculated in the previous table by Year 3. For the purpose of remaining conservative in its volume projections, FirstHealth assumes that patients will seek referrals to FHCH and surgeons will schedule surgical cases at the new hospital during their established block times, rather than requiring Hoke County patients to travel outside of Hoke County outpatient surgeries.

The following table identifies the number of outpatient surgical cases projected to be performed during the first three years of operation:

	2016	2017	2018
Hoke County OP Surgical Cases	1,778	1,778	1,778
FHCH Market Share	20.2%	23.6%	27.0%
FHCH Outpatient Surgical Cases - 90%	360	420	480
Cumberland County OP - 10%	40	47	53
Scotland County OP - 0%	0	0	0
Robeson County OP— 0%	0	0	0
Total FHCH OP Surgery Cases	**400**	**467**	**533**

The previous table does not include then number of outpatient surgical cases that result from ED discharged and observation patients. These surgical patients are projected in Step 3."

In Section IV.1, page 209, the applicant provides projected utilization of the two operating rooms, as follows:

"Step 4.

Using the SMFP standard of 1.5 hours per outpatient case, FirstHealth calculated the number of outpatient surgical hours by multiplying the OP surgical cases calculated in Step 1 by 1.5 hours per case and adding the OP

surgical hours for ED discharges and observation patients calculated in Step 6 of the Emergency Department Need Methodology. FirstHealth then calculated the utilization rate of the two operating rooms by adding the inpatient surgical hours to OP surgical hours and dividing by the capacity of the operating rooms.

FHCH
Surgical Cases

		2016	2017	2018
OP Surgical Cases		400	467	533
Hours per OP Surgical Case	x	1.5	1.5	1.5
OP Surgical Hours	=	600	700	800
ED OP Surgical Hours	+	15	19	22
Total OP Surgical Hours	=	615	719	822
Total Inpatient Surgical Hours	+	1,767	2,426	3,076
Total Surgical Hours	=	2,383	3,145	3,898
OR Capacity in Hours (2,340 hours per OR x 2)	/	4,680	4,680	4,680
OR Utilization	=	50.9%	67.2%	83.3%
OR Need (Total Surgical Hours /1,872)		1.3	1.7	2.1

Projected utilization of the operating rooms is not based on reasonable, credible and supported assumptions, as set forth below:

In Step 8, page 202, the applicant provides total projected inpatient surgical cases. On page 209, the applicant provides projected outpatient surgical cases and provides a table combining inpatient and outpatient surgical cases. Projected surgical cases are dependent on (i.e. derived in part) projected emergency department visits and direct inpatient admissions. As discussed above, the projected utilization for each of those service components is not based on reasonable, credible and supported assumptions. Therefore, the projected utilization of the operating rooms is not based on reasonable, credible and supported assumptions. Consequently, the applicant does not adequately demonstrate the need for the proposed operating rooms.

Ancillary Services, including Imaging Equipment

The applicant proposes to acquire one computed tomography (CT) scanner, general radiology, mammography, and ultrasound equipment. Also, the applicant proposes to provide MRI services with a mobile MRI scanner.

In Section IV.1, page 208, the applicant provides projected utilization for all imaging equipment during each of the first three operating years, as illustrated in the table below.

FHCH
Total Imaging Procedures
FY2016 - FY2018

	2016	2017	2018
General Radiography	11,835	15,924	19,762
CT Scan	4,183	5,455	6,624
MRI Scan	632	917	1,192
Ultrasound	1,960	2,591	3,177
Mammography	428	869	1,318
Nuclear Medicine	1,839	2,321	2,753

Total projected utilization of the proposed imaging equipment was derived by adding projected imaging procedures generated from emergency room visits (see Steps # 13-14, pages 190-192), projected imaging procedures generated from direct inpatient admissions (see Step #6, pages 199-200) and projected outpatient imaging procedures (see Step #2, pages 205-208). Steps # 13, 14, 6 and 2 are quoted below.

"Step 13.

Using the sample data pull for FY2008 through FY2010 of 4-County Service Area residents treated at the FMRH Emergency Department used in Step 10, FirstHealth calculated the percent of inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes by observation patient, inpatient, and discharged patient to identify the 3-year average to apply to future projections.

Please refer to Exhibit A, for Table 3, which shows the number, percentage, and 3-year average of inpatient surgical hours, imaging procedures, laboratory tests, and other ancillary volumes associated with the Emergency Department observation, inpatients, and discharge patients for FY2008 through FY2010 from the 4-County Service Area.

Table 4 shows the projected number of inpatient surgical cases, imaging procedures, laboratory tests, and other ancillary volumes associated with the Emergency Department observation, inpatients, and discharge patients for FY2016 through FY2018 using the 3-year average observation, inpatient, and discharge patient utilization rates per 100 patients shown in Step 13, Table 3, Exhibit A. For example, Table 3 shows the 3-year average laboratory tests for discharge patients to be 175 laboratory tests per 100 discharged ED patients; this can be further simplified to 1.7 laboratory tests per discharged ED patient. FirstHealth multiplied the 3-year average ancillary volume per 100 patients by the number of projected Emergency Department patients by observation, inpatient, or discharge divided by 100.

Table 4
FHCH Emergency Department
Ancillary Volumes by Observation, Inpatient, and Discharge Patient
FY2016 - FY2018

	Units	3-YR AVG	2016	2017	2018
Projected Ancillary Volumes by Discharge Patient					
ED Discharge Patients			*8,871*	***11,083***	*13,034*
Laboratory	*Tests*	*175.3*	*15,554*	*19,433*	*22,853*
Pharmacy	*Units*	*212.2*	*18,828*	*23,523*	*27,664*
General Radiology	*Procedures*	*20.4*	*1,813*	*2,265*	*2,664*
CT Scanner	*Scans*	*21.9*	*1,944*	*2,428*	*2,856*
MRI Scanner	*Scans*	*1.1*	*94*	*117*	*138*
Ultrasound	*Procedures*	*8.4*	*750*	***936***	*1,101*
Nuclear Medicine	*Procedures*	*0.3*	*24*	***30***	*35*
Operating Room	*Hours*	*0.0*	*4*	*5*	*6*
Projected Ancillary Volumes by Observation Patient					
ED Discharge Patients			***188***	***235***	*276*
Laboratory	*Tests*	*1,494.5*	*2,808*	*3,508*	*4,126*
Pharmacy	*Units*	*2,439.3*	*4,583*	*5,726*	*6,734*
General Radiology	*Procedures*	*110.4*	*207*	*259*	*305*
CT Scanner	*Scans*	*47.2*	*89*	*111*	*130*
MRI Scanner	*Scans*	*7.2*	*14*	*17*	*20*
Ultrasound	*Procedures*	*15.2*	*29*	*36*	*42*
Nuclear Medicine	*Procedures*	*261.1*	*491*	*613*	*721*
Operating Room	*Hours*	*5.9*	*11*	*14*	*16*
Projected Ancillary Volumes by Inpatient					
ED Discharge Patients			***1,913***	***2,390***	***2,811***
Laboratory	*Tests*	*3,407.0*	*65,176*	*81,430*	*95,764*
Pharmacy	*Units*	*9,665.6*	*184,900*	*231,013*	*271,679*
General Radiology	*Procedures*	*394.7*	*7,551*	*9,434*	*11,095*
CT Scanner	*Scans*	*86.7*	*1,658*	*2,071*	*2,436*
MRI Scanner	*Scans*	*16.4*	*315*	*393*	*462*
Ultrasound	*Procedures*	*43.9*	*840*	*1,050*	*1,235*
Nuclear Medicine	*Procedures*	*61.2*	*1,170*	*1,462*	*1,720*
Operating Room	*Hours*	*16.7*	*319*	*398*	*468*

"Step 14.

FirstHealth summed the projected FHCH ancillary service volumes for observation, inpatients, and discharge patients, calculated in Step 13, to identify the FHCH ancillary service volumes generated by Emergency Department patients for FY2016 through FY2018.

FHCH Emergency Department
Total Ancillary Volumes
FY2016 — FY2018

	Units	*2016*	*2017*	*2018*
Total Ancillary Service Volumes				
Patients	*Visits*	*10,972*	*13,708*	*16,121*
Inpatients	*Admissions*	*1,913*	*2,390*	*2,811*
Laboratory	*Tests*	*83,537*	*104,371*	*122,744*
Pharmacy	*Units*	*208,311*	*260,263*	*306,077*
General Radiology	*Procedures*	*9,572*	*11,959*	*14,064*
CT Scanner	*Scans*	*3,690*	*4,610*	*5,422*
MRI Scanner	*Scans*	*422*	*527*	*620*
Ultrasound	*Procedures*	*1,618*	*2,022*	*2,378*
Nuclear Medicine	*Procedures*	*1,685*	*2,105*	*2,476*
Operating Room	*Hours*	*334*	*417*	*491*

Even without considering the clear need for ancillary services given the Emergency Department utilization projections, every Emergency Department needs to have these services readily available as part of the basic standard of care for patients presenting to an Emergency Department. In the American College of Emergency Physicians publication, Emergency ***Department Design*** *(pages 163 and 164); imaging, laboratory, and pharmacy services are detailed in their inclusion in the design for Emergency Departments. Furthermore, to be licensed as a hospital in North Carolina, a facility must have at least two acute care beds and ancillary services such as lab, imaging and pharmacy. See 10A NCAC 13B.3201.*

Please refer to Exhibit B for copies of the Emergency Department Design pages."

"Step 6.

Using the sample data pull for FY2008 through FY2010 of 4-County Service Area residents directly admitted to FirstHealth Moore Regional Hospital, FirstHealth calculated the percent of imaging procedures, laboratory tests, and other ancillary volumes by inpatient to identify the 3-year average to apply to future projections.

The following table shows the number, rate, and 3-year average of inpatient surgical hours, imaging procedures, laboratory tests, and other ancillary volumes associated with the direct inpatient admissions to FirstHealth for FY2008 through FY2010 from the 4-County Service Area.

FMRH Direct Admissions from the 4-County Service Area
Ancillary Volumes
FY2008 - FY2010

	Units	*3-YR AVG*	*2008*	*2009*	*2010*
Ancillary Volumes					
Direct Inpatient Admission		*2,833*	*845*	*905*	*1,083*
Laboratory	*Tests*	*66,543*	*22,933*	*20,164*	*23,446*
Pharmacy	*Units*	*247,397*	*82,034*	*79,858*	*85,505*
General Radiology	*Procedures*	*2,810*	*800*	*1,165*	*845*
CT Scanner	*Scans*	*702*	*235*	*232*	*235*
MRI Scanner	*Scans*	*160*	*72*	*48*	*40*
Ultrasound	*Procedures*	*565*	*205*	*169*	*191*
Nuclear Medicine	*Procedures*	*436*	*156*	*169*	*111*
Operating Room	*Hours*	*4,104*	*1,202*	*1,263*	*1,640*
Ancillary Volume Rate					
Direct Inpatient Admission		*2,833*	*845*	*905*	*1,083*
Laboratory	*Tests*	*2,348.9*	*2,714.0*	*2,228.1*	*2,164.9*
Pharmacy	*Units*	*8,732.7*	*9,708.2*	*8,824.1*	*7,895.2*
General Radiology	*Procedures*	*99.2*	*94.7*	*128.7*	*78.0*
CT Scanner	*Scans*	*24.8*	*27.8*	*25.6*	*21.7*
MRI Scanner	*Scans*	*5.6*	*8.5*	*5.3*	*3.7*
Ultrasound	*Procedures*	*19.9*	*24.3*	*18.7*	*17.6*
Nuclear Medicine	*Procedures*	*15.4*	*18.5*	*18.7*	*10.2*
Operating Room	*Hours*	*144.9*	*142.2*	*139.5*	*151.4*

The following table shows the projected number of inpatient surgical hours, imaging procedures, laboratory tests, and other ancillary volumes associated with the direct inpatient admissions for FY2016 through FY2018 using the 3-year average inpatient utilization rates per 100 patients generates. For example, the table shows the 3-year average laboratory tests for discharge patients to be 2,349 laboratory tests per 100 direct inpatient admissions; this can be further simplified to 23 laboratory tests per direct inpatient admission. FirstHealth multiplied the 3-year average ancillary volume per 100 patients by the number of projected direct inpatient admissions divided by 100."

Projected Ancillary Volumes
FY2016 - FY2018

	Units	*3-YR AVG*	*2016*	*2017*	*2018*
Projected Ancillary Volumes					
FY2016-FY2018			*1,000*	*1,400*	*1,800*
Laboratory	*Tests*	*2,348.9*	*23,489*	*32,884*	*42,279*
Pharmacy	*Units*	*8,732.7*	*87,327*	*122,258*	*157,188*
General Radiology	*Procedures*	*99.2*	*992*	*1,389*	*1,785*
CT Scanner	*Scans*	*24.8*	*248*	*347*	*446*
MRI Scanner	*Scans*	*5.6*	*56*	*79*	*102*
Ultrasound	*Procedures*	*19.9*	*199*	*279*	*359*
Nuclear Medicine	*Procedures*	*15.4*	*154*	*215*	*277*
Operating Room	*Hours*	*144.9*	*1,449*	*2,028*	*2,608*

"Step 2.

FirstHealth used outpatient imaging use rates by age and sex per 1000 population that were included in an Imaging Economics, June 2005 article titled ***Radiology 2005: State of the Industry****. The outpatient imaging use rates were developed by National Imaging Associates and represent patients imaged between 2000 and 2004. FirstHealth is using these outpatient imaging use rates because they address the utilization implications of a growing population and a population changing due to the aging of the Baby Boomer Generation. FirstHealth believed it best to utilize this data, even though it is six years old, so that the relatively young population of Hoke County does not impact projected outpatient imaging cases by over projecting them based on the utilization of older residents.*

Please refer to Exhibit A for the Imaging Economics article.

Outpatient Imaging Procedure Use Rates
By Age and Sex

	0-19		*20-44*		*45-64*		*65+*	
	F	*M*	*F*	*M*	*F*	*M*	*F*	*M*
CT Scan	*26*	*28*	*71*	*56*	*132*	*111*	*237*	*251*
Fluoroscopy	*5*	*5*	*18*	*14*	*34*	*26*	*61*	*54*
General Radiology	*256*	*318*	*289*	*281*	*574*	*449*	*1,127*	*933*
Mammography	*3*	*0*	*157*	*0*	*668*	*1*	*568*	*2*
MRI Scan	*18*	*18*	*54*	*44*	*95*	*75*	*103*	*92*
Ultrasound	*18*	*13*	*47*	*22*	*82*	*62*	*127*	*173*

Source: Imaging Economics, June 2005, Radiology 2005: State of the Industry.

NCOSBM Hoke County
Population Projection by Age and Sex

	0-19		20-44		45-64		65+		Total	
	F	M	F	M	F	M	F	M	F	M
2016	87,039	87,566	101,444	101,802	72,443	61,695	36,961	25,297	297,887	276,360
2017	87,882	88,396	101,597	100,954	73,223	62,795	38,090	25,961	300,792	278,106
2018	88,560	89,338	101,695	100,265	73,772	63,836	39,200	26,667	303,227	280,106

Source: NCOSBM, September2010.

Please note: Population breakdowns by age and sex are not available based on the 2010 US Census. The NCOSBM will not be releasing updated age and sex breakdowns until early 2012, as a result FirstHealth is using the most current population breakdowns by age and sex available, which were projected in September 2010.

FirstHealth multiplied the outpatient imaging procedure use rates by age and sex by the NCOSBM Hoke County population projection by age and sex divided by 1,000 to calculate the number of outpatient imaging procedures that a population that mirrors Hoke County's population would generate.

Hoke County Projected Outpatient Imaging Procedures
By Age and Sex

	0-19		20-44		45-64		65+		Total		Total
2016	F	M	F	M	F	M	F	M	F	M	
CT Scan	2,263	2,452	7,203	5,701	9,562	6,848	8,760	6,350	27,788	21,350	49,138
Fluoroscopy	435	438	1,826	1,425	2,463	1,604	2,255	1,366	6,979	4,833	11,812
General Radiology	22,282	27,846	29,317	28,606	41,582	27,701	41,655	23,602	134,837	107,756	242,592
Mammography	261	-	15,927	-	48,392	62	20,994	51	85,574	112	85,686
MRI Scan	1,567	1,576	5,478	4,479	6,882	4,627	3,807	2,327	17,734	13,010	30,744
Ultrasound	1,567	1,138	4,768	2,240	5,940	3,825	4,694	4,376	16,969	11,579	28,548

	0-19		20-44		45-64		65+		Total		Total
2017	F	M	F	M	F	M	F	M	F	M	
CT Scan	2,285	2,475	7,213	5,653	9,665	6,970	9,027	6,516	28,191	21,615	49,806
Fluoroscopy	439	442	1,829	1,413	2,490	1,633	2,323	1,402	7,081	4,890	11,971
General Radiology	22,498	28,110	29,362	28,368	42,030	28,195	42,927	24,222	136,817	108,895	245,711
Mammography	264	-	15,951	-	48,913	63	21,635	52	86,762	115	86,877
MRI Scan	1,582	1,591	5,486	4,442	6,956	4,710	3,923	2,388	17,948	13,131	31,079
Ultrasound	1,582	1,149	4,775	2,221	6,004	3,893	4,837	4,491	17,199	11,755	28,953

	0-19		20-44		45-64		65+		Total		Total
2018	F	M	F	M	F	M	F	M	F	M	
CT Scan	2,303	2,501	7,220	5,615	9,738	7,086	9,290	6,693	28,551	21,896	50,447
Fluoroscopy	443	447	1,831	1,404	2,508	1,660	2,391	1,440	7,173	4,950	12,123
General Radiology	22,671	28,409	29,390	28,174	42,345	28,662	44,178	24,880	138,585	110,127	248,711
Mammography	266	-	15,966	-	49,280	64	22,266	53	87,777	117	87,894
MRI Scan	1,594	1,608	5,492	4,412	7,008	4,788	4,038	2,453	18,132	13,261	31,392
Ultrasound	1,594	1,161	4,780	2,206	6,049	3,958	4,978	4,613	17,401	11,938	29,340

Finally, to remain conservative in its outpatient imaging procedure projections FirstHealth does not project to perform more than 1.5 percent of projected outpatient imaging procedure at FHCH. The following tables show a ramped up outpatient imaging service increasing from 0.5 percent in FY2016 to 1.5 percent in FY2018.

FHCH Outpatient Imaging Procedures
FY2016-FY2018

Projected Hoke County Imaging Procedures				
	2016	*2017*	*2018*	
CT Scan	*49,138*	*49,806*	*50,447*	
Fluoroscopy	*11,812*	*11,971*	*12,123*	
General Radiology	*242,592*	*245,711*	*248,711*	
Mammography	*85,686*	*86,877*	*87,894*	*A*
MRI Scan	*30,744*	*31,079*	*31,392*	
Ultrasound	*28,548*	*28,953*	*29,340*	

FHCH Market Share	*0.5%*	*1.0%*	*1.5%*	*B*

Projected FHCH County Imaging Procedures				
	2016	*2017*	*2018*	
CT Scan	*246*	*498*	*757*	
Fluoroscopy	*59*	*120*	*182*	
General Radiology	*1,213*	*2,457*	*3,731*	*C*
Mammography	*428*	*869*	*1,318*	
MRI Scan	*154*	*311*	*471*	
Ultrasound	*143*	*290*	*440*	

Source: C = A x B

Projected utilization of the proposed ancillary services is based on projected utilization of the proposed emergency department, acute care beds, and operating rooms. As discussed above, projected utilization for each of those service components is not based on reasonable, credible and supported assumptions. Therefore, projected utilization of the ancillary services is not based on reasonable, credible and supported assumptions. Consequently, the applicant does not adequately demonstrate the need for the proposed ancillary services.

Need for the proposed 65-bed hospital in Hoke County in addition to approved 41-bed hospital

As noted in the discussion above, FHCH predicates the need for its proposed 65-bed hospital in McLauchlin Township, Hoke County on Hoke County not having a hospital. However, two hospitals have already been approved to be developed in McLauchlin Township, Hoke County.

If both of the 2010 conditional approvals are upheld on appeal and the hospitals constructed, Hoke County would have 2 hospitals, both located in McLauchlin Township, with a combined total of 49 acute care beds (including 4 ICU beds and 16 obstetrical beds), 3 shared operating rooms, a dedicated C-Section operating room and 2 emergency departments with a total of 24 treatment rooms. In addition, both hospitals would offer diagnostic imaging, laboratory, pharmacy and rehabilitation services.

The applicant stated that the most appropriate location in the Cumberland-Hoke Acute Care Bed Service Area was in McLauchlin Township, Hoke County. The approved location for the 41-bed hospital is in McLauchlin Township, Hoke County. The approved locations for the 41-bed hospital and the 8-bed hospital are both on US route 401, approximately 3.5 miles apart. The 65-bed hospital would be located on the same site as the approved 8-bed hospital but the 8-hospital would not be developed if the 65-bed hospital is approved.

The applicant does not adequately demonstrate that 106 acute care beds [41 + 65 = 106] are needed in Hoke County. The following table illustrates this point.

A	Total # Hoke County residents admitted to an acute care bed 2010*	3,981
B	Average Length of Stay*	4 days
C = A x B	Total Acute Care Patient Days*	15,925
D = C/365	Average Daily Census	43.63
E = D/0.667	# Acute Care Beds Needed at 66.7% Target Occupancy	65.4
F	Total # acute care beds (approved and proposed)	106
G	(Surplus) Deficit	(40.6)

*From Section IV.1, page 198. The applicant states it assumes no growth in the number of Hoke County inpatients.

As shown in the table above, based on the applicant's assumptions about the total number of acute care patient days to be provided to residents of Hoke County, only 65 acute care beds are needed assuming 100% of Hoke County residents were to utilize a hospital located in Hoke County, which is unlikely since none of the proposed or approved Hoke County hospitals would provide all the services available at a tertiary hospital like FMRH or CFVMC (Owen Drive). For example, neither the approved hospitals nor the proposed hospital propose to provide cardiac catherization, open heart or neurosurgical services.

The applicant did not adequately demonstrate the need for a 65-bed hospital in Hoke County in addition to the approved 41-bed hospital.

Analysis of Need

For all the following reasons and the reasons discussed above, FHCH does not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions:

- Projected utilization of the emergency department is based on two factors: 1) patients who currently utilize the existing emergency department at FMRH are expected to "shift" to the emergency department at FHCH based on proximity. However, the applicant did not provide adequate documentation that existing FMRH emergency department patients from Cumberland and Scotland counties would, in fact, live closer to the FHCH emergency department. In addition, the applicant did not adequately demonstrate that it took into account that Cumberland County residents would have to drive by the emergency department at the approved 41-bed hospital to go to FHCH; and 2) increasing its market share of the emergency department visits generated from the proposed service area. However, the applicant did not adequately demonstrate that it took into account the impact of the approved 41-bed hospital in McLauchlin Township, Hoke County located on the same transportation corridor between the proposed 65-bed hospital and Cumberland County.

- In the methodologies used by the applicant, emergency room visits are integral to projected utilization for all of the other service components.

- Projected utilization for the acute care beds, operating rooms, imaging and ancillary services is all predicated on, at least in part, projected emergency room visits, thus projected utilization for those service components is also not based on reasonable, credible or supported assumptions.

- Pursuant to the Criteria and Standards for Acute Care Beds promulgated in 10A NCAC 14C .3803 Performance Standards, the applicant must demonstrate that the average annual occupancy for the proposed 65 acute care beds will be at least 66.7 percent in the third operating year. The applicant projects an average annual occupancy of 66.9 percent [(15,879 days of care)/ (65 beds x 365 days) x 100 = 66.9%] in the third operating year. See Section II.8, page 119. If the number of acute care days is just 149 fewer days than projected, the average annual occupancy for the 65 acute care beds would be only 66.3% [15,730 days of care) / (65 x 365 days) x 100 = 0.663 or 66.3%], which is not consistent with the rule.

- For the purposes of projecting utilization of acute care beds, operating rooms, imaging and ancillary services, the applicant divided projected emergency room visits into Levels I – V. Level I visits have the lowest acuity and Level V visits have the highest acuity. The higher the acuity level, the greater the need for additional ancillary services or the likelihood of being admitted to an acute care bed. See Section IV.1, pages 185-190. There are two issues with this approach: 1) the applicant provided three years worth of data from FMRH but only used the most recent year, 2010. The percentage of Level V emergency department visits for 2010 was much higher than the two previous years: 2010-19.4%; 2009-5.1%; 2008-3.2%. The applicant neither offered an explanation for this difference nor provided justification for using the Level V percentage from 2010 as opposed to say a three year average. 2) The applicant utilized the experience of the

emergency department at FMRH to project for FHCH. However, FMRH is a tertiary hospital offering services (see application pages 23-26) that FHCH will not be offering. The applicant did not adjust in any discernable way for the differences in acuity level for the emergency room visits that FMRH is capable of handling versus what FHCH would have the ability to handle.

- Projected acute care admissions are based, in part, on projected emergency department visits and on the Level of emergency department visit. The percentages for those Levels are based on the experience at FMRH. The applicant does not adequately demonstrate that any acuity adjustment was made. However, FMRH is a tertiary hospital and FHCH will not be a tertiary hospital. Therefore, those projected acute care admissions are not based on reasonable, credible and supported assumptions.

- In addition, a portion of projected inpatient admissions are based on anticipated physician referrals. In Section IV.1, page 195, the applicant projects that 900 residents from Cumberland County will be admitted in the third operating year (2018) Physician support letters are found in Exhibit U. However, only 4 or 5 of the physicians who provided letters of support are appear to be located in Cumberland County. In addition, the letters of support do not specifically state that the physician has patients from Cumberland County who they would then refer to FHCH. Based on the absence in the other letters of a statement that patients from Cumberland County would be referred to FHCH, the assumption that 900 Cumberland County residents would be admitted in 2018 is not adequately supported.

- As illustrated in the table on page 113 of the findings, which is based on data from page 198 of the FHCH application, the applicant did not demonstrate a need for 106 acute care beds (41 + 65 = 106) in Hoke County.

- The applicant proposes to offer obstetrical services, including three LDRP beds. However, the applicant does not propose a Level I nursery, including unlicensed bassinets. According to the Acute and Home Care Licensure and Certification Section, DHSR, FHCH would be required to develop a Level I nursery. Without the projected obstetrical days of care, FHCH would not meet the performance standard in 10A NCAC 14C .3803.

- The applicant converts the number of inpatients into "days of care" to determine the number of LDRP days of care, the number of ICU days of care and the occupancy rate for the acute care beds. The applicant states *"The inpatient percentages and days of care by service area are* [i.e., LDRP or ICU] *based on FirstHealth's experience in providing these services at three acute care hospitals."* See page 201 of the application. One of those hospitals is FMRH which is a tertiary hospital offering additional services which will not be offered at FHCH. For ICU patients the applicant does not adequately demonstrate that it

made adjustments for the difference in acuity levels at FMRH versus FHCH. With no adjustment for the difference in acuity levels, assumptions with respect to the LDRP and ICU percentages are not reasonable, credible or supported.

In summary, the applicant does not adequately demonstrate the need for its proposal and the application is nonconforming with this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C
CFV North
FHCH

CFV North. CFV North proposes to relocate two shared operating rooms from Highsmith Rainey Specialty Hospital (HRSH) to CFV North. HRSH is long term acute care hospital operated by CFVHS, licensed for four shared surgical operating rooms. The applicant is already approved to relocate one HRSH operating room to HCMC pursuant to the conditional approval of Project ID # N-8499-10. That decision is currently under appeal. Upon completion of this project and Project ID # N-8499-10, HRSH would be licensed for one shared operating room.

In Section III.6(d), pages 153-154, the applicant states

"CFV North will result in a shift of inpatient days from CFVMC as discussed above. Projected patient days which will shift from CFVMC are reflected in Exhibit 33, Table 39.

In addition, the Applicant is relocating existing operating rooms from HRSH to CFV North. CFVMC reviewed existing surgical utilization at HRSH and determined that the current patient origin supports the relocation of one operating room to HCMC as approved in Project I.D. # N-8499-10, and two operating rooms to CFV North. The following table illustrates this shift in volume and resulting need for only one operating room at HRSH in the future.

Proposed Shift in HRSH Surgical Volumes

HRSH Surgical Volumes	*FFY 2010*
Total Outpt Surgery	*2,768*
HRSH Outpt Volume Shifted to HCMC	*614*
HRSH Outpt Volume Shifted to CFV North	*572*
Remaining Outpt	*1,582*
Inpatient Volume	*66*
Weighted Inpt+ Outpt (SMFP Time per Case)	*2,571.5*
ORs Needed	*1.4*
Weighted Inpt + Outpt (Actual Time per Case per 2010 LRA)	*2,220.8*
ORs Needed	*1.2*

Source: Exhibit 33, Table 51

As reflected in the previous table, after outpatient surgical volumes for patients living closer to the CON approved HCMC and the proposed CFV North community hospitals shift to those respective facilities, the remaining surgical volume at HRSH is sufficient to justify the need for only one operating room. This result is the same when calculating operating room need for HRSH using either the time per case for inpatient and outpatient cases as defined in the annual SMFP, or using the time per case for inpatient and outpatient case reported in the HRSH annual Licensure Renewal Application."

In Section III.6, page 101, the applicant provides projected utilization of the one shared operating room at HRSH in the first three operating years of the project, as shown in the table below.

HRSH
Projected Utilization Operating Rooms
October 2010 — September 2017

	FFY 2010 - (actual)	FFY 2011 (projected)	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Inpatient Surgical Cases	66	66	66	66	66	66	66	66
Outpatient Surgical Cases	2,768	2,768	2,768	2,768	2,308	1,817	1,668	1,582
Weighted Surgical Hours **	3 822	3 822	3 822	4 350	3 659	2 924	2 700	2,571
ORs Needed at 1,872 Hours per OR per year	2.0	2.0	2.0	2.3	2.0	1.6	1.4	1.4

Source: Exhibit 33, Table 50
*Projected volumes are adjusted for surgical cases to be shifted to CFV North and HCMC.
**3 hours per inpatient surgical case and 1.5 hours per outpatient surgical case.

As shown in the table above, the applicant projects that the one remaining operating room at HRSH will provide adequate capacity to meet projected utilization of surgical services at HRSH in the third year of operation (FY2017) following completion of the proposed project.

In summary, the applicant demonstrated that the needs of the population presently served at HRSH will be adequately met following the relocation of two operating rooms to CFV North.

Therefore, the application is conforming to this criterion.

FHCH. The applicant proposes to relocate two operating rooms from FMRH in Moore County to FHCH in Hoke County. FMRH is currently licensed for 16 operating rooms.

In Section III.6(d), page 171, the applicant states

"It is FirstHealth's desire to decrease the number of inpatients and Emergency Department visits originating from Hoke County residents who travel outside of Hoke County to Pinehurst or Fayetteville for healthcare services, With the development of FHCH in Hoke County and the associated inpatient, surgical, ancillary and support services, FirstHealth believes that Hoke County residents will not bypass a fully-staffed and operational hospital in Hoke County to travel to a hospital outside of Hoke County."

In Section III.7(c), page 173, the applicant states that FMRH has a surplus of operating rooms.

"Using the Operating Room need methodology in the 2011 SMFP to determine 2010 operating room need at FMRH, FMRH calculated a 2010 surplus of 2.5 operating rooms, prior to the licensing of the two converted GI endoscopy rooms, This number was calculated as follows:

- *[((6,360 IP cases x 3.0 hours) + (4,183 OP cases x 1.5 hours)) /1,872) = 13.5 operating rooms]*
- *[16.0 operating rooms - 13.5 operating rooms = 2.5 operating rooms]*

As a result, FMRH would decrease its 2011 operating room surplus to 0.5 operating rooms, through the relocation of two (2) existing operating rooms to Hoke County."

The applicant states that the relocation of the two operating rooms would not have a negative impact on the patients currently served in terms of changes in services, costs to the patients or level of access by medically underserved populations.

"No negative impact will occur. In fact, FMRH fully expects to expand its treatment of the medically underserved in the future because of existing economic and social conditions of Hoke County and surrounding counties, FMRH will have an adequate number of operating rooms after the relocation. FMRH does not plan any increase in cost to the patient, through non-inflation related charge increases, and fully expects both its charity care and bad debt

expenses to increase into the future. As calculated in 10A NCAC .2102(c)(5), Step 4, FMRH's 16 operating rooms will be utilized at 65.7 percent."

As indicated above, the applicant projects that the 14 operating rooms remaining at FMRH after relocating two to FHCH will provide adequate capacity to meet projected utilization of surgical services at FMRH in the third year of operation (2017) following completion of the proposed project.

In summary, the applicant demonstrated that the needs of the population presently served will be adequately met following the relocation of two operating rooms to the proposed facility in Hoke County. Consequently, the application is conforming with this criterion.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC
CFV North
FirstHealth

CFV North. In Section III.3, pages 143-145, the applicant describes the alternatives it considered prior to the submission of its application which include: maintain the status quo; add 65 new acute care beds to CFVMC; add new acute care beds to CFVMC and HRSH; convert HRSH back to an Acute Care Hospital; and construct a community hospital in North Cumberland County.

However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (13b), (18a), (20), 10A NCAC 14C .3800 and 10A NCAC 14C .2100 for discussion. Therefore, the applicant did not adequately demonstrate that its proposal is the least costly or most effective alternative and the application is nonconforming to this criterion.

FHCH. In Section III.3, pages 153-165, the applicant describes the alternatives it considered prior to the submission of its application which include: 1) Do not submit CON application because of CFVMC's approved 41-bed hospital in Hoke County; 2) Expand FMRH; 3) Joint venture any proposed project; 4) Develop a combined urgent care center/diagnostic center in Moore County; 5) Develop a combined urgent care center/diagnostic center in Hoke County; 6) Develop urgent care center at FirstHealth Family Care Center – Raeford; 7) Develop diagnostic center at FirstHealth Family Care Center – Raeford; 8) Develop a freestanding Emergency Department in Moore County; 9) Develop a freestanding Emergency Department in Hoke County; 10) Develop a Critical Access Hospital in Hoke County; 11) Develop an acute care hospital in Hoke County; 12) Develop a larger Emergency Department; 13) Develop a smaller Inpatient Unit; 14) Develop a larger Surgical Services; 15) Locate proposed hospital on FirstHealth - Raeford

campus; 16) Locate proposed hospital another location in Hoke County; and 17) Acquire less land for the project.

However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (7), (8), (18a), 10A NCAC 14C .3800, 10A NCAC 14C .1200, 10A NCAC 14C .2100, 10A NCAC 14C .2300, and 10A NCAC 14C .1400 for discussion. Therefore, the applicant did not adequately demonstrate that its proposal is the least costly or most effective alternative and the application is nonconforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C
CFV North

NC
FHCH

CFV North. In Section VIII.1, page 197, the applicant states the total capital cost of the project will be $87,332,825. In Section IX, page 202, the applicant projects it will incur $1,050,650 in start-up expenses and $8,405,202 in initial operating expenses, for total working capital of $9,455,853 for the proposed project. In Section VIII.3, page 198, the applicant states that the total capital cost of the project will be financed with a tax-exempt bond issue. In Section IX.2, page 277, the applicant states that the working capital needs of the project will be financed with the accumulated reserves of Cumberland County Hospital System, Inc. Exhibit 4 contains a letter from the Managing Director of BB&T's Capital Markets, dated May 24, 2011, which states:

> *"BB&T Capital Markets, Healthcare Finance Group (BB&T) understands that Cumberland County Hospital System, inc.* [sic], *d/b/a Cape Fear Valley Health System ("CFVHS") is applying for a Certificate of Need ("CON') for construction of a new hospital in Cumberland County (the "Project"). It is our understanding that the intent is to fund part of the Project with $87 million of tax-exempt bond proceeds.*
>
> *Based upon review to date of relevant documents and materials, we believe that it is reasonable to assume all necessary approvals required for the issuance of hospital revenue bonds can be obtained. Based upon CFVHS's finances, BB&T would expect to underwrite a publicly sold tax-exempt issue that would be issued with CFVHS's stand-alone ratings. We*

believe that this funding would result in an investment grade rating for the financing. We anticipate that the proposed bond issue would have a 30 or 35 year final maturity and could be issued at an average interest cost that would not be expected to exceed 7.5% and would likely be closer to 6.0% in the current market."

In Section VIII.3, page 198, the applicant states the bond issue will be in the amount of $86,470,000. The sale will also generate another $862,825 in net premium. The Managing Director rounded up the amount of the bond issue ($86,470,000 rounds to $87 million) and does not mention the net premium. Regardless, the letter is sufficient documentation to support a conclusion that the applicant will be able to obtain the proposed bond financing.

Exhibit 4 also contains a letter from the Chief Financial Officer of Cumberland County Hospital System, Inc., dated June 15, 2011, which states

"Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System ("CFVHS"), intends to file a CON application to build a 65-bed acute care satellite hospital in Northern Cumberland County, called Cape Fear North Hospital. This letter is to confirm the availability of funding sufficient to cover the capital and operating needs of that project and CFVHS's commitment to provide that funding.

Specifically, the Cape Fear Valley North Hospital Application includes total capital costs of $87,332,825 including project costs, funding deposits, and financing costs to be financed through tax-exempt bond proceeds. Additionally, the Application projects a need for start-up and initial operating expenses of $9,455,853 during the period prior to operation and sixty days subsequent to opening the new facility. These expenses would be funded through accumulated reserves of CFVHS.

Attached are copies of our two most recent audited financial statements for the fiscal years ending 9/30/09 and 9/30/10. As you will note the Balance Sheet contains "Cash and Cash Equivalents and Short Term Investments" in excess of the above projected accumulated reserves which are available for this project. Additionally, these funds can be made available for this project should capital and operating needs exceed the projected amounts."

Exhibit 5 contains the audited financial statements for Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System which shows, on page 8 of the exhibit, $67,262,000 in Cash and Cash Equivalents, $41,841,000 in Short-term investments, and Total Net Assets of $341,918,000 of as of September 30, 2010. CFV North adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project.

In the projected revenue and expense statements for CFV North (Form B), the applicant projects revenues will exceed operating expenses in the third operating year of the project, as shown in the table below

	First Full FY (10/1/14 – 9/30/15)	Second Full FY (10/1/15 – 9/30/16)	Third Full FY (10/1/16 – 9/30/17)
Gross Patient Revenue	$185,842,241	$226,253,599	$286,072,419
Deductions from Gross Patient Revenue	$139,129,399	$170,543,091	$217,102,007
Net Patient Revenue	$46,712,842	$55,710,508	$68,970,412
Other Revenue	$3,408,531	$3,844,465	$4,591,217
Total Revenue	$50,121,373	$59,554,973	$73,561,629
Total Expenses (Direct and Indirect)	$54,534,922	$61,676,344	$71,674,826
Net Income	($4,413,549)	($2,121,371)	$1,886,803

The Gross Patient Revenue and the Total Expenses set forth in Form B for the third project year of CFV North are supported by the Gross Patient Revenue and the Total Expenses set forth in the Form Cs for the individual service components as illustrated in the tables below.

Third Full FY: (10/1/16 – 9/30/17)
Gross Patient Revenue

	Form B- Gross Patient Revenue	Form C- Gross Patient Revenue	Difference
Inpatient Medical and Surgical Services		$127,098,478	
Outpatient Emergency Department Services		$97,939,764	
Outpatient Surgery		$25,957,884	
Outpatient Observation Services		$4,828,304	
Other Outpatient Services		$30,247,988	
Total	$286,072,419	$286,072,419	($0)

Third Full FY: (10/1/16 – 9/30/17)
Total Expenses

	Form B- Total Expenses	Form C- Total Expenses	Difference
Inpatient Medical and Surgical Services		$30,824,964	
Outpatient Emergency Department Services		$18,527,630	
Outpatient Surgery		$9,539,598	
Outpatient Observation Services		$2991,038	
Other Outpatient Services		$9,791,595	
Total	$71,674,826	$71,674,825	($1)

The assumptions used by the applicant in preparation of the pro forma financial statements provided in the application are reasonable, including projected utilization. See Criterion (3) for discussion of projected utilization. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is conforming to this criterion.

FHCH. In Section VIII.1, page 271, the applicant states the total capital cost of the project will be $81,397,816. In Section IX, page 277, the applicant projects it will incur $1,476,908 in start-up expenses and $8,250,000 in initial operating expenses, for total working capital of $9,726,908 for the proposed project. In Section VIII.3, page 272, the applicant states that the total capital cost of the project will be financed with the accumulated reserves of FirstHealth of the Carolinas, Inc. In Section IX.2, page 277, the applicant states that the working capital needs of the project will be financed with the unrestricted cash of FirstHealth of the Carolinas. Exhibit P contains a letter from the Chief Financial Officer of FirstHealth of the Carolinas, dated June 13, 2011, which states:

> *"FirstHealth of the Carolinas, Inc. will provide $81,397,816 through Accumulated Reserves (Assets Limited as to use: Internally Designated for Capital Projects) to fund the land acquisition and development of the proposed FirstHealth Hoke Community Hospital in Hoke County. Please accept my assurance that the anticipated $81,397,816 will be paid from these designated funds for the project.*
>
> *FirstHealth of the Carolinas, Inc. will provide $9,726,908 through Accumulated Reserves (Current Assets: Cash and Cash Equivalents) to fund the working capital for the proposed FirstHealth Hoke Community Hospital in Hoke County.*
>
> *Please accept my assurance that the anticipated $9,726,908 will be paid from these designated funds for this project."*

Exhibit Q contains the audited financial statements for FirstHealth of the Carolinas, Inc. and Affiliates which shows $292,769,000 in Assets Limited As to Use: Internally Designated for Capital Projects and $49,370,000 in Cash and Cash Equivalents and Total Net Assets of $499,182,000 of as of September 30, 2010.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

In the projected revenue and expense statement for FHCH (Form B), the applicant projects revenues will exceed operating expenses in the third operating year of the project, as shown in the table below.

	First Full FY (10/1/15 – 9/30/16)	Second Full FY (10/1/16 – 9/30/17)	Third Full FY (10/1/17 – 9/30/18)
Gross Patient Revenue	$104,188,815	$141,938,811	$179,800,714
Deductions from Gross Patient Revenue	$74,580,490	$101,621,850	$128,744,415
Net Patient Revenue	$29,608,325	$40,316,961	$51,056,299
Other Revenue	-na-	-na-	-na-
Total Revenue	$29,608,325	$40,316,961	$51,056,299
Total Expenses (Direct and Indirect)	$35,370,358	$42,461,581	$49,034,661
Net Income	($5,762,033)	($2,244,620)	$2,021,638

However, the Gross Patient Revenue and the Total Expenses set forth in Form B for the third project year of FHCH are not supported by the Gross Patient Revenue and the Total Expenses set forth in the Form Cs for the individual service components as illustrated in the tables below.

Third Full FY: (10/1/17 – 9/30/18)
Gross Patient Revenue

	Form B- Gross Patient Revenue	Form C- Gross Patient Revenue	Difference
Inpatient Department (Med/Surg, Peds, Gyn)		$90,811,479	
Surgical Department		$32,953,605	
Emergency Department		$22,136,715	
Inpatient Department (ICU)		$22,755,388	
LDRP**	?????	?????	
Imaging Department		$8,278,956	
Total	$179,800,714	$176,936,142	($2,864,571)

**In addition, there is a cover page for Form C for the LDRP Department on page 342 of the application however, there is no Form C for the LDRP Department.

Third Full FY: (10/1/17 – 9/30/18)
Total Expenses

	Form B- Total Expenses	Form C- Total Expenses	Difference
Inpatient Department (Med/Surg, Peds, Gyn)		$13,732,352	
Surgical Department		$6,451,862	
Emergency Department		$4,288,184	
Inpatient Department (ICU)		$4,104,744	
LDRP**	?????	?????	?????
Imaging Department		$4,593,853	
Total	$49,034,661	$33,170,995	($15,863,666)

**In addition, there is a cover page for Form C for the LDRP Department on page 342 of the application however, there is no Form C for the LDRP Department.

As shown in the tables above, the applicant provided a cover page for a Form C for the LDRP beds but did not provide a Form C. The project analyst is unable to determine if the differences between the Form C's and Form B are "explained" by the absences of a Form C for the LDRP beds.

Furthermore, projected utilization in each of the first three operating years is unsupported and unreliable. Consequently, costs and revenues which are based on that utilization are also unsupported and unreliable. See Criterion (3) for discussion of projected utilization. As a result, the applicant did not adequately demonstrate that the financial feasibility of the proposed project is based on reasonable projections of costs and revenues. Consequently, the application is nonconforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C
CFV North

NC
FHCH

CFV North. The 2011 State Medical Facilities Plan (2011 SMFP) includes an Acute Care Bed Need Determination for 65 additional acute care beds in the Cumberland Hoke Multi County Acute Care Bed Service Area. The applicant proposes to develop 65 acute care beds in Cumberland County. The applicant does not propose to develop more acute care beds than are determined to be needed in the service area. The applicant adequately demonstrates the need for its proposal. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

FHCH. The 2011 State Medical Facilities Plan (2011 SMFP) includes an Acute Care Bed Need Determination for 65 additional acute care beds in the Cumberland Hoke Multi County Service Area. The applicant proposes to develop 65 acute care beds in Hoke County. The applicant does not propose to develop more acute care beds than are determined to be needed in the service area. However, the applicant does not adequately demonstrate that its proposal would not result in unnecessary duplication of existing or approved health services or health service facilities. Specifically, there are two approved hospitals in Hoke County with a total of 49 acute care beds, 4 operating rooms (including 3 shared and 1 C-Section) and 2 emergency departments. If this proposal were to be approved, the 8-bed hospital would not be developed and there would be two hospitals with a total of 106 acute care beds, 5 operating rooms (including 4 shared and 1 C-Section) and 2 emergency departments. FHCH does not adequately demonstrate the need to develop the proposed 65-bed hospital in Hoke County in addition to the approved 41-bed hospital and 8-bed hospital in Hoke

County. See Criterion (3) for additional discussion. Therefore, FHCH does not adequately demonstrate its proposal would not unnecessarily duplicate the approved 41-bed acute care hospital.

Consequently, the application is not conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C
CFV North

NC
FHCH

CFV North. In Section VII, page 187, and Exhibit 36, the applicant projects a total of 329.2 full-time equivalent (FTE) positions at CVF North in the second full operating year of the proposed project. In Section VII.6, pages 191-193, the applicant describes its experience and procedures for recruiting and retaining personnel. In Section V.5(c), page 172, the applicant identifies Dr. Eugene Wright, as the Vice President and Chief Medical Officer of CFVHS who will "*provide executive medical leadership for the proposed hospital.*" Dr. Divyang Patel is identified as the current Chief of Medical Staff at CFVHS and Exhibit 26 contains a letter from Dr. Patel stating that *"I serve as Chief of Staff of the Cape Fear Valley Health System and will continue in this capacity with the addition of the new satellite facility in northern Cumberland County."* Exhibit 26 also contains letters from other physicians expressing their support of CFV North and their willingness to refer patients to CFV North. In Section V.3, pages 166-173, and Section V.4, pages 173-175, the applicant describes efforts to develop relationships with local physicians and physicians who have expressed support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and administrative personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

FHCH. In Section VII, page 256, and Exhibit L, the applicant projects a total of 338.4 FTE positions at FirstHealth in the second full operating year of the proposed project. In Section VII.6, pages 259-262, the applicant describes its experience and procedures for recruiting and retaining personnel. In Section VII.8, page 267, the applicant identifies Daniel Barnes, DO as the Chief of Staff/Medical Director for FirstHealth, and Exhibit F contains a letter indicating Daniel Barnes, DO's agreement to serve as the Medical Director of FirstHealth. Exhibit U also contains letters from other physicians expressing their support of FirstHealth and their willingness to refer patients to FirstHealth. In Section V.3, p.214, and Section V.4, pages 215-217 the applicant both describes efforts to develop relationships with

local physicians and physicians who have expressed support for the proposed project.

However, the applicant proposes to offer obstetrical services, including three labor, delivery, recovery, post-partum (LDRP) beds. According to the Acute and Home Care Licensure and Certification Section, DHSR, FirstHealth would be required to develop a Level I nursery, including unlicensed bassinets. However, the applicant did not propose a Level I nursery. Pursuant to 10A NCAC 14C. 1405(1), the applicant is required to demonstrate that: a) nursing care shall be supervised by an RN in charge of perinatal facilities; and b) a physician is designated to be responsible for neonatal care. FHCH does not adequately demonstrate that its proposal would meet these requirements. The applicant does not adequately demonstrate the availability of the staff required to provide neonatal services. Therefore, FHCH does not adequately demonstrate the availability of sufficient health manpower and administrative personnel for the provision of the proposed services. Thus, the application is nonconforming with this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C
CFV North

NC
FHCH

CFV North. In Section II.2, pages 24-29, the applicant describes the necessary ancillary and support services for the proposed services that will be provided at the proposed hospital. Exhibit 43 contains a letter from the Chief Operating Officer of CFVHS, which states "*In my capacity as Chief Operating Officer, I am responsible to assure that for all the key services that will be offered at the new satellite acute care hospital in northern Cumberland County – the necessary hospital-based clinical and non-clinical ancillary and support services – will be available 24 hours per day, 7 days per week.*" In Section V.2, page 166, the applicant provides a list of healthcare facilities with which CFVHS currently has transfer agreements. Exhibit 40 contains both a draft transfer agreement between CFVHS and CFV North and an example of an existing CFVHS transfer agreement. Exhibit 26 contains letters from physicians supporting the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system and that the necessary ancillary and support services will be available. Therefore, the application is conforming to this criterion.

FHCH. In Section II.2, pages 51-52, the applicant states that the majority of the necessary ancillary and support services for the proposed services will be provided at the proposed hospital, and a few support services will be provided through service agreements with FMRH. In Exhibit 6 the applicant provides letters from the Interim Chief Nursing Officer and the Chief Financial Officer of FirstHealth of the Carolinas, Inc. documenting provision of pharmaceutical services and that *"the necessary ancillary and support services required to operate an acute care hospital will be provided at FirstHealth Hoke Community Hospital through either hospital staff or provided by FirstHealth corporate services through a Services Agreement."* The letter from the Chief Financial Officer documents the ancillary and support services that will be provided through a service agreement. In Section V.2, page 212, the applicant states, *"Transfer agreements currently exist between FMRH and the provider facilities listed. FirstHealth will arrange for these agreements to extend to FHCH.*

- *Womack Army Medical Hospital*
- *Scotland Memorial Hospital*
- *UNC Hospitals"*

Exhibit D contains copies of correspondence from FirstHealth to arrange transfer agreements with FHCH with the following hospitals

- FirstHealth Moore Regional Hospital
- Cape Fear Valley Medical Center
- Womack Army Medical Hospital
- Scotland Memorial Hospital
- Southeast Regional Medical Center

Exhibit U contains letters of physician support for the proposed project. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system.

However, the applicant proposes to offer obstetrical services, including three LDRP beds. According to the Acute and Home Care Licensure and Certification Section, DHSR, FHCH would be required to develop a Level I nursery, including unlicensed bassinets. However, the applicant did not propose a Level I nursery. Pursuant to 10A NCAC 14C .1404(1),(2),(3) and (6) the applicant is required to demonstrate: (1) competence to manage uncomplicated labor and delivery of normal term newborn; (2) capability of continuous fetal monitoring; (3) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother; and (6) capability of cesarean section within 30 minutes at any hour of the day. Furthermore, pursuant to 10A NCAC 14C .1405 (4) and (5) the applicant is required to: (4) submit documentation which demonstrates the availability of appropriate in-service training or continuing

education programs for neonatal staff; (5) submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home. FHCH does not adequately demonstrate that its proposal would meet these requirements. FHCH does not adequately demonstrate provision all necessary ancillary and support services. Thus, the application is nonconforming with this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:(i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C
CFV North

NC
FHCH

CFV North. The applicant proposes to add 138,457 square feet to an existing 51,267 square foot building and renovate 10,973 square feet of the existing building. In Exhibit 10, the architect certifies that the total construction cost is estimated to be $44,372,384 and site preparation costs are estimated to be $3,838,732. These costs are consistent with the costs reported by the applicant in Section VIII.1, page 197. In Section XI.7, page 210, and Exhibit 10, the applicant describes the applicable energy savings features will be incorporated into the plans. See Criterion (1) for additional discussion. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project it proposes, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

FHCH. The applicant proposes to construct a new four-story, 65-bed community hospital with 160,092 square feet of space. In Exhibit R, the engineer certifies that the total construction cost is estimated to be $52,376,707. This cost is consistent with the costs reported by the applicant in Section VIII.1, page 271. In Section XI.7, page 291, the applicant states that applicable energy savings features will be incorporated into the plans and lists specific methods that will be incorporated into the design of the facility to maintain energy operations and contain costs of utilities. Exhibit S contains a copy of the mechanical, plumbing, and electrical system narratives.

However, the applicant proposes to offer obstetrical services, including three LDRP beds. According to the Acute and Home Care Licensure and Certification Section, FHCH would be required to develop a Level I nursery, including unlicensed bassinets. The design schematic does not show a Level I nursery. In response to written comments, FHCH states *"FHCH is not... proposing to develop a Level I nursery ... there is no nursery ... proposed."* However, a Level I nursery would be required to obtain a hospital license. Therefore, the applicant did not adequately demonstrate that the cost and design represents the most reasonable alternative for the project it proposes. The design schematics would have to be changed. The application does not contain sufficient information for the Project Analyst to determine the impact on the capital cost. The applicant is required to include in its application sufficient information to show it conforms with all applicable statutory and regulatory review criteria. FHCH did not do this with regard to the cost and design of the proposed 65-bed hospital. Consequently, the application is nonconforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of

priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C
CFV North
FHCH

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of CY2008-2009. The data in the table was obtained November 14, 2011. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)**
County			
Cumberland	18%	7.4%	20.3%
Harnett	17%	6.2%	20.3%
Sampson	25%	10.1%	24.0%
Hoke	19%	6.9%	21.9%
Robeson	31%	13.2%	23.9%
Scotland	30%	12.9%	21.5%
Statewide	17%	6.7%	19.7%

*Source: DMA Website: http://www.ncdhhs.gov/dma/pub/index.htm

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the inpatient services offered by acute care hospitals.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and

older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of November 14, 2011 no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The following tables show the average inpatient utilization (admissions) for acute general hospitals by payer category for North Carolina and Cumberland County. (The data includes normal newborns.) Hoke County does not have an existing hospital. For North Carolina, data are based on 1,113,423 inpatient admissions. For Cumberland County, data are based on 35,956 inpatient admissions.

North Carolina Hospital Admissions by Payer Category-FY2009

Payer Category	Percent of Total
Commercial/HMO	32.9%
Medicare	36.0%
Medicaid	21.9%
Other	3.1%
Uninsured	6.1%
Total	**100.0%**

Source: Cecil B. Sheps Center for Health Services Research

Cumberland County Hospital Admissions by Payer Category-FY2009

Payer Category	Percent of Total
Commercial/HMO	20.4%
Medicare	35.7%
Medicaid	29.8%
Other-Gov.	8.0
Other	0.2%
Uninsured	6.0%
Total	**100.0%**

Source: Cecil B. Sheps Center for Health Services Research

CFV North. In Section VI.12, page 183, the applicant states CFV North is not an existing facility, and therefore does not have any historical payer mix experience. However, in Section VI.12, page 183, the applicant provides the payer mix during FY2010 for all services provided at CFVMC, as illustrated in the table below.

CFVMC
Last Full Fiscal Year- FY2010

Payer Category	Patient Days as % of Total Utilization
Self Pay/ Indigent	4.0%
Medicare	51.3%
Medicaid	24.7%
Commercial	4.1%
Managed Care	5.1%
Blue Cross	5.9%
Other	4.9%
Total	100.0%

The applicant demonstrates that medically underserved populations currently have adequate access to CFVMC's existing services and is conforming to this criterion.

FHCH. In Section VI.2, pages 238-239, the applicant states that it does not discriminate on the basis of income, race, ethnicity, gender, handicap, age, or any other factor which might restrict access to services. The proposed 65-bed hospital in Hoke County does not yet exist. The applicant operates an existing hospital in Moore County (FMRH). In Section VI.12, page 249, the applicant provides the payer mix during FY2010 for all services provided at FMRH, as shown in the table below.

FMRH
Last Full Fiscal Year 10/1/2009 – 9/30/2010

Payer Category	Patient Days as % of Total Utilization
Self Pay/ Charity/ Other	10.0%
Medicare / Medicare Managed Care	59.8%
Medicaid	8.9%
Commercial Insurance/ Managed Care	21.3%
Total*	100.0%

*May not foot due to rounding.

The applicant demonstrates that medically underserved populations currently have adequate access to FMRH's existing services and is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NC
CFV North
C
FHCH

CFV North. Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 182, the applicant states

"In October 1985, the Health System was informed that it had fulfilled all of its Hill-Burton requirements. However, the Health System continues its admission policy to provide equal access to care without discrimination and without regard to race, color, age, creed, national origin, or source of payment. The Board of Trustees adopted a Charity Care Program, a copy of which is included along with the Admission and Credit/Charity Policy in Exhibit 20."

In Section VI.10, page 182, the applicant states that one civil rights access complaint against Highsmith Rainey Memorial Hospital was filed with the Office of Civil Rights in August 2007, but the complaint was determined to be unsubstantiated in February 2008.

However, in response to the question *"Was the facility* [Cape Fear Valley Medical Center] *in compliance with all applicable Medicare conditions of participation during the last 18 months?"* the Acute and Home Care Licensure and Certification Section, DHSR, in an email dated November 18, 2011, provided the following response

"EMTALA violations were cited during a complaint survey on 03/03/2011 and were upheld by CMS, who placed the facility on termination track, with an effective date of termination scheduled for 12/29/2011 if the deficiencies were not corrected by then.

Another EMTALA complaint survey was just conducted on 11/16-17/2011. EMTALA violations were found and we are in the process of writing report to send to CMS, who will determine compliance."

Therefore, the application is nonconforming to this criterion.

FHCH. Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 248, the applicant states

"In June 1995, FMRH fulfilled its Hill-Burton quota to provide uncompensated care, community service, and access to minorities and handicapped persons under Hill-Burton."

In Section VI.10, page 247, the applicant states that no civil rights access complaints have been filed against FirstHealth or FMRH in the last five years. The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C – Both Applicants

CFV North

In Section VI.14(a), page 183, the applicant projects the following payer mix for the proposed services in the second full fiscal year of operation (FY2016).

CFV North
Second Full Fiscal Year- FY2106 (10/1/15 – 9/30/16)
Entire Facility

Payer Category	Patient Days as % of Total Utilization
Self Pay/ Indigent	13.0%
Medicare	26.9%
Medicaid	29.6%
Commercial	1.1%
Managed Care	16.3%
Blue Cross	8.3%
Other	4.8%
Total	100.0%

In Section VI.14(b), page 184, the applicant states *"Payor mix for CFV North project was based on review of the FY2010 payor mix data from Cape Fear Valley Health System Inpatients and Outpatients that included patients from the CFV North service area and received the type of services proposed for this project."*

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and the application is conforming with this criterion.

FHCH. In Section VI.14, page 252, the applicant projects the following payer mix for FHCH in the second operating year (10/1/2016 – 9/30/2017), as illustrated in the table below.

FHCH
Second Full Fiscal Year: 10/1/2016 – 9/30/2017

Payer Category	Patient Days as % of Total Utilization
Self Pay/ Charity	1.1%
Medicare / Medicare Managed Care	47.6%
Medicaid	8.5%
Commercial Insurance/ Managed Care	40.3%
Other (Specify)	2.6%
TOTAL*	100.0%

*Total may not foot due to rounding.

In Section VI.14, page 252, the applicant states, *"Overall FHCH payer mix is based on the payer mixes for the individual service lines."*

In Section VI.15, pages 253-255, the applicant projects the following payer mix for each service component at FHCH in the second operating year (10/1/2016 – 9/30/2017) as illustrated in the tables below.

FHCH Inpatient Services
Second Full Fiscal Year 10/1/2016 – 9/30/2017

Payer Category	Patient Days as % of Total Utilization
Self Pay/ Charity/ Other	3.9%
Medicare / Medicare Managed Care	56.8%
Medicaid	11.6%
Commercial Insurance/ Managed Care	23.7%
Other (Government)	4.0%
Total*	100.0%

*Totals may not foot due to rounding.

FHCH Emergency Services
Second Full Fiscal Year 10/1/2016 – 9/30/2017

Payer Category	Projected Visits as % of Total Utilization
Self Pay/ Charity/ Other	19.2%
Medicare / Medicare Managed Care	22.8%
Medicaid	24.3%
Commercial Insurance/ Managed Care	29.4%
Other (Government)	4.2%
Total*	100.0%

*Totals may not foot due to rounding.

FHCH Obstetrical Services (inpatient)
Second Full Fiscal Year 10/1/2016 – 9/30/2017

Payer Category	Patient Days as % of Total Utilization
Self Pay/ Charity/ Other	0.8%
Medicare / Medicare Managed Care	0.0%
Medicaid	44.7%
Commercial Insurance/ Managed Care	43.5%
Other (Government)	11.0%
Total*	100.0%

*Totals may not foot due to rounding.

FHCH Imaging Services
Second Full Fiscal Year 10/1/2016 – 9/30/2017

Payer Category	Procedures as % of Total Utilization
Self Pay/ Charity/ Other	2.4%
Medicare / Medicare Managed Care	43.1%
Medicaid	10.0%
Commercial Insurance/ Managed Care	39.1%
Other (Government)	5.4%
Total*	100.0%

*Totals may not foot due to rounding.

FHCH Inpatient Surgical Services
Second Full Fiscal Year 10/1/2016 – 9/30/2017

Payer Category	Cases as % of Total Utilization
Self Pay/ Charity/ Other	1.9%
Medicare / Medicare Managed Care	47.1%
Medicaid	9.7%
Commercial Insurance/ Managed Care	34.5%
Other (Government)	6.9%
Total*	100.0%

*Totals may not foot due to rounding.

FHCH Outpatient Surgical Services
Second Full Fiscal Year 10/1/2016 – 9/30/2017

Payer Category	Cases as % of Total Utilization
Self Pay/ Charity/ Other	3.6%
Medicare / Medicare Managed Care	33.4%
Medicaid	9.6%
Commercial Insurance/ Managed Care	40.9%
Other (Government)	12.5%
Total*	100.0%

*Totals may not foot due to rounding.

In Section VI.15, pages 253-255, the applicant states "*FirstHealth assumes no change in payer mix of the Hoke County patients who received care at FMRH in FY2010.*"

The applicant demonstrated that medically underserved populations will have adequate access to the proposed services and is conforming with this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C – Both Applicants

See Section VI.9 of the respective applications for documentation of a range of means by which persons will have access to the proposed services. The information provided in each application is reasonable and credible and supports a finding of conformity with this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C – Both Applicants

CFV North. In Section V.1 of the application, the applicant states it has extensive relationships with many health professional training programs. On pages 162-163, the applicant provides a list of institutions with which it has these arrangements. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

FHCH. In Section V.1 of the application, the applicant states it has extensive relationships with many health professional training programs. In Exhibit C, the applicant provides a list of institutions with which it has these arrangements. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the

services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC
CFV North
FHCH

CFV North. See Section II.6, pages 35-36, Section II.7, pages 36-38, Section III.2, pages 137-143, and Section VI, pages 177-186. However, the applicant does not adequately demonstrate that its proposed project would have a positive impact on the quality of and access to the proposed services because: 1) CFVMC has not demonstrated that it has provided quality care in the past (See Criterion (20) for additional discussion.) and 2) CFVMC had a substantiated EMTALA violation in the past (See Criterion (13b) for additional discussion.) Therefore, the application is nonconforming to this criterion.

FHCH. See Section II.6, page 65-66, Section II.7, pages 67-69, Section III.2, pages 150-152, and Section VI, pages 238-255. However, the applicant does not adequately demonstrate that its proposed project would have a positive impact on the cost-effectiveness and quality of the proposed services for the following reasons:

a) the applicant does not adequately demonstrate the need for its proposal [see Criterion (3) for additional discussion]; and
b) the applicant does not adequately demonstrate the financial feasibility of the proposal is based on reasonable assumptions regarding revenues and expenses [see Criterion (5) for additional discussion]. and
c) the applicant did not adequately demonstrate that FirstHealth will provide quality services [see Criteria (7) and (8) for additional discussion].

Therefore, the application is nonconforming with this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NC
CFV North

C
FHCH

CFV North. Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Medical Center is licensed by the NC Department of Health and Human Services. In response to the question *"Was the facility* [Cape Fear Valley Medical Center] *in compliance with all applicable Medicare conditions of participation during the last 18 months?"* the Acute and Home Care Licensure and Certification Section, DHSR, in an email dated November 18, 2011, provided the following response:

> *"Non-compliance with the following Conditions was determined during a complaint survey on 10/21/2011: Governing Body, Quality Assessment/Performance Improvement, Patients' Rights, and Nursing Services. An Immediate Jeopardy was also identified during the same survey, which placed the facility on a 23 day termination track.*
>
> ...
>
> *Furthermore, EMTALA violations were cited during a complaint survey on 03/03/2011 and were upheld by CMS, who placed the facility on termination track, with an effective date of termination scheduled for 12/29/2011 if the deficiencies were not corrected by then."*

A letter dated November 23, 2011 to Michael Nagowski, CEO of Cape Fear Valley Medical Center from the Acute Care and Home Care Licensure and Certification Section states

> *"Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the Full and Follow up survey conducted November 9, 2011 through November 17, 2011. The purpose of conducting the survey was to evaluate the Hospital's compliance with the Federal Medicare Conditions of Participation for Hospitals and to follow-up on the on-going Immediate Jeopardy identified on October 21, 2011 during the complaint survey conducted October 17, 2011 through October 21, 2011.*
>
> *As discussed in the exit conference, the State Agency is recommending removal of the Immediate Jeopardy as of November 10, 2011 at 1530. Based on survey findings, the State Agency recommends the hospital to be out of compliance with the following Conditions of Participation:* ***482.12 Governing Body, 482.13 Patient's Rights, 482.21 Quality Assessment and Performance Improvement, 482.23 Nursing Services, 482.41 Physical Environment, and 482.55 Emergency Services.*** *Additionally, Standard Level deficiencies were found in the area of 482.51 Surgical Services. Deficiencies affecting the Condition of Participation must be corrected within 30 days of the survey date. A follow-up visit will be conducted if a 'Credible Allegation of Compliance' from the provider is received by the State Agency within 10 calendar days of receipt. The State Agency is recommending a 90-day termination from the Medicare program effective* ***January 19, 2012****."*

The applicant has not provided sufficient evidence that CFVMC has provided quality care in the 18 months immediately preceding the date of this decision. Therefore, the application is nonconforming to this criterion.

FHCH. FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital is accredited by the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations) and is certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NC
CFV North
FHCH

CVF North. The applicant proposes to construct a new campus of CFVMC to include 57 acute care beds, 8 ICU beds and two operating rooms. The ICU beds will be relocated from CFVMC and the operating rooms will be relocated from HRSH. The following regulatory review criteria are applicable to this review:

- Criteria and Standards for Acute Care Beds, promulgated in 10A NCAC 14C .3800; and
- Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100.

The application is not conforming to all applicable Criteria and Standards. The specific criteria are discussed below.

FHCH. The applicant proposes to construct a four story acute care hospital in Hoke County to include 54 Medical/Surgical beds, 8 ICU beds and 3 LDRP Beds,

two operating rooms, and a CT scanner. The following regulatory review criteria are applicable to this review:

- Criteria and Standards for Acute Care Beds, promulgated in 10A NCAC 14C .3800; and
- Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100.
- Criteria and Standards for Intensive Care Services, promulgated in 10A NCAC 14C .1200; and
- Criteria and Standards for Computed Tomography Equipment, promulgated in 10A NCAC 14C .2300; and
- Criteria and Standards for Neonatal Services promulgated in 10A NCAC 14C .1400.

The application is not conforming to all applicable Criteria and Standards. The specific criteria are discussed below.

SECTION .3800 - CRITERIA AND STANDARDS FOR ACUTE CARE BEDS

10A NCAC 14C .3802 INFORMATION REQUIRED OF APPLICANT
(a) An applicant that proposes to develop new acute care beds shall complete the Acute Care Facility/Medical Equipment application form.

-C- **Both Applicants.** Both applicants completed the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to develop new acute care beds shall submit the following information:

(1) the number of acute care beds proposed to be licensed and operated following completion of the proposed project;

-C- **CFV North.** In Section II.8, page 65, the applicant states that it proposes to develop 65 licensed and operational acute care beds at CFV North upon completion of the project. On page 66, the applicant provides a table showing all of the existing, approved and proposed Acute Care Beds in the Cape Fear Valley Health System.

-C- **FHCH.** In Section II.8, page 112, the applicant states that it proposes to develop 65 licensed and operational acute care beds at FHCH upon completion of the project.

(2) documentation that the proposed services shall be provided in conformance with all applicable facility, programmatic, and service specific licensure, certification, and JCAHO accreditation standards;

-C- **CFV North.** In Section II.8, page 66, and Exhibits 39 and 43, the applicant provides documentation that the services will be provided in conformance with all applicable facility, programmatic, and service specific licensure, certification, and Joint Commission accreditation standards.

-NC- **FHCH.** See Section II.8, page 112, and Exhibit 37, for the applicant's response to this Rule. However, the applicant proposes to offer obstetrical services, including 3 LDRP beds. According to the Acute Care and Home Care Licensure and Certification Section, DHSR, FHCH would be required to have a Level I nursery, including unlicensed bassinets. However, FHCH does not propose a Level I nursery. See Exhibit 14, page 641, and Section II.1, pages 34-35 and 39-41. Therefore, the applicant does not adequately demonstrate that the proposed services will be provided in conformance with all applicable facility and service specific licensure standards and the application is nonconforming with this Rule.

(3) documentation that the proposed services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

-C- **CFV North.** In Section II.8, page 66, and Exhibit 43, the applicant provides documentation that the services will be provided in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

-NC- **FHCH.** See Section II.8, page 112, and Exhibit 23 for the applicant's response to this Rule. However, the applicant proposes to offer obstetrical services including 3 LDRP beds. According to the Acute Care and Home Care Licensure and Certification Section, DHSR, FHCH would be required to have a Level I nursery, including unlicensed bassinets. However, FHCH does not propose a Level I nursery. See Exhibit 14, page 641, and Section II.1, pages 34-35 and 39-41. Therefore, the applicant does not adequately demonstrate that the proposed services will be provided in conformance with all applicable facility and service specific licensure standards and the application is nonconforming with this Rule.

(4) if adding new acute care beds to an existing facility, documentation of the number of inpatient days of care provided in the last operating year in the existing licensed acute care beds by medical diagnostic category, as classified by the Centers for Medicare and Medicaid Services according to the list set forth in the applicable State Medical Facilities Plan;

-C- **CFV North.** In Section II.8, page 67, the applicant documented the number of inpatient days of care provided in the last operating year in the

existing licensed acute care beds at Owen Drive by medical diagnostic category, as classified by the Centers for Medicare and Medicaid Services according to the list set forth in the applicable State Medical Facilities.

-NA- **FHCH.** The applicant is not proposing to add new acute care beds to an existing facility.

(5) the projected number of inpatient days of care to be provided in the total number of licensed acute care beds in the facility, by county of residence, for each of the first three years following completion of the proposed project, including all assumptions, data and methodologies;

-C- **CFV North.** In Section II.8, pages 67-68, the applicant provides the projected number of inpatient days of care to be provided in the total number of licensed acute care beds in the facility, by county of residence, for each of the first three operating years following completion of the project. In Section III.1(b), pages 97-137, and Exhibit 33, Tables 1-52, the applicant provides the assumptions, data and methodology used for the projections. See Criterion (3) for discussion regarding the reasonableness of the projections.

-C- **FHCH.** In Section II.8, page 113, the applicant provides the projected number of inpatient days of care to be provided in the total number of licensed acute care beds in the facility, by county of residence, for each of the first three operating years following completion of the project as illustrated in the table below.

County	*FY2016*	*FY2017*	*FY2018*
Hoke	*6,141*	*7,945*	*9,545*
Cumberland	*2,627*	*3,667*	*4,711*
Scotland	*816*	*926*	*1,037*
Robeson	*474*	*530*	*586*
Total	*10,059*	*13,068*	*15,879*

In Section IV, pages 174-210, the applicant provides the assumptions, data and methodology used for the projections. See Criterion (3) for discussion regarding the reasonableness of the projections.

(6) documentation that the applicant shall be able to communicate with emergency transportation agencies 24 hours per day, 7 days per week;

-C- **CFV North.** In Section II.8, page 68, and Exhibit 43, the applicant provides documentation that CFV North will be able to communicate with emergency transportation agencies 24 hours per day, 7 days per week.

-C- **FHCH.** In Section II.8, page 113, and Exhibit 20, the applicant provides documentation that the proposed hospital will be able to communicate with emergency transportation agencies 24 hours per day, 7 days per week.

(7) documentation that services in the emergency care department shall be provided 24 hours per day, 7 days per week, including a description of the scope of services to be provided during each shift and the physician and professional staffing that will be responsible for provision of those services;

-C- **CFV North.** In Section II.8, page 69, and Exhibit 43, the applicant describes the scope of services to be provided in the emergency department and provides documentation that the hospital's emergency department services will be available 24 hours per day, 7 days per week.

-C- **FHCH.** In Section II.8, page 113, Section III, page 160, and Exhibits 25 and 26, the applicant describes the scope of services to be provided in the emergency department and provides documentation that the hospital's emergency department services will be available 24 hours per day, 7 days per week.

(8) copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

-C- **CFV North.** In Section II.8, page 69, and Exhibits 20, the applicant provides written administrative policies documenting that CFV North will prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay.

-C- **FHCH.** In Section II.8, page 114, and Exhibit 38, the applicant provides written administrative policies documenting that the hospital will prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay.

(9) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs;

-C- **CFV North.** In Section II.8, page 69, and Exhibit 43, the applicant provides a written commitment from the COO of CFVHS documenting CFVMC's commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs.

-C- **FHCH.** In Section II.8, page 114, and Exhibit 39, the applicant provides a written commitment from the Chief Financial Officer of FirstHealth of the

Carolinas, Inc. to participate in and comply with conditions of participation in the Medicare and Medicaid programs.

(10) documentation of the health care services provided by the applicant, and any facility in North Carolina owned or operated by the applicant's parent organization, in each of the last two operating years to Medicare patients, Medicaid patients, and patients who are not able to pay for their care;

-C- **CFV North.** In Section II.8, page 69, the applicant provides a chart showing the percentages for Medicare, Medicaid, other and uninsured patients at CFVHS facilities for FFY2009 and FFY2010.

-NC- **FHCH.** In Section II.8, page 115, the applicant provides a table showing the extent to which health care services were provided to Medicare, Medicaid, and uninsured patients by FirstHealth facilities for just the last operating year (FY2010) not each of the last two operating years as required by the Rule. Therefore, the application is nonconforming with this Rule.

(11) documentation of strategies to be used and activities undertaken by the applicant to attract physicians and medical staff who will provide care to patients without regard to their ability to pay; and

-C- **CFV North.** In Section II.8, page 70, and Exhibit 43, the applicant provides documentation of strategies to be used and activities undertaken by the applicant to attract physicians and medical staff who will provide care to patients without regard to their ability to pay.

-C- **FHCH.** In Section II.8, page 116, and Exhibits 30 and 40, the applicant provides documentation of strategies to be used and activities undertaken by the applicant to attract physicians and medical staff who will provide care to patients without regard to their ability to pay.

(12) documentation that the proposed new acute care beds shall be operated in a hospital that provides inpatient medical services to both surgical and non-surgical patients.

-C- **CFV North.** In Section II.8, page 70, and Exhibit 43, the applicant provides documentation that the proposed new acute care beds at CFV North will provide inpatient medical services to both surgical and non-surgical patients.

-C- **FHCH.** In Section II.8, page 116, and Exhibit 41, the applicant provides documentation that FHCH will provide inpatient medical services to both surgical and non-surgical patients.

(c) An applicant proposing to develop new acute care beds in a new licensed hospital or on a new campus of an existing hospital shall also submit the following information:

(1) the projected number of inpatient days of care to be provided in the licensed acute care beds in the new hospital or on the new campus, by major diagnostic category as recognized by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the applicable State Medical Facilities Plan;

-C- **CFV North.** In Section II.8, pages 70-72, the applicant provides the projected number of inpatient days of care to be provided in the licensed acute care beds in both CFV North and CFVMC by major diagnostic category according to the list shown in the 2011 SMFP.

-C- **FHCH.** In Section II.8, page 117, the applicant provides the projected number of inpatient days of care to be provided in the licensed acute care beds in the new hospital by major diagnostic category according to the list shown in the 2011 SMFP. However, see Criterion (3) for discussion regarding the reasonableness of the projections.

(2) documentation that medical and surgical services shall be provided in the proposed acute care beds on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the applicable State Medical Facilities Plan;

-C- **CFV North.** In Section II.8, page 73, and Exhibits 43 and 44, the applicant provides documentation that medical and surgical services will be provided in the proposed acute care beds on a daily basis within at least five of the major diagnostic categories.

-C- **FHCH.** In Section II.8, page 118, the applicant provides documentation that medical and surgical services will be provided in the proposed acute care beds on a daily basis within at least five of the major diagnostic categories.

(3) copies of written policies and procedures for the provision of care within the new acute care hospital or on the new campus, including but not limited to the following:
(A) the admission and discharge of patients, including discharge planning,
(B) transfer of patients to another hospital,
(C) infection control, and

(D) safety procedures;

-NC- **CFV North.** The applicants Exhibits 16, 20, and 23, contain copies of the applicant's written policies regarding admissions, discharge planning, transfers, infection control and safety. However, while the Patient Safety Plan in Exhibit 16 explicitly list a Discharge Planning Process policy, a copy of that policy was not provided in the application as required by this Rule. Therefore, the application is not conforming to this Rule.

-C- **FHCH.** Exhibits 16 and 19 contain copies of the applicant's written policies regarding admissions, discharge planning, transfers, infection control and safety.

(4) documentation that the applicant owns or otherwise has control of the site on which the proposed acute care beds will be located; and

-C- **CFV North.** In Section II.8, page 73, and Exhibit 41, the applicant provides a copy of an agreement for purchase of real property documenting that CFVHS owns or otherwise has control of the site on which CFV North will be developed.

-C- **FHCH.** In Section II.8, page 118, and Exhibit 42, the applicant provides a copy of an agreement for purchase of real property documenting that FirstHealth controls the site on which the proposed hospital will be developed.

(5) documentation that the proposed site is suitable for development of the facility with regard to water, sewage disposal, site development and zoning requirements; and provide the required procedures for obtaining zoning changes and a special use permit if site is currently not properly zoned; and

-C- **CFV North.** In Section II.8, page 74, and in a letter from the development consultant in Exhibit 43, the applicant states "*As the development consultant working with CFVMC to identify, have inspected and coordinate the acquisition of additional property for the proposed CFV North project please accept this letter as documentation that in conjunction with other professionals we believe the proposed expanded site is suitable for development of the proposed facility with regard to water, sanitary sewage, site development and zoning requirements. In addition, the property is zoned correctly for use as a medical facility at this time....*"

-C- **FHCH.** In Section II.8, page 118, and Exhibit 42, the applicant states the proposed site is suitable for development of the proposed hospital with

regard to water, sewage disposal, site development and zoning requirements.

(6) *correspondence from physicians and other referral sources that documents their willingness to refer or admit patients to the proposed new hospital or new campus.*

-C- **CFV North.** Exhibit 26 contains copies of correspondence from physicians and other referral sources documenting their willingness to refer or admit patients to the proposed new hospital.

-C- **FHCH.** Exhibit U contains copies of correspondence from physicians indicating their willingness to refer or admit patients to the proposed new hospital.

10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

-C- **CFV North.** In Section II.8, pages 74-75 and Exhibit 33, the applicant provides projected utilization of the total number of licensed acute care beds CFVMC (including CFV North) will operate in the Cumberland/Hoke Acute Care Bed service area in the third operating year (FFY2017) following completion of the project, which is summarized below:

Cape Fear Valley Medical Center (including CFV North)
Projected Acute Care Bed Utilization
October 2014 – September 2017

CFV North	FFY 2015	FFY 2016	FFY 2017
Projected Patient Days	12,591	14,353	16,986
ADC	34.5	39.3	46.5
Occupancy Rate	53.1%	60.5%	71.6%
CFVMC (Owen Drive only)	**FFY 2015**	**FFY 2016**	**FFY 2017**
Projected Patient Days	149,890	149,720	150,600
ADC	410.7	410.2	412.6
Occupancy Rate	83.8%	83.7%	84.2%
Total	**FFY 2015**	**FFY 2016**	**FFY 2017**
Projected Patient Days	162,481	164,073	167,586
ADC	445.2	449.5	459.1
Occupancy Rate	80.2%	81.0%	82.7%

Source: Exhibit 33, Tables 2, 39

-NC- **FHCH.** In Section II.8, page 119, the applicant states "*FirstHealth projects that in the third year of operation, the sixty-five (65) acute care beds will operate at 66.9 percent [(15,879 days of care) / (65 beds x 365) x 100 = 66.9%]. This calculation is derived from data in Section IV, Step 7 of the Direct Inpatient Admission need methodology.*" However, the applicant did not adequately demonstrate projected utilization is based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming with this Rule.

(b) An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this rule and demonstrate that they support the projected inpatient utilization and average daily census.

-C- **CFV North.** The applicant's assumptions and data used to develop the projections required in this Rule are provided in Section III.1(b), pages 97-137, and Exhibit 33, Tables 1-52. The applicant's assumptions regarding projected inpatient utilization and average daily census are reasonable and credible and support a finding of conformity with this rule. See Criterion (3) for additional discussion.

-NC- **FHCH.** The applicant's assumptions and data used to develop the projections required in this Rule are provided in Section IV, pages 174-210. However, the applicant's assumptions regarding projected inpatient utilization and average daily census are not reasonable and supported, and thus do not support a finding of conformity with this Rule. See Criterion (3) for additional discussion. Therefore, the application is nonconforming with this rule.

10A NCAC 14C .3804 SUPPORT SERVICES

(a) An applicant proposing to develop new acute care beds shall document that each of the following items shall be available to the facility 24 hours per day, 7 days per week:

(1) laboratory services including microspecimen chemistry techniques and blood gas determinations;
(2) radiology services;
(3) blood bank services;
(4) pharmacy services;
(5) oxygen and air and suction capability;
(6) electronic physiological monitoring capability;
(7) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
(8) endotracheal intubation capability;
(9) cardiac arrest management plan;
(10) patient weighing device for a patient confined to their bed; and
(11) isolation capability;

-C- **CFV North.** Exhibit 43 contains a letter from the Chief Operating Officer (COO) of CFVHS which states that all of the items listed above will be available 24 hours per day, seven days per week at CFV North.

-C- **FHCH.** Exhibit 43 contains a letter from the hospital's Interim Chief Nursing Officer which states that all of the items listed above will be available 24 hours per day, seven days per week at the hospital.

(b) If any item in Paragraph (a) of this Rule will not be available in the facility 24 hours per day, 7 days per week, the applicant shall document the basis for determining the item is not needed in the facility.

-C- **CFV North.** In Section II.8, page 76, the applicant states that all of the items in Paragraph (a) of this Rule will be available 24 hours per day, seven days per week.

-C- **FHCH.** In Section II.8, page 121, and Exhibit 43, the applicant states that all of the items in Paragraph (a) of this Rule will be available 24 hours per day, seven days per week.

(c) If any item in Paragraph (a) of this Rule will be contracted, the applicant shall provide correspondence from the proposed provider of its intent to contract with the applicant.

-C- **CFV North.** In Section II.8, page 76, the applicant states that none of the items listed in Paragraph (a) of this Rule will be contracted.

-C- **FHCH.** In Section II.8, page 120, the applicant states that none of the items listed in Paragraph (a) of this Rule will be contracted.

10A NCAC 14C .3805 STAFFING AND STAFF TRAINING
(a) An applicant proposing to develop new acute care beds shall demonstrate that the proposed staff for the new acute care beds shall comply with licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals.

-C- **CFV North.** In Section II.8, page 76, that applicant states, "*Please see Section VII and a letter from Michael Harrington, CFVHS COO included in Exhibit 43 for documentation that the proposed staff of CFV North shall comply with licensure requirements set forth in Title 10A NCAC 13B Licensing of Hospitals.*" Exhibit 43 contains a letter from the COO of CFVHS documenting that the proposed staff for the new acute care needs will comply with the licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals.

-NC- **FHCH.** In Section II.8, page 122, the applicant states "*The staffing analysis in Exhibit 34 demonstrates that the proposed staffing complies with licensure requirements forth in Title 10A NCAC 13B, Licensing of Hospitals.*" Exhibit 34 contains a staffing assumptions worksheet for FHCH for years 2016, 2017 and 2018. However, the applicant proposes to offer obstetrical services, including three LDRP beds. According to the Acute Care and Home Care Licensure and Certification Section, DHSR, FHCH would be required to develop a Level I nursery, including unlicensed bassinets. However, the applicant did not propose a Level I nursery. Pursuant to 10A NCAC 14C. 1405(1), the applicant is required to demonstrate that: a) nursing care shall be supervised by an RN in charge of perinatal facilities; and b) a physician is designated to be responsible for neonatal care. FHCH does not adequately document that its proposal would meet these requirements. Therefore, FHCH does not adequately demonstrate the availability of the staff required to provide neonatal services and the application is nonconforming with this Rule.

(b) An applicant proposing to develop new acute care beds shall provide correspondence from the persons who expressed interest in serving as Chief Executive Officer and Chief Nursing Executive of the facility in which the new acute care beds will be located, documenting their willingness to serve in this capacity.

-C- **CFV North.** In Section II.8, page 76, the applicant identifies the two individuals who will serve as Chief Executive Officer and Chief Nursing Executive. Exhibit 43 contains letters from each individual which documents their willingness to serve in the capacities as required by this rule.

-C- **FHCH.** In Section II.8, page 121, the applicant identifies the two individuals who will serve as Chief Executive Officer and Chief Nursing Executive. Exhibit 44 contains letters from each individual which documents their willingness to serve in the capacities as required by this rule.

(c) An applicant proposing to develop new acute care beds in a new hospital or on a new campus of an existing hospital shall provide a job description and the educational and training requirements for the Chief Executive Officer, Chief Nursing Executive and each department head which is required by licensure rules to be employed in the facility in which the acute care beds will be located.

-C- **CFV North.** Exhibit 43 contains the required job descriptions.

-C- **FHCH.** Exhibit T contains the required job descriptions.

(d) An applicant proposing to develop new acute care beds shall document the availability of admitting physicians who shall admit and care for patients in each of the major diagnostic categories to be served by the applicant.

-C- **CFV North.** In Exhibits 26 and 43, the applicant provides documentation regarding the availability of admitting physicians who will admit and care for patients in each of the major diagnostic categories to be served at CFV North. In Section II.8, page 77, the applicant states, *"In addition, the applicant will establish a hospitalist program at CFV North, similar to the hospitalist program that exists at CFVMC. The Medical Director for the CFVMC hospitalist program has committed to establish a program at CFV North. Please see Exhibit 26 for a CFV North Hospitalist Medical Director's letter and Exhibit 43 for a letter from Dr. Eugene Wright, CFVHS Chief Medical Officer."*

-C- **FHCH.** In Exhibit U the applicant provides documentation regarding the availability of admitting physicians who will admit and care for patients in each of the major diagnostic categories to be served at FHCH.

(e) An applicant proposing to develop new acute care beds shall provide documentation of the availability of support and clinical staff to provide care for patients in each of the major diagnostic categories to be served by the applicant.

-C- **CFV North.** In Sections VII.1 and VII.8, Exhibit 26 and Exhibit 43, which includes a letter from the COO of CFVHS, the applicant provides documentation of the availability of support and clinical staff to provide care for patients in each of the major diagnostic categories to be served at CFV North.

-NC- **FHCH.** See Section II.8, pages 123-126, and Section VII, pages 256-269, for the applicant's response to this Rule. However, the applicant proposes to provide neonatal services. According to the Acute Care and Home Care Licensure and Certification Section, DHSR, FHCH would be required to have a Level 1 nursery, including unlicensed bassinets. However, the applicant does not propose a Level 1 nursery. Furthermore, pursuant to 10A NCAC 13B .4307 and 10A NCAC 14C .1405(1), FHCH would be required to have a registered nurse in charge of perinatal facilities and supervising the nursing care, a designated physician to be responsible for neonatal care, and physician coverage to meet the specific needs of patients on a 24 hour basis. In Section VII and Exhibit L, FHCH does not document that it will have the required neonatal clinical staff. Therefore, the application is nonconforming with this Rule.

SECTION .2100 - CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify each of the following specialty areas that will be provided in the facility:

(1) gynecology;
(2) otolaryngology;
(3) plastic surgery;
(4) general surgery;
(5) ophthalmology;
(6) orthopedic;
(7) oral surgery; and
(8) other specialty area identified by the applicant.

-C- **CFV North.** In Section II.8, page 41, the applicant states that "*CFV North will be licensed as part of CFVMC and will have two shared surgical operating rooms, which will be relocated from HRSH. CFV North will provide the specialty areas listed in (1) through (7) above in addition to any other surgical services clinically appropriate for the proposed facility.*"

-C- **FHCH.** In Section II.8, page 80, the applicant states that the proposed hospital will provide all of the surgical specialties listed in this Rule as well as pediatrics, dental, vascular and neurosurgery.

(b) An applicant proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide the following information:

(1) the number and type of operating rooms in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area, (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(2) the number and type of operating rooms to be located in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;

(5) a description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

(6) the hours of operation of the proposed new operating rooms;

(7) if the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items included in the reimbursement; and

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-NA- **Both Applicants.** Neither of the applicants proposes to increase the number of operating rooms in a service area, to convert a specialty

ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program. Cumberland Hoke is a single service area. CFV North proposes to relocate the ORs within Cumberland County. Moore Hoke is a single service area. FirstHealth proposes to relocate the ORs from Moore to Hoke which is within the same service area.

(c) An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:

(1) the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- **CFV North.** In Section II.8, pages 42-43, the applicant provides the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease, as shown in the table below.

	CON Licensed and Approved Operating Rooms*	Proposed Change in Operating Rooms	Total Proposed, Licensed and CON Approved Operating Rooms
Cape Fear Valley Medical Center- Shared OR's	13	0	13
Care Fear Valley Medical Center- Open Heart	2	0	2
Cape Fear Valley Medical Center- C-Section	3	0	3
Cape Fear Valley Medical Center-CFV North	0	2	2
Highsmith-Rainey Specialty Hospital (LTACH)	3	-2	1
Total Impact CFVHS Operating Rooms	21	0	21

Source: 2011 LRAs; Project ID N-8499-10.
*Reflects the OR changes approved in Project I.D. #N-8499-10 and those proposed in this application.

-C - **FHCH.** In Section II.8, page 81, the applicant states that "*FirstHealth does not propose to relocate existing operating rooms between existing licensed facilities within the same service area. FirstHealth proposes to relocate two (2) existing operating rooms to FHCH, a proposed hospital, which cannot become a licensed facility until it is constructed.*" For informational purposes, FirstHealth provided the following table showing number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease:

Existing and Approved Operating Rooms- FY2011

Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	C-Section ORs	Trauma/Burn ORs	Total ORs
FMRH	2	0	16	0	0	18
FHCH	0	0	0	0	0	0

Source: Section II.8, page 81.

Note: As a part of Project ID # H-7427-05, FirstHealth has converted two (2) GI endoscopy rooms into shared operating room, effective with the completion of the Reid Heart Center in January 2011.

(2) the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- **CFV North.** In Section II.8, page 43, the applicant provides the number and type of existing and approved operating rooms in each affected facility after completion of the proposed project and all previously approved projects related to these facilities, as shown in the table below.

	CON Licensed and Approved Operating Rooms*	Proposed Change in Operating Rooms	Total Proposed, Licensed and CON Approved Operating Rooms
Cape Fear Valley Medical Center- Shared OR's	13	0	13
Care Fear Valley Medical Center- Open Heart	2	0	2
Cape Fear Valley Medical Center- C-Section	3	0	3
Cape Fear Valley Medical Center-CFV North	0	2	2
Highsmith-Rainey Specialty Hospital (LTACH)	3	-2	1
Total Impact CFVHS Operating Rooms	21	0	21

Source: 2011 LRAs; Project ID N-8499-10.

*Reflects the OR changes approved in Project I.D. #N-8499-10 and those proposed in this application.

-C- **FHCH.** In Section II.8, page 91, the applicant provides the number and type of existing and approved operating rooms in each affected facility after completion of the proposed project and all previously approved projects related to these facilities, as shown in the table below.

Proposed and Previously Approved Operating Rooms- FY2011

Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	C-Section ORs	Trauma/Burn ORs	Total ORs
FMRH	2	0	14	0	0	16
FHCH	0	0	2	0	0	2

Source: Section II.8, page 91.

(3) *the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;*

-C- **CFV North.** In Section II.8, pages 43-44, the applicant provides the number of inpatient and outpatient surgical cases performed in the most recent 12 month period, as shown in the table below.

Surgical Cases
October 2009- September 2010

CFVMC	
Inpatient	6,243
Open Heart	234
C-Section	1,437
Outpatient	6,606
Total	14,520
HRSH	
Inpatient	66
Outpatient	2,768
Total	2,834

Source: Cape Fear Valley Medical Center and Highsmith Rainey Memorial Hospital 2011 LRAs.

CFV North is not an existing facility.

-C- **FHCH.** In Section II.8, page 82, the applicant provides the number of inpatient and outpatient surgical cases performed at FMRH and FHCH in FY2010, as shown in the table below

Surgical Cases
FY2010

Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	C-Section ORs	Trauma/Burn ORs	Total ORs
FMRH IP	339	0	6,021	0	0	6,360
FMRH OP	0	0	4,183	0	0	4,183
FMRH Total	339	0	10,204	0	0	10,543
FHCH IP	0	0	0	0	0	0
FHCH OP	0	0	0	0	0	0
FHCH Total	0	0	0	0	0	0

Source: Section II.8, page 82.

(4) *the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;*

-C- **CFV North.** In Section II.8, page 44, the applicant provides the number of inpatient and outpatient surgical cases projected to be performed at Cape Fear Valley Medical Center, HRSH and CFV North in the first three operating years of the proposed project, as shown in the table below.

	FFY 2015	FFY 2016	FFY 2017
CFV North			
Inpatient Surgical Cases	347	393	462
Outpatient Surgical Cases	1,157	1,332	1,592
CFVMC (Owen Drive only)			
Inpatient Surgical Cases	5,731	5,653	5,606
Outpatient Surgical Cases	5,951	5,734	5,663
HRSH			
Inpatient Surgical Cases	66	66	66
Outpatient Surgical Cases	1,725	1,668	1,582

Source: Exhibit 33, Tables 22, 49, 50.
Excludes open heart and C-Section rooms and volumes; Volumes at CFVMC reflect the impact of cases shifted from Owen Drive to HCMC and CFV North.

-C- **FHCH.** In Section II.8, page 83, the applicant provides the number of inpatient and outpatient surgical cases projected to be performed at FMRH and FHCH in the first three operating years of the proposed project, as shown in the following tables.

FMRH- Projected Surgical Cases
FY2016 – FY 2018

FMRH	Inpatient ORs	Ambulatory ORs	Shared ORs	C-Section ORs	Trauma/Burn ORs	Total
FY 2016 IP	340	0	5,971	0	0	6,311
FY2016 OP	0	0	4,058	0	0	4,058
FY2016 Total	**340**	**0**	**10,029**	**0**	**0**	**10,369**
FY2017 IP	340	0	5,907	0	0	6,247
FY2017 OP	0	0	4,036	0	0	4,036
FY2017 Total	**340**	**0**	**9,943**	**0**	**0**	**10,283**
FY2018 IP	340	0	5,849	0	0	6,189
FY2018 OP	0	0	4,014	0	0	4,014
FY2018 Total	**340**	**0**	**9,863**	**0**	**0**	**10,203**

Source: Section II.8, page 83

FHCH- Projected Surgical Cases
FY2016 – FY 2018

FHCH	Inpatient ORs	Ambulatory ORs	Shared ORs	C-Section ORs	Trauma/Burn ORs	Total
FY 2016 IP	0	0	589	0	0	589
FY2016 OP	0	0	415	0	0	415
FY2016 Total	**0**	**0**	**1,004**	**0**	**0**	**1,004**
FY2017 IP	0	0	809	0	0	809
FY2017 OP	0	0	482	0	0	482
FY2017 Total	**0**	**0**	**1,291**	**0**	**0**	**1,291**
FY2018 IP	0	0	1,205	0	0	1,205
FY2018 OP	0	0	548	0	0	548
FY2018 Total	**0**	**0**	**1,573**	**0**	**0**	**1,573**

Source: Section II.8, page 83

However, see Criterion (3) for discussion regarding the reasonableness of the applicant's projections.

(5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

-C- **CFV North.** In Section II.8, page 44, the applicant states "*Please see section III.1.(b) and Exhibit 33 for a detailed step by step discussion of the methodology and all assumptions used.*" Section III.1(b), pages 97-137, and Exhibit 33 contain the assumptions and methodology used to develop the projections required by this Rule. The applicant provides adequate documentation to support its assumptions.

-NC- **FHCH.** The applicant's assumptions and methodology used to develop the projections required by this Rule are provided in Section II.8, pages

84-86, and in Section IV, pages 174-210. However, the applicant does not provide adequate documentation to support its assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming with this Rule.

(6) the hours of operation of the facility to be expanded;

-C- **CFV North.** In Section II.8, page 45, the applicant states that the "*CFV North will operate two shared surgical operating rooms, 260 days a year, 10 hours a day from 7 a.m. to 5 p.m. Monday through Friday which represents a capacity of 10 hours per room or 2,600 hours annually. After hours, on-call coverage will be provided for emergency and emergent cases which are clinically appropriate to be served at CFV North.*"

-C- **FHCH.** In Section II.8, page 86, the applicant states that the "*operating room will operate for scheduled inpatient and outpatient surgical cases from 7:00 AM – 4:00 PM and will be available on-call after hours for emergencies.*"

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;

-C- **CFV North.** In Section II.8, pages 45-49, the applicant provides the average reimbursement received per procedure for the following: 1) the 20 inpatient surgical procedures most commonly performed at CFVMC during the preceding 12 months; 2) the 20 outpatient surgical procedures most commonly performed at CFVMC during the preceding 12 months; 3) the 20 inpatient surgical procedures most commonly performed at HRSH during the preceding 12 months; and 4) the 20 outpatient surgical procedures most commonly performed at HRSH during the preceding 12 months. The applicant identifies the services and items included in the reimbursement.

-C- **FHCH.** In Section II.8, page 87, the applicant provides the average reimbursement received per procedure for the 20 surgical procedures most commonly performed at FMRH during the preceding 12 months, and identifies the services and items included in the reimbursement.

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and

-C- **CFV North.** In Section II.8, pages 49-53, the applicant provides the projected average reimbursement to be received per procedure for the following: 1) the 20 inpatient surgical procedures most commonly performed at CFVMC during the preceding 12 months; 2) the 20 outpatient surgical procedures most commonly performed at CFVMC during the preceding 12 months; 3) the 20 inpatient surgical procedures most commonly performed at HRSH during the preceding 12 months; and 4) the 20 outpatient surgical procedures most commonly performed at HRSH during the preceding 12 months. The applicant identifies the services and items included in the reimbursement.

-C- **FHCH.** In Section II.8, page 88, the applicant provides the projected average reimbursement to be received per procedure for the 20 surgical procedures the applicant projects will be performed most often at FHCH, and identifies the services and items included in the reimbursement.

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-C- **CFV North.** In Section II.8, page 53, the applicant identifies the providers of pre-operative services and procedures which will not be included in the facility's charge.

-C- **FHCH.** In Section II.8, page 89, the applicant states "*All pre-operative services and procedures can be performed at FHCH and are included in the facility charge.*"

(d) An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:

(1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;

(2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;

(3) a commitment that the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;

(4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;

(5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;

(6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self-pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable

amount per self-pay surgical case and multiply that amount by the projected number of self-pay surgical cases;

(7) *for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;*

(8) *for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;*

(9) *for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;*

(10) *for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;*

(11) *a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;*

(12) *a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;*

(13) *descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;*

(14) *if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;*

(15) *a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;*

(16) *a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;*

(17) *a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:*

- (A) *patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;*
- (B) *patient outcome results for each of the applicant's patient outcome measures;*
- (C) *the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and*

(D) the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.

-NA- **Both Applicants.** Neither applicant is proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to a demonstration project in the 2011 State Medical Facilities Plan.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

-C- **CFV North.** In Section II.8, page 55, the applicant states the operating rooms at CFVMC and CFV North will be available for use five days per week and 52 weeks a year.

-C- **FHCH.** In Section II.8, page 91, the applicant states the proposed facility will be available for use five days per week and 52 weeks a year.

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-C- **CFV North.** In Section II.8, page 56, the applicant states that the Cumberland County Operating Room Service Area has more than 10 operating rooms. The following table illustrates projected surgical cases at CFVMC, including CFV North.

	FFY 2015	FFY 2016	FFY 2017
CFV North (Ramsey Street)			
Inpatient Surgical Cases	347	393	462
Outpatient Surgical Cases	1,157	1,332	1,592
Weighted Surgical Hours	**2,775**	**3,177**	**3,775**
CFVMC (Owen Drive only)			
Inpatient Surgical Cases	5,731	5,653	5,606
Outpatient Surgical Cases	5,951	5,734	5,663
Weighted Surgical Hours	**25,981**	**25,560**	**25,314**
Total Weighted Surgical Hours (Ramsey Street and Owen Dr.)	**28,756**	**28,737**	**29,089**
ORs Needed at 1872 Hours per OR	15.4	15.4	15.5

Source: Section II.8, page 56; Section III, pages 101-102.
Excludes open heart and C-Section operating rooms and volumes; Volumes at CFVMC reflect the impact of cases shifted from Owen Drive to HCMC and CFV North.

As shown in the table above, projected surgical hours at CFVMC including CFV North, supports a need for 15.5 operating rooms. CFVMC is currently licensed for 13 shared operating rooms. Upon completion of this project, CFVMC would be licensed for 15 shared operating rooms (2 shared ORs would be relocated from HRSH, which is owned by CFVHS). The applicant adequately demonstrates the proposal is conforming to this rule.

-NC- **FHCH.** In Section II.8, page 92, and in Section IV, the applicant states

"First Health projects that FHCH will treat the following surgical cases in the third year of operation and is utilizing the SMFP identified average hours per case to determine total surgical hours and thus utilization:

	4-County Service Area Cases	*Hours per Case*	*Total Surgical Hours*
Inpatient Cases	*1,025*	*3.0*	*3,075*
Outpatient Cases	*548**	*1.5*	*822*
Total Surgical Cases	*1,573*		*3,897*

Source: Section IV, Volume Projections

**Includes 533 OP case referrals and 15 OP cases from ED discharges and observation patients based on operating room hours.*

Based on Year 3 surgical volumes projections, FHCH is projected to operate at 83.3% [(3,897 / 4,680) x 100 = 83.3%] and shows a local need for 2.1 operating rooms.

Please refer to the need methodology in Section IV for the assumptions used in projecting surgical cases."

However, projected utilization of the operating rooms at FHCH is not based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the applicant does not adequately demonstrate the need for two operating rooms at FHCH and the application is nonconforming with this Rule.

(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of

projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-NA- **Both Applicants.** Neither applicant proposes to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area. Cumberland Hoke is a single service area. CFV North proposes to relocate the ORs within Cumberland County. Moore Hoke is a single service area. FirstHealth proposes to relocate the ORs from Moore to Hoke which is within the same service area.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- **Both Applicants.** Neither applicant proposes to develop an additional dedicated C-section operating room in a facility with one more existing or approved dedicated C-section operating rooms.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- **Both Applicants.** Neither applicant proposes to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- **CFV North.** The applicant adequately documents the assumptions and provides data supporting its methodology in Section III.1(b), pages 97-137, and Exhibit 33. See Criterion (3) for discussion.

-NC- **FHCH.** The applicant provides the assumptions and data for its methodology in Section IV, pages 174-210. However, projected utilization is not based on reasonable and supported assumptions and data. See Criterion (3) for discussion. Therefore, the application is nonconforming with this Rule.

10A NCAC 14C .2104 SUPPORT SERVICES

(a) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.

-NC- **CFV North.** In Section II.8, pages 58-59, the applicant states "*CFV North will be included on the CFVMC license. As such, CFV North will have the same patient, referral, transfer, and discharge policies and procedures that are applicable at CFVMC facilities.*" However, the applicant did not provide a copy of the policies as required by this Rule. Therefore, the application is nonconforming with this Rule.

-C- **FHCH.** In Exhibit 16, the applicant provides copies of patient referral, transfer and follow-up policies.

(b) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:

(1) emergency services;

-C- **CFV North.** In Section II.8, page 59, the applicant states that CFV North will have ready and continuous access to "*Emergency services in the CFV North ED and when necessary, emergency services to CFVMC via critical care transport provided by Cape Fear Valley Lifelink, also owned by the Cape Fear Valley Health System. The state-of-the-are transport service is staffed 24 hours a day by a team of registered nurses and is equipped with the technology, medication and resources of a hospital critical care unit. Please see Exhibit 31.*"

-C- **FHCH.** In Section II.8, page 95, the applicant states emergency services, support services, and ancillary services will be provided on-site at the proposed hospital, and public transportation is available locally by appointment only through Hoke Area Transit Services ("HATS"). Exhibit 29 contains HATS information.

(2) support services;

-C- **CFV North.** In Section II.8, page 59, the applicant states that CFV North will have ready and continuous access to "*Support services from the applicable departments (such as sterile processing, pre-and post-operative services, recovery room, environmental service, medical records, information technology, human resources, security, maintenance,*

purchasing, etc.) at CFV North and when necessary, support services from CFVMC."

-C- **FHCH.** In Section II.8, page 95, the applicant states emergency services, support services, and ancillary services will be provided on-site at the proposed hospital, and public transportation is available locally by appointment only through Hoke Area Transit Services ("HATS"). Exhibit 29 contains HATS information.

(3) ancillary services; and

-C- **CFV North.** In Section II.8, pages 59-60, the applicant states that CFV North will have ready and continuous access to "*Ancillary services, such as imaging, pharmacy, laboratory, and pathology will be provided within CFV North.*

Anesthesia services at CFV North will be provided on site by board-certified anesthesiologists from Cumberland Anesthesia Associates, P.A. and by CRNAs working at CFV North under the supervison of Cumberland Anesthesia Associates, P.A. The professional fee for anesthesia also will be billed directly to the patient. Please see Exhibit 42 for documentation from Cumberlan Anesthesia Associates, P.A.

Preoperative lab work will be completed at CFV North and contracted referenced labs and billed directly to the patient. Pathology services will be provided by the pathologists of Fayetteville Associates in Laboratory Medicine, P.A. and billed directly to the patient. Fayetteville Associates in Laboratory Medicine, P.A. currently provide services at existing CFVHS hospitals facilities to support those surgical programs, and will expand their coverage to include CFV North. Please see Exhibit 42 for documentation from Fayetteville Associates in Laboratory Medicine, P.A.

Radiology services will be provided as needed by Carolina Regional Radiology and billed directly to the patient. Please see Exhibit 42 for documentation from Carolina Regional Radiology."

-C- **FHCH.** In Section II.8, page 95, the applicant states emergency services, support services, and ancillary services will be provided on-site at the proposed hospital, and public transportation is available locally by appointment only through Hoke Area Transit Services ("HATS"). Exhibit 29 contains HATS information.

(4) public transportation.

-C- **CFV North.** In Section II.8, pages 59-60, the applicant states that "*public transportation is available via Fayetteville Area System of Transit (FAST). FAST buses take persons to work, shopping, medical centers, schools and libraries—with comfort and safety. FAST operates ten bus routes and two shuttle routes between the hours of 5:30 am – 7:30 pm. The FAST connector is a shuttle van service used to extend service to areas less accessible to larger buses. With 24-hour advance notice, FAST will arrange a wheelchair bus for a route. The FAST connector service can be used the same way as the bus service. Beginning in the summer of 2011, the City of Fayetteville has plans to add a route to include stops at Health Pavilion. (Please see Exhibit 35).*

Passengers who have challenges riding the FAST fixed bus system, may be eligible through the Americans with Disabilities Act (ADA) to benefit from FASTTRAC! Services.

Cumberland County Department of Social Services, Adult Services Division, provides medical transportation to authorized Medicaid eligible persons."

-C- **FHCH.** In Section II.8, page 95, the applicant states emergency services, support services, and ancillary services will be provided on-site at the proposed hospital, and public transportation is available locally by appointment only through Hoke Area Transit Services ("HATS"). Exhibit 29 contains HATS information.

10A NCAC 14C .2105 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in a facility, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas in the facility to be developed or expanded:

(1) administration;
(2) pre-operative;
(3) post-operative;
(4) operating room; and
(5) other.

-C- **CFV North.** In Section II.8, pages 60-61, and Section VII.2, the applicant provides the proposed staffing for the facility for each of the areas listed above. The applicant adequately justifies and documents the availability of the proposed staff. CFV North is not an existing facility.

-C- **FHCH.** In Section II.8, pages 96-97, and in Section VII.2, page 257, the applicant provides the proposed staffing for the facility for each of the areas listed above. The applicant adequately justifies and documents the availability of the proposed staff. FHCH is not an existing facility.

(b) The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.

-C- **CFV North.** In Section II.8, page 61, the applicant states it estimates that 134 physicians are expected to utilize the proposed shared use surgical operating rooms at CFV North. Exhibit 19 contains copies of CFVMC medical staff credentialing policies and procedures, which will be applicable at CFV North. Exhibit 19 also includes a letter from the Chief of Staff for CFVMC, regarding credentialing for surgical and anesthesia services at CFV North and Exhibit 42 contains a letter from Dr. Eugene Wright, CFVHS Chief Medical Officer, stating *"I can confirm the credentialing criteria for surgery and anesthesia privileges at the new satellite hospital will be the same as those for physicians seeking surgery and anesthesia privileges at all Cape Fear Valley Health System facilities in North Carolina".*

-C- **FHCH.** In Section II.8, page 97, the applicant states, *"No surgeons currently perform at FHCH; however, over 30 physicians are expected to perform procedures when FHCH becomes operational.*

All physicians practicing in the service area may apply for medical staff privileges at FHCH. Please refer to Section V.3(b) for a brief description of the privileging process and to Exhibit 30 for the FMRH Medical Staff Bylaws, which include the procedures for credentialing of medical staff."

(c) The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.

-C- **CFV North.** In Section II.8, page 62, the applicant states *"The proposed two shared surgical operating rooms at CFV North will operate as a part of CFVMC. All physicians who seek CFV North surgical privileges will be seeking privileges on the CFV North medical staff. Thus, these physicians will be active members in good standing at CFV North, part of CFVMC. Please see credentialing policy (see Exhibit 19) and letter from Dr. Eugene Wright, CFVHS Chief Medical Officer in Exhibit 42."*

-C- **FHCH.** In Section II.8, page 97, the applicant states, *"All physicians seeking privileges to perform surgical procedures at FHCH will be on the Active Medical Staff and in good standing at FHCH.*

The FMRH Medical Staff Bylaws, included as Exhibit 30, delineate the procedure each physician must complete for appointment to the Medical Staff for clinical privileges. Article III. Section 2. (A-B) requires each physician to be licensed in the State of North Carolina, be located in the service area, possess current, valid professional liability insurance coverage, and several other requirements.

FirstHealth will add a 'Hoke Community Hospital' section to the Medical Staff Bylaws, which will commit FHCH to the same quality-related requirements as FMRH."

(d) The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.

-NA- **Both Applicants.** Neither applicant proposes to develop a single specialty demonstration facility.

10A NCAC 14C .2106 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

-NA- **Both Applicants.** Neither applicant proposes to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

(b) An applicant proposing to establish a licensed ambulatory surgical facility or a new hospital shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.

-C- **CFV North.** In Section II.8, pages 62-63, the applicant states that *"CFV North will be licensed as part of CFVMC which is fully accredited by the*

Joint Commission. Please see Exhibit 39..." Exhibit 42 contains a letter from the COO of CFVHS assuring CFV North shall receive accreditation from the Joint Commission within two years of completion of the facility.

-C- **FHCH.** In Section II.8, page 98, the applicant states that the facility will be accredited by the Joint Commission within two years of completion of operation.

(c) All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.

-C- **CFV North.** In Section II.8, page 63, and Exhibit 42, the applicant documents that the physical environment of CFV North will conform to the requirements of federal, state, and local regulatory bodies.

-C- **FHCH.** In Section II.8, page 98, and Exhibit 23, the applicant documents that the operating suite in the facility will conform to the requirements of federal, state, and local regulatory bodies. See discussion in 10A NCAC 14C .1400, Criterion (12) and Criterion (3) regarding conformity with respect to neonatal services.

(d) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a floor plan of the proposed facility identifying the following areas:

(1) receiving/registering area;
(2) waiting area;
(3) pre-operative area;
(4) operating room by type;
(5) recovery area; and
(6) observation area.

-C- **CFV North.** Exhibit 9 contains a design schematic of the proposed CFV North which identifies the areas required by this Rule.

-C- **FHCH.** Exhibit 14 contains a design schematic of the proposed facility which identifies the areas required by this Rule.

(e) An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:

(1) physicians;
(2) ancillary services;

(3) support services;
(4) medical equipment;
(5) surgical equipment;
(6) receiving/registering area;
(7) clinical support areas;
(8) medical records;
(9) waiting area;
(10) pre-operative area;
(11) operating rooms by type;
(12) recovery area; and
(13) observation area.

-NA- **Both Applicants.** Neither applicant proposes to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility.

SECTION .1200 – CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

These rules apply only to FHCH, who proposes to develop new intensive care unit (ICU) beds. CFV North proposes to relocate existing ICU beds from the Owen Drive campus.

10A NCAC 14C .1202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes new or expanded intensive care services shall use the Acute Care Facility/Medical Equipment application form.

-C- FHCH used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing new or expanded intensive care services shall submit the following information:

(1) the number of intensive care beds currently operated by the applicant and the number of intensive care beds to be operated following completion of the proposed project;

-C- In Section II.8, page 72, FHCH provides a table showing that FirstHealth currently operates 62 ICU beds: 50 at FMRH and 12 at FRMH. The applicant proposes to develop 8 ICU beds in the new hospital.

(2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including:
(A) the number of inpatient days of care provided to intensive care patients;

(B) the number of patients initially treated at the facility and referred to other facilities for intensive care services; and
(C) the number of patients initially treated at other facilities and referred to the applicant's facility for intensive care services.

-NA- FHCH proposes to develop a new facility.

(3) the projected number of patients to be served and inpatient days of care to be provided by county of residence by specialized type of intensive care for each of the first twelve calendar quarters following completion of the proposed project, including all assumptions and methodologies;

-C- In Section II.8, page 73, FHCH provides tables showing the projected number of patients to be served and inpatient days of care to be provided by county of residence for the eight proposed general ICU beds for each of the first twelve calendar quarters following completion of the proposed project. The applicant's assumptions and methodology are discussed in Section IV, pages 174-210. However, FHCH's projections are not based on reasonable and supported assumptions. See Criterion (3) for discussion.

(4) data from actual referral sources or correspondence from the proposed referral sources documenting their intent to refer patients to the applicant's facility;

-C- Exhibit U contains copies of letters from physicians documenting their intent to refer patients to the proposed facility.

(5) documentation which demonstrates the applicant's capability to communicate effectively with emergency transportation agencies;

-C- Exhibit 20 contains a copy of a letter from the Interim Chief Nursing Officer of FirstHealth documenting that the proposed hospital will be capable of communicating effectively with emergency transportation agencies.

(6) documentation of written policies and procedures regarding the provision of care within the intensive care unit, which includes the following:
(A) the admission and discharge of patients;
(B) infection control;
(C) safety procedures; and
(D) scope of services.

-C- Exhibit 21 contains documentation of written policies and procedures regarding the provision of care within the ICU which include each of the areas set forth in subparagraphs (A) through (D) above.

(7) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access;

-C- Exhibit 22 contains a letter documenting that ICU services will be operated in an area is organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access.

(8) documentation to show that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

-C- Exhibit 23 contains a letter from the project architect documenting that the services will be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

(9) a floor plan of the proposed area drawn to scale; and

-C- Exhibit 14 contains a floor plan.

(10) documentation of a means for observation by unit staff of all patients in the unit from at least one vantage point.

-C- In Section II.8, page 74, FHCH states, *"Please refer to Exhibit 24 for a floor plan showing observation by unit staff of all patients in the unit from at least one vantage point."*

10A NCAC 14C .1203 PERFORMANCE STANDARDS

(a) The applicant shall demonstrate that the proposed project is capable of meeting the following standards:

(1) the overall average annual occupancy rate of all intensive care beds in the facility, excluding neonatal and pediatric intensive care beds, over the 12 months immediately preceding the submittal of the proposal, shall have been at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds; and

-NA- FHCH proposes to develop a new facility.

(2) the projected occupancy rate for all intensive care beds in the applicant's facility, exclusive of neonatal and pediatric intensive care beds, shall be at

least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds, in the third operating year following the completion of the proposed project.

-NC- In Section II.8, page 75, FHCH states it will provide 1,844 patient days in the proposed 8-bed ICU in the third operating year (FFY2018), for a projected occupancy rate of 63.2 percent. However, the applicant did not adequately demonstrate that projected utilization is based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming with this Rule.

(b) All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided.

-NC- FHCH's assumptions and data supporting the methodology by which the occupancy rates were determined are provided in Section IV, pages 174-210. However, projected utilization is not based on reasonable and supported assumptions and data. See Criterion (3) for discussion. Therefore, the application is nonconforming with this Rule.

10A NCAC 14C .1204 SUPPORT SERVICES

(a) An applicant proposing new or additional intensive care services shall document the extent to which the following items are available:

(1) twenty-four hour on-call laboratory services including microspecimen chemistry techniques and blood gas determinations;
(2) twenty-four hour on-call radiology services, including portable radiological equipment;
(3) twenty-four hour blood bank services;
(4) twenty-four hour on-call pharmacy services;
(5) twenty-four hour on-call coverage by respiratory therapy;
(6) oxygen and air and suction capability;
(7) electronic physiological monitoring capability;
(8) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
(9) endotracheal intubation capability;
(10) cardiac pacemaker insertion capability;
(11) cardiac arrest management plan;
(12) patient weighing device for bed patients; and
(13) isolation capability.

-C- Exhibit 25 contains a letter from the Interim Chief Nursing Officer documenting that the services listed in (1) through (13) above will be available at the proposed FHCH.

(b) *If any item in Subparagraphs (a)(1) - (13) of this Rule will not be available, the applicant shall document the reason why the item is not needed for the provision of the proposed services.*

-C- In Section II.8, page 76, FHCH states that it proposes to offer all of the items in Subparagraphs (a)(1) - (13) of this Rule at the proposed FHCH.

10A NCAC 14C .1205 STAFFING AND STAFF TRAINING

The applicant shall demonstrate the ability to meet the following staffing requirements:

(1) nursing care shall be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support;

-C- Exhibit T contains the job description for ICU registered nurses.

(2) direction of the unit shall be provided by a physician with training, experience and expertise in critical care;

-C- In Section II.8, page 77, FHCH states "*Please refer to Exhibit T for the ICU Medical Director Agreement which identifies the required training, experience, and expertise needed to act as a medical director, specifically listed under 3.a.ii.*"

(3) assurance from the medical staff that twenty-four hour medical and surgical on-call coverage is available; and

-C- Exhibit 26 contains a letter from the President of FMRH's Medical Staff indicating that twenty-four hour medical and surgical on-call coverage will be extended to FHCH.

(4) inservice training or continuing education programs shall be provided for the intensive care staff.

-C- Exhibit 24 contains copies of the in-service training and continuing education programs available to the intensive care staff. Exhibit 28 contains a letter from the Interim Chief Nursing Office documenting that the regulations in 10A NCAC 14C.1205 will be meet at FHCH.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

These rules apply only to FHCH, who proposes to acquire a new CT scanner. CFV North proposes to incorporate the existing CT scanner at the Health Pavilion into the radiology Department at CFV North.

10A NCAC 14C .2302 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire a CT scanner shall use the acute care facility/medical equipment application form.

-C- FHCH used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire a CT scanner shall provide the number of CT scans that have been performed on each existing CT scanner which the applicant or a related entity owns a controlling interest in and is located in the proposed CT service area for each type of CT scan listed in this Paragraph for the previous 12 month period:

(1) head scan without contrast;
(2) head scan with contrast;
(3) head scan without and with contrast;
(4) body scan without contrast;
(5) body scan with contrast;
(6) body scan without contrast and with contrast;
(7) biopsy in addition to body scan with or without contrast; and
(8) abscess drainage in addition to body scan with or without contrast.

-NA- In Section II.8, page 101, FHCH states neither the applicant nor a related entity owns a controlling interest in an existing CT scanner in the proposed CT service area (Hoke, Cumberland, Robeson, and Scotland counties.)

(c) The applicant shall project the number of CT scans to be performed on the proposed CT scanner for each type of CT scan listed in this Paragraph for each of the first three years the new CT scanner is proposed to be operated:

(1) head scan without contrast;
(2) head scan with contrast;
(3) head scan without and with contrast;
(4) body scan without contrast;
(5) body scan with contrast;
(6) body scan without contrast and with contrast;
(7) biopsy in addition to body scan with or without contrast; and
(8) abscess drainage in addition to body scan with or without contrast.

-C- In Section II.8, page 102-103, FHCH provides the projected number of CT scans to be performed on the proposed CT scanner for each type of CT scan listed in this Paragraph for each of the first three operating years.

(d) The applicant shall convert the historical and projected number of CT scans to HECT units as follows:

	Type of CT Scan	No. of Scans		Conversion Factor		HECT Units
1	Head without contrast		X	1.00	=	
2	Head with contrast		X	1.25	=	
3	Head without and with contrast		X	1.75	=	
4	Body without contrast		X	1.50	=	
5	Body with contrast		X	1.75	=	
6	Body without contrast and with contrast		X	2.75	=	
7	Biopsy in addition to body scan with or without contrast		X	2.75	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00	=	

-C- In Section II.8, pages 102-104, FHCH converts the projected number of CT scans to be performed on the proposed CT scanner for each type of CT scan to HECT units as shown in this Rule for each of the first three operating years.

(e) An applicant proposing to acquire a mobile CT scanner shall provide the information requested in Paragraphs (b), (c), and (d) of this Rule for each proposed host facility.

-NA- FHCH does not propose to acquire a mobile CT scanner.

(f) The applicant shall provide projected charges for each of the 20 most frequent CT scans to be performed for each of the first three years the new CT scanner is proposed to be operated.

-C- In Section II.8, page 105, FHCH provides the projected charges for each of the 20 most frequent CT scans to be performed for each of the first three operating years.

(g) If an applicant that has been utilizing a mobile CT scanner proposes to acquire a fixed CT scanner for its facility, the applicant shall demonstrate that its projected charge

per CPT code shall not increase more than 10 percent over its current charge per CPT code on the mobile CT scanner.

-NA- FHCH has not been utilizing a mobile CT scanner.

(h) An applicant proposing to acquire a mobile CT scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities of the new CT scanner.

-NA- FHCH does not propose to acquire a mobile CT scanner.

(i) An applicant proposing to acquire a CT scanner shall demonstrate that it has a written commitment from a radiologist, licensed to practice medicine in North Carolina, to provide professional interpretation services for the applicant.

-C- Exhibit 32 contains letters from radiologists licensed to practice medicine in North Carolina offering to provide professional interpretation services for FHCH.

(j) An applicant proposing to acquire a CT scanner shall demonstrate that the CT scanner shall be available and staffed for performing CT scan procedures at least 66 hours per week.

-C- In Section II.8, page 106, FHCH states "*The 16-slice CT scanner will be available and staffed 24 hours per day/7 days per week. Scheduled outpatient CT procedures will be available from 9:00 AM-5:00PM M-S.*"

10A NCAC 14C .2303 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

(1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;

-NC- In Section II.8, page 107, FHCH projects the proposed CT scanner will perform 10,449 HECT units in the third year of operation (FY2018). However, projected utilization is not based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming with this Rule.

(2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and

-NA- In Section II.8, page 107, FHCH states "*FirstHealth does not own or operate a CT scanner in the proposed service area, which includes Hoke, Cumberland, Robeson, and Scotland counties.*"

(3) each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.

-NA- In Section II.8, page 107, FHCH states "*FirstHealth does not own or operate a CT scanner in the proposed service area, which includes Hoke, Cumberland, Robeson, and Scotland counties.*"

10A NCAC 14C .2304 SUPPORT SERVICES

(a) With the exception of applicants that currently provide CT services, an applicant proposing to acquire a CT scanner shall document the availability of the following diagnostic services:

(1) diagnostic radiology services;
(2) therapeutic radiology services;
(3) nuclear medicine services; and
(4) diagnostic ultrasound services.

-C- The applicant currently provides CT services in Moore County. In Section II.8, page 108, the applicant states "*...please refer to Exhibit 33 for documentation that the previously identified diagnostic services are available.*" Exhibit 33 contains documentation that the diagnostic services listed in (1) through (4) of this Rule will be available at the proposed FHCH in Hoke County.

(b) An applicant proposing to acquire a mobile CT scanner shall provide:

(1) referral agreements between each host site and at least one other provider of CT services in the proposed CT service area to document the availability of CT services if patients require them when the mobile unit is not in service at that host site; and
(2) documentation that each of the services listed in Paragraphs (a) and (b) of this Rule shall be available at each host facility or shall be available through written affiliation or referral agreements.

-NA- FHCH does not propose to acquire a mobile CT scanner.

10A NCAC 14C .2305 STAFFING AND STAFF TRAINING

(a) With the exception of applicants that currently provide CT services, an applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements:

(1) one radiologist who is certified by the American Board of Radiologists and has had:

(A) training in computed tomography as an integral part of his or her residency training program; or

(B) six months of supervised CT experience under the direction of a diagnostic radiologist who is certified by the American Board of Radiologists; or

(C) at least six months of fellowship training, or its equivalent, in CT; or

(D) a combination of CT experience and fellowship training equivalent to Parts (a)(1) (A), (B), or (C) of this Rule;

-C- The applicant currently provides CT services in Moore County. Exhibit 32 contains a letter Pinehurst Radiology and Charlotte Radiology radiologists who will provide radiology services at FHCH in Hoke County.

(2) at least one radiology technologist registered by the American Registry of Radiologic Technologists shall be present during the hours of operation of the CT unit; and

-C- The applicant currently provides CT services in Moore County. In Section II.8, page 109, and Exhibit 34 the applicant states that one at least one radiology technologist registered by the American Registry of Radiologic Technologists will be present during the hours of operation of the proposed CT scanner at FHCH in Hoke County. Exhibit T contains job descriptions, including the required certifications of staff.

(3) a radiation physicist with training in medical physics shall be available for consultation for the calibration and maintenance of the equipment. The radiation physicist may be an employee or an independent contractor.

-C- The applicant currently provides CT services in Moore County. In Section II.8, page 109, the applicant states "*Bill DeForest with ProPhysics Innovations, FirstHealth's contract physicist, will be available for consultation for the calibration and maintenance of the CT scanner.*" Exhibit 35 contains a letter from William DeForest expressing his willingness to provide consultation for the calibration and maintenance services on the CT scanner in Hoke County.

(b) With the exception of applicants that currently provide CT services, an applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided to clinical personnel:

(1) certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support; and

-C- In Section II.8, page 110, the applicant states *"FirstHealth currently provides CT services."* Exhibit 36 contains the CPR and basic life support training schedule.

(2) an organized program of staff education and training which is integral to the services program and ensures improvements in technique and the proper training of new personnel.

-C- In Section II.8, page 110, the applicant states *"FirstHealth currently provides CT services... FirstHealth of the Carolinas is accredited by the North Carolina Medical Society to provide continuing medical education for physicians and will expand to cover FHCH. Continuing medical education programs on various topics are routinely held and are open to FirstHealth physicians as well as other interested physicians from FirstHealth's service area. FirstHealth has a corporate educations program, FirstU, which is available to all staff and volunteers. FirstU provides courses in management training and patient care. Many other training programs to support quality patient care are available as needed. FirstHealth's Health Sciences Library is centrally located and has medical, nursing, allied health, leadership development and community collections. These collections include texts, journals and electronic resources. Interlibrary loans are also available as needed. The library resources can be quickly accessed throughout FirstHealth by electronic means.*

FirstU has a wide ranging continuing education and training program."

Exhibit 27 contains a complete list of education classes and courses offered by FirstU.

(c) An applicant proposing to acquire a mobile CT scanner shall document that the requirements in Paragraphs (a) and (b) of this Rule shall be met at each host facility.

-NA- FHCH does not propose to acquire a mobile CT scanner.

SECTION .1400 – CRITERIA AND STANDARDS FOR NEONATAL SERVICES

10A NCAC 14C .1402 INFORMATION REQUIRED OF APPLICANT

These rules apply only to FHCH, who proposes to offer obstetrical services, including 3 LDRP beds. FHCH asserts in response to written comments that it did not respond to these rules because it believed they were not applicable because it didn't propose to develop a Level I nursery. However, according to the Acute and Home Care Licensure and Certification Section, DHSR, FHCH would be required to have a Level I nursery. Therefore, the rules promulgated in 10A NCAC .1400 apply to this review.

(a) An applicant proposing to develop a Level I nursery in the facility for the first time or new or additional Level II, III or IV neonatal beds shall use the Acute Care Facility/Medical Equipment application form.

-C- FHCH used the Acute Care Facility/ Medical Equipment application form.

(b) An applicant proposing to develop a Level I nursery in the facility for the first time or new or additional Level II, III or IV neonatal beds shall provide the following information:

(1) the current number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds operated by the applicant;

-NA- FHCH is not an existing facility.

(2) the proposed number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds to be operated following completion of the proposed project;

-C- FHCH does not propose any Level I nursery bassinets. Note: According to the Acute and Home Care Licensure and Certification Section, FHCH would be required to have a Level I nursery, including unlicensed bassinets because it proposes to offer obstetrical services.

(3) evidence of the applicant's experience in treating the following patients at the facility during the past twelve months, including:
(A) the number of obstetrical patients treated at the acute care facility;

(B) the number of neonatal patients treated in Level I nursery bassinets, Level II beds, Level III beds and Level IV beds, respectively;

(C) the number of inpatient days at the facility provided to obstetrical patients;

(D) the number of inpatient days provided in Level II beds, Level III beds and Level IV beds, respectively;

(E) the number of high-risk obstetrical patients treated at the applicant's facility and the number of high-risk obstetrical patients referred from the applicant's facility to other facilities or programs; and

(F) the number of neonatal patients referred to other facilities for services, identified by required level of neonatal service (i.e. Level II, Level III or Level IV);

-NA- FHCH is not an existing facility.

(4) *the projected number of neonatal patients to be served identified by Level I, Level II, Level III and Level IV neonatal services for each of the first three years of operation following the completion of the project, including the methodology and assumptions used for the projections;*

-NC- In Section II.8, page 117, FHCH provides the number of neonatal patient days of care it projects to provide in each of the first three operating years, as illustrated in the table below.

FHCH- Neonatal Days of Care

	PY1 2016	PY2 2017	PY3 2018
MDC 15 newborn and other neonates (perinatal period)	382	521	657

The applicant provides a description of its methodology and assumptions used for other projections in Section IV.1, pages 174-201. However, the applicant does not describe how it determined the number of neonatal patients. Indeed, the applicant does not even provide the projected number of neonatal patients to be served, as required by this Rule. Therefore, the application is nonconforming with this Rule.

(5) *the projected number of patient days of care to be provided in Level I bassinets, Level II beds, Level III beds, and Level IV beds, respectively, for each of the first three years of operation following completion of the project, including the methodology and assumptions used for the projections;*

-NC- In Section II.8, page 117, FHCH provides the number of neonatal days of care to be provided in each of the first three operating years, as illustrated in the table below.

FHCH- Neonatal Days of Care

	PY1 2016	PY2 2017	PY3 2018
MDC 15 newborn and other neonates (perinatal period)	382	521	657

The applicant provides a description of its methodology and assumptions used for other projections in Section IV.1, pages 174-201 of the

application. However, the applicant does not describe how it determined the number of neonatal days of care, as required by this Rule. Therefore, the application is nonconforming with this Rule.

(6) *if proposing to provide Level I or Level II neonatal services in the facility for the first time, documentation that at least 90 percent of the anticipated patient population is within 30 minutes driving time one-way from the facility;*

-NC- FHCH proposes to provide Level I neonatal services at FHCH for the first time. However, the applicant did not provide documentation that at least 90 percent of the anticipated patient population is within 30 minutes driving time one-way from the facility. Therefore, the application is nonconforming with this Rule.

(7) *if proposing to provide Level I or Level II neonatal services in the facility for the first time, documentation of a written plan to transport infants to Level III or Level IV neonatal services as the infant's care requires;*

-NC- FHCH proposes to provide Level I neonatal services in the facility for the first time. The applicant did not provide documentation of a written plan to transport infants to Level III or Level IV neonatal services as the infant's care requires. Therefore, the application is nonconforming with this Rule.

(8) *evidence that the applicant shall have access to a transport service with at least the following components:*

(A) trained personnel;
(B) transport incubator;
(C) emergency resuscitation equipment;
(D) oxygen supply, monitoring equipment and the means of administration;
(E) portable cardiac and temperature monitors; and
(F) a mechanical ventilator;

-NC- FHCH did not provide evidence that it would have access to a transport service with each component listed above, particularly a transport incubator. Therefore, the application is nonconforming with this rule.

(9) *documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access;*

-NC- FHCH did not provide documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access. Indeed, the design schematic in Exhibit 14

and Section II, page 41, does not show a Level I nursery. Therefore, the application is non-conforming with this Rule.

(10) documentation to show that the new or additional Level I, Level II, Level III or Level IV neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

-NC- FHCH did not provide documentation that new Level I neonatal services would be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies. Therefore, the application is nonconforming with this rule.

(11) a floor plan of the proposed area drawn to scale;

-NC- Exhibit 14 contains design schematics of the proposed FHCH. However, there is no Level I nursery even though FHCH proposes to offer obstetrical services. According to the Acute and Home Care Licensure and Certification Section, DHSR, FHCH would be required to have a Level I nursery, including unlicensed bassinets. Therefore, the application is nonconforming with this rule.

(12) documentation of visual observation by unit staff of all patients from one or more vantage points; and

-NC- FHCH did not provide documentation of visual observation by unit staff of all patients from one or more vantage points. Indeed, there is no Level I nursery proposed. Therefore, the application is nonconforming with this rule.

(13) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.

-NC- FHCH did not provide documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies. Indeed, there is no Level I nursery proposed. Therefore, the application is nonconforming with this rule.

(c) If proposing to provide Level III or Level IV neonatal services in the facility for the first time, the applicant shall also provide the following information:

(1) documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide specialized

levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients;

(2) evidence that existing and approved neonatal services in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level III and Level IV services;

(3) an analysis of the proposal's impact on existing Level III and Level IV neonatal services which currently serve patients from the applicant's primary service area;

(4) the availability of high risk OB services at the site of the applicant's planned neonatal service;

(5) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and

(6) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including the following:

(A) the admission and discharge of patients;

(B) infection control;

(C) safety practices;

(D) the triaging of patients requiring consultations, including the transfer of patients to another facility; and

(E) the protocols for obtaining emergency physician care for a sick infant.

-NA- FHCH does not propose to provide Level III or Level IV neonatal services.

10A NCAC 14C .1403 PERFORMANCE STANDARDS

(a) An applicant shall demonstrate that the proposed project is capable of meeting the following standards:

(1) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level III and Level IV beds), the overall average annual occupancy of the combined number of existing Level II, Level III and Level IV beds in the facility is at least 75 percent, over the 12 months immediately preceding the submittal of the proposal;

(2) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level III and Level IV beds), the projected overall average annual occupancy of the combined number of Level II, Level III and Level IV beds proposed to be operated during the third year of operation of the proposed project shall be at least 75 percent; and

(3) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this rule.

-NA- FHCH only proposes Level I neonatal services for the first time.

(b) If an applicant proposes to develop a new Level III or Level IV service, the applicant shall document that an unmet need exists in the applicant's defined neonatal service area, unless the State Medical Facilities Plan includes a need determination for neonatal beds in the service area. The need for Level III and Level IV beds shall be computed for the applicant's neonatal service area by:

(1) identifying the annual number of live births occurring at all hospitals within the proposed neonatal service area, using the latest available data compiled by the State Center for Health Statistics;

(2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in (1) of this Paragraph, using the latest available data compiled by the State Center for Health Statistics;

(3) dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and

(4) determining the need for Level III and Level IV beds in the proposed neonatal service area as the product of:

(A) the product derived in (3) of this Paragraph, and

(B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in (1) of this Paragraph by the number 1000.

-NA- FHCH only proposes Level I neonatal services for the first time.

10A NCAC 14C .1404 SUPPORT SERVICES

(a) An applicant proposing to provide new Level I, Level II, Level III or Level IV services shall document that the following items shall be available, unless an item shall not be available, then documentation shall be provided obviating the need for that item:

(1) competence to manage uncomplicated labor and delivery of normal term newborn;

-NC- FHCH did not provide documentation that competence to manage uncomplicated labor and delivery of normal term newborn would be available nor did FHCH document that this item would not be needed. Therefore, the application is nonconforming with this Rule.

(2) capability for continuous fetal monitoring;

-NC- FHCH did not provide documentation that the capability for continuous fetal monitoring would be available nor did FHCH document that this item would not be needed. Therefore, the application is nonconforming with this Rule.

(3) *a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;*

-NC- FHCH did not provide documentation that a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother would be available nor did FHCH document that this item would not be needed. Therefore, the application is nonconforming with this Rule.

(4) *obstetric services;*

-C- FHCH provides documentation that obstetric services would be available. See Section II, page 34-35, 39, 41, Section III, page 128, Section IV, page 201, and Exhibits L and T.

(5) *anesthesia services;*

-C- FHCH provides documentation that anesthesia services would be available. See Section II, pages 44, 87-88, and Exhibits L and T.

(6) *capability of cesarean section within 30 minutes at any hour of the day; and*

-NC- FHCH did not provide documentation that it would have the capability of cesarean section within 30 minutes at any hour of the day would be available nor did FHCH document that this item would not be needed. Therefore, the application is nonconforming with this Rule.

(7) *twenty-four hour on-call blood bank, radiology, and clinical laboratory services*

-C- FHCH provides documentation that twenty-four hour on-call blood bank, radiology, and clinical laboratory services. See Section II.8, page 76 and Exhibit 25..

(b) *An applicant proposing to provide new Level III Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:*

(1) *competence to manage labor and delivery of premature newborns and newborns with complications;*

(2) *twenty-four hour availability of microchemistry hematology and blood gases;*

(3) *twenty-four hour coverage by respiratory therapy;*

(4) twenty-four hour radiology coverage with portable radiographic capability;
(5) oxygen and air and suction capability;
(6) electronic cardiovascular and respiration monitoring capability;
(7) vital sign monitoring equipment which has an alarm system that is operative at all times;
(8) capabilities for endotracheal intubation and mechanical ventilatory assistance;
(9) cardio-respiratory arrest management plan;
(10) isolation capabilities;
(11) social services staff;
(12) occupational or physical therapies with neonatal expertise; and
(13) a registered dietician or nutritionist with training to meet the special needs of neonates.

-NA- FHCH does not propose to provide new Level III Level IV services.

(c) An applicant proposing to provide new Level IV services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:
(1) pediatric surgery services;
(2) ophthalmology services;
(3) pediatric neurology services;
(4) pediatric cardiology services;
(5) on-site laboratory facilities;
(6) computed tomography and pediatric cardiac catheterization services;
(7) emergency diagnostic studies available 24 hours per day;
(8) designated social services staff; and
(9) serve as a resource center for the statewide perinatal network.

-NA- FHCH does not propose to provide new Level IV neonatal services.

10A NCAC 14C .1405 STAFFING AND STAFF TRAINING
An applicant shall demonstrate that the following staffing requirements for hospital care of newborn infants shall be met:
(1) If proposing to provide new Level I or II services the applicant shall provide documentation to demonstrate that:
(a) the nursing care shall be supervised by a registered nurse in charge of perinatal facilities;

-NC- FHCH did not provide adequate documentation to demonstrate that the nursing care shall be supervised by a registered nurse in charge of perinatal facilities. Therefore, the application is nonconforming with this Rule.

(b) a physician is designated to be responsible for neonatal care; and

-NC- FHCH did not provide adequate documentation to demonstrate that the physician is designated to be responsible for neonatal care. Therefore, the application is nonconforming with this Rule.

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

-C- FHCH provides documentation to demonstrate that the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis. See Section II.8, page77, and Exhibit 26..

(2) If proposing to provide new Level III services the applicant shall provide documentation to demonstrate that:

(a) the nursing care shall be supervised by a registered nurse;

(b) the service shall be staffed by a pediatrician certified by the American Board of Pediatrics; and

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

-NA- FHCH does not propose to provide Level III service.

(3) If proposing to provide new Level IV services the applicant shall provide documentation to demonstrate that:

(a) the nursing care shall be supervised by a registered nurse with educational preparation and advanced skills for maternal-fetal and neonatal services;

(b) the service shall be staffed by a full-time board certified pediatrician with certification in neonatal medicine; and

(c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.

-NA- FHCH does not propose to provide a new Level IV service.

(4) All applicants shall submit documentation which demonstrates the availability of appropriate in-service training or continuing education programs for neonatal staff.

-NC- FHCH did not provide any documentation which demonstrates the availability of appropriate in-service training or continuing education programs for neonatal staff. Therefore, the application is nonconforming with this Rule.

(5) All applicants shall submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.

-NC- FHCH did not provide any documentation which demonstrates the proficiency and ability of the nursing staff to teach parents how to care for neonatal patients following discharge to home. Therefore, the application is nonconforming with this Rule.

(6) All applicants shall submit documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, state and local regulatory bodies.

-NC- FHCH did not provide any documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, state and local regulatory bodies. Indeed, FirstHealth failed to include a Level I nursery in its proposal even though it proposes to offer obstetrical services. According to the Acute and Home Care Licensure and Certification Section, DHSR, FHCH would be required to have a Level I nursery, including unlicensed bassinets. Therefore, the application is nonconforming with this rule.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2011 SMFP, no more than 65 acute care beds may be approved for the Cumberland Hoke Multi-County Acute Care Bed Service Area. Because the two applications in this review propose a total of 130 acute care beds, both of the applications cannot be approved. The analyst considered all of the information in each application and reviewed each application individually against all applicable review criteria. Based on that review, neither application is approvable standing alone. Nevertheless, the analyst conducted a comparative analysis of the proposals.

For the reasons set forth in the rest of the findings, the applications submitted by CFV North, Project I.D. # M-8689-11, and the application submitted by FHCH, Project I.D. # N-8690-11, are denied.

Geographic Accessibility

The 2011 SMFP identifies a need for 65 acute care beds for the Cumberland Hoke Multi-County Acute Care Bed Service Area. The 2011 SMFP need determination does not indicate where in either of those counties the beds should be located. The following table identifies the location of the existing and approved acute care beds in the Cumberland Hoke Multi-County Acute Care Bed Service Area.

Facility	Existing/ Approved Acute Care Beds	Location Within the Cumberland Hoke Multi-County Acute Care Bed Service Area	City/Town
Cape Fear Valley Medical Center	490	Cumberland County- Central	Fayetteville-South
Hoke Community Medical Center	41	Hoke County - Central/East	McLauchlin Township
FirstHealth Hoke Community Hospital*	8	Hoke County- Central/East	McLauchlin Township

*If FHCH's application in this review were approved, the application for the 8-bed hospital would be withdrawn.

The following table identifies the location of the acute care beds proposed to be developed in this review.

Facility	Proposed Acute Care Beds	Location Within the Cumberland Hoke Multi-County Acute Care Bed Service Area	City/Town
FirstHealth Hoke Community Hospital	65	Hoke County- Central/East	McLauchlin Township
Cape Fear Valley-North	65	Cumberland County- North	Fayetteville-North

As shown above, FHCH proposes a site in central/eastern Hoke County in McLauchlin Township. The proposed site for CFV North is in northern Cumberland County. However, the proposed site for the FirstHealth application is located approximately 3.5 miles from the site of the Hoke Community Medical Center, an approved 41-bed acute care hospital currently under appeal. FHCH proposes to develop the 65-bed acute care hospital on the same site for which it was approved to construct an 8-bed acute care hospital (which approval is currently under appeal). FHCH did not adequately demonstrate the need for the 65-bed hospital in addition to the approved 41-bed hospital. See Criteria (3) and (6) for discussion. Therefore, with regard to improving geographic access to the proposed services, the CFV North application is determined to be more effective than the FHCH application.

Access by Underserved Groups

The following tables show the average inpatient utilization (admissions) for acute general hospitals by payer category for North Carolina and Cumberland County. (The data includes normal newborns.) Hoke County does not have an existing hospital. For North Carolina, data are based on 1,113,423 inpatient admissions. For Cumberland County, data are based on 35,956 inpatient admissions.

North Carolina Hospital Admissions by Payer Category-FY2009

Payer Category	Percent of Total
Commercial/HMO	32.9%
Medicare	36.0%
Medicaid	21.9%
Other	3.1%
Uninsured	6.1%
Total	**100.0%**

Source: Cecil B. Sheps Center for Health Services Research

Cumberland County Hospital Admissions by Payer Category-FY2009

Payer Category	Percent of Total
Commercial/HMO	20.4%
Medicare	35.7%
Medicaid	29.8%
Other-Gov.	8.0
Other	0.2%
Uninsured	6.0%
Total	**100.0%**

Source: Cecil B. Sheps Center for Health Services Research

The following table shows each applicants' projected percentage of hospital services to be provided to Medicaid and Medicare recipients in the second year following completion of the project, as stated by the applicants in Section VI.14(a) of the applications.

Applicant	Projected Percentage of Services to be Provided to Medicare Recipients	Projected Percentage of Services to be Provided to Medicaid Recipients
CFV North	26.9%	29.6%
FHCH	47.6%	8.5%

With regard to access by Medicaid recipients, CFV North projects the highest percentage of total services to be provided to Medicaid recipients and FHCH projects the lowest percentage of total services to be provided to Medicaid recipients. This is somewhat surprising since FHCH proposes to offer obstetrical services, a service which often has a high percentage of Medicaid recipients. In contrast, obstetrical services will not be offered at CFV North. Those services will be available as they are now on the Owen Drive campus. On the other hand, CFVMC had a substantiated EMTALA during the 18 months immediately preceding the date of the decision, which casts doubt on whether CFVMC will provide adequate access to medically underserved populations. See Criterion (13b) for discussion.

With regard to access by Medicare recipients, FHCH projects the highest and CFV North projects the lowest percentage of total services to be provided to Medicare recipients.

Demonstration of Need

CFV North adequately demonstrates the need for all components of its proposal based on projected utilization which is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion. In contrast, FHCH does not adequately demonstrate the need for its proposal. See Criterion (3) for discussion. Therefore, the application submitted by CFV North, with regard to demonstration of need for the proposed services, is a more effective alternative than the application submitted by FHCH.

Financial Feasibility

CFV North adequately demonstrated that the financial feasibility of its proposed project is based upon reasonable projections of costs and revenues. See Criterion (5) for discussion. In contrast, FHCH did not adequately demonstrate that the financial feasibility of its proposed project is based upon reasonable projections of costs and revenues. See Criterion (5) for discussion. Therefore, with regard to financial feasibility, the application submitted by CFV North is a more effective alternative than the application submitted by FHCH.

Quality of Care

CFV North did not adequately demonstrate that it would provide quality care. See Criterion (20) for discussion. In contrast, FHCH did adequately demonstrate that it would provide quality care. See Criterion (20) for discussion. Therefore, with regard to quality

of care, the application submitted by FHCH is a more effective alternative than the application submitted by CFV North.

Revenues

The following table shows the gross revenue per adjusted patient day for the third operating year for each applicant. Gross revenue and adjusted patient days are taken from Form B, Form C, and the table in Section X.3 of the applications. Comparisons can be made between the two applications proposing to develop new acute care hospitals, since the applications propose to develop new acute care hospitals that are similar in size and scope of services.

Gross Revenue Comparison - Third Year of Operation

Applicant	Gross Revenue	Adjusted Patient Days	Gross Revenue Per Adjusted Patient Day
CFV North	$286,072,419	38,232	$7,482.54
FHCH	$179,800,714	24,659	$7,291.48

As shown in the table above, FHCH projects the lowest gross revenue per adjusted patient day in the third year of operation, and CFV North projects the highest gross revenue per adjusted patient day in the third year of operation. However, gross revenue projections for the FHCH proposal are not reliable to the extent they are based on projected utilization. FHCH did not adequately demonstrate that its projected utilization is based on reasonable and supported assumptions. See Criterion (3) for additional discussion. Thus, any comparison of average gross revenue per adjusted patient day for FHCH to the other application is questionable.

The following table shows the net revenue per adjusted patient day for the third operating year for each applicant. Net revenue and adjusted patient days are taken from the table in Section X.3 of the applications.

Net Revenue Comparison - Third Year of Operation

Applicant	Net Revenue	Adjusted Patient Days	Net Revenue Per Adjusted Patient Day
CFV North	$68,970,412	38,232	$1,804
FHCH	$51,056,961	24,659	$2,070

As shown in the table above, CFV North projects the lowest net revenue per adjusted patient day in the third year of operation, and FHCH projects the highest net revenue per adjusted patient day in the third year of operation. However, net revenue projections for the FHCH proposal are not reliable to the extent they are based on projected utilization. FHCH did not adequately demonstrate that its projected utilization is based on reasonable and supported assumptions. See Criterion (3) for additional discussion. Thus, any

comparison of average net revenue per adjusted patient day for FHCH to the other application is questionable.

Operating Expenses

The following table shows the operating costs (expenses) per adjusted patient day for the third operating year for each applicant. Operating costs are taken from the table in Section X.3 of the applications. Comparisons can be made between the two applications proposing to develop new acute care hospitals, since the applications propose to develop new acute care hospitals that are similar in size and scope of services.

Operating Costs Comparison - Third Year of Operation

Applicant	Operating Costs	Adjusted Patient Days	Operating Costs Per Adjusted Patient Day
CFV North	$71,674,826	38,232	$1,875
FHCH	$49,034,661	24,659	$1,989

As shown in the table above, CFV North projects the lowest operating cost per adjusted patient day in the third year of operation, and FHCH projects the highest operating costs per adjusted patient day in the third year of operation. However, operating costs projections for the FHCH proposal are not reliable to the extent they are based on projected utilization. FHCH did not adequately demonstrate that its projected utilization is based on reasonable and supported assumptions. See Criterion (3) for additional discussion. Thus, any comparison of average operating cost per adjusted patient day for FHCH to the other application is questionable.

CONCLUSION

G.S.131E 183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the CON Section. The CON Section determined that neither the application submitted by CFV North nor the application submitted by FHCH is approvable standing alone. Therefore, both applications are denied.

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center • Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary
919-855-4620

http://www.ncdhhs.gov/dhsr
Drexdal Pratt, Division Director

Azzie Y. Conley, Chief
Phone:

Fax: 919-715-3073

** Via Electronic Mail **

October 25, 2011

Micheal Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive P O Box 2000
Fayetteville, NC 28302

RE: Complaint Investigation – Intake # NC00076070

Dear Mr. Nagowski,

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the survey conducted October 17, 2011 through October 21, 2011. The purpose of conducting the complaint survey was to evaluate the Hospital's compliance with the Federal Medicare Conditions of Participation. The complaint investigation resulted in an Immediate Jeopardy (IJ) identification as of **October 21, 2011** at **10:00 AM** as a result of incidents occuring on April 17, 2011.

Specifically, pursuant to **482.13 Patients' Rights and 482.23 Nursing Services**, a behavioral health patient was physically restrained in the Emergency Department on April 17, 2011 at 9:15 PM by hospital contracted security staff that were not trained in therapeutic physical holds or patient de-descalation techniques and without adequate nursing supervision during the restraint to ensure the patient's safety, resulting in harm to the patient.

As discussed during the survey, the information gathered was forwarded to the CMS Regional Office in Atlanta (Region IV). Our state agency is recommending 23 day termination due to noncompliance with the **Conditions of Participation: 482.12 Governing Body, 482.13 Patients' Rights, 482.21 Quality Assessment/Performance Improvement, and 482.23 Nursing Services.** The Immediate Jeopardy is ongoing. CMS Regional Office in Atlanta will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina:

Ms. Rosemary Robinson
Division of Survey and Certification
CMS Atlanta Regional Office
Sam Nunn Atlanta Federal Center
61 Forsyth Street, SW Suite 4T-20
Atlanta, Georgia 30303-8909
(404) 562-7343

EXHIBIT
tabbies
a

Sincerely,

Tammy Holleman, RN

Tammy Holleman, RN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

cc: Azzie Conley, Section Chief

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite. 4T20
Atlanta, Georgia 30303-8909

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

October 28, 2011

Mr. Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive (P O Box 2000)
Fayetteville, NC 28302

RE: CMS Certification Number (CCN): 34-0028

Dear Mr. Nagowski,

Institutions accredited as hospitals by The Joint Commission (TJC) are deemed to meet all of the Medicare Conditions of Participation for hospitals, with the exception of utilization review and the special staffing and medical record requirements for psychiatric hospitals. Section 1864 of the Social Security Act authorizes the Secretary of Health and Human Services to conduct surveys of accredited hospitals participating in the Medicare program if there are "substantial allegations" indicating serious deficiencies that could potentially affect the health and safety of patients.

A substantial allegation survey was conducted at Cape Fear Valley Medical Center on **October 17, 2011 through October 21, 2011**, with immediate jeopardy being identified. A copy of the deficiencies cited during this survey is enclosed. Specifically, the facility does not meet the following conditions of participation:

42 CFR 482.12 Governing Body
42 CFR 482.13 Patient Rights
42 CFR 482.21 Quality Assessment/Performance Improvement
42 CFR 482.23 Nursing Services

When a hospital, regardless of its TJC accreditation status, is found to be out of compliance with one or more Conditions of Participation, and immediate or serious threat to patient health and safety exists, a determination must be made that the facility no longer meets the requirements for participation as a provider of services in the Medicare program. Such a determination has been made in the case of Cape Fear Valley Medical Center and accordingly, the Medicare provider agreement between Cape Fear Valley Medical Center and the Secretary of the Department of Health and Human Services is being terminated. This termination will be effective **November 13, 2011.**

The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after **November 13, 2011.** For patients admitted prior to **November 13, 2011,** payment may continue to be made for a maximum of 30 days for inpatient hospital services furnished on or after **November 13, 2011.** You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your hospital on **November 13, 2011,** to your fiscal intermediary to facilitate payment for these individuals.

We will publish a public notice in a local newspaper prior to the termination date. Termination can only be averted by correction of these deficiencies by **November 13, 2011.** Should we not hear from you, we will assume that the situation has not been corrected. **If you believe that compliance has been achieved, you should notify CMS and the North Carolina State Survey Agency in writing on or before November 13, 2011, describing in detail the specific corrective measures taken to resolve these problems and include acceptable completion dates. An acceptable plan of corrections should be received NLT 7 days from the date of receipt of this notice.** ***An acceptable plan of correction must contain the following elements:***

1) The plan of correcting the specific deficiency cited. The plan should address the processes that lead to the deficiency cited;
2) The procedure for implementing the acceptable plan of correction for the specific deficiency cited;
3) The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements;
4) The title of the person responsible for implementing the acceptable plan of correction.

If your "credible allegation" of compliance is accepted, the North Carolina State Survey Agency will be authorized to conduct a resurvey to determine if the conditions which constituted immediate jeopardy have been removed and a full survey of all conditions of participation. Please be advised, however, that failure to remove conditions that constituted immediate jeopardy will result in your hospital's termination under Medicare, effective **November 13, 2011.** If the Centers for Medicare & Medicaid Services determines that the reasons for termination remain, the effective date of the termination remains **November 13, 2011,** and you will be so informed in writing. If corrections have been made, the termination procedures will be halted, and you will be notified in writing.

If you believe that this termination decision is incorrect, you may request a hearing before an Administrative Law Judge (ALJ) at the Departmental Appeals Board, Department of Health and Human Services. Procedures governing this process are set out in section 42 CFR 498.40, et seq. To be effective, a written request for a hearing must be filed not later than 60 days after the date you receive this letter. Such a request may be made to the following address:

Sandra M. Pace
Associate Regional Administrator
Centers for Medicare & Medicaid Services
61 Forsyth Street, SW, Suite 4T20
Atlanta, Georgia 30303-8909

We will forward your request to the Departmental Appeals Board. The request for a hearing should state why CMS's decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearing, and you may be represented by legal counsel.

If there are any questions, please contact Rosemary L. Robinson at (404) 562-7405 or Rosemary.Robinson@cms.hhs.gov.

Sincerely,

Sandra M. Pace
Associate Regional Administrator
Division of Survey & Certification

Enclosure
CMS 2567

cc: TJC
State Agency

NT OF HEALTH AND HUMAN VICES CENTERS FC MEDICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMIT L

ID: ANPE11

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

Facility ID: 943057

MEDICAID PROVIDER NO.
40028
VENDOR OR MEDICAID NO.

3. NAME AND ADDRESS OF FACILITY
(L3) CAPE FEAR VALLEY MEDICAL CENTER
(L4) 1638 OWEN DRIVE P O BOX 2000
(L5) FAYETTEVILLE, NC (L6) 28302

4. TYPE OF ACTION: 6 (L8)

1. Initial 2. Recertification
3. Termination 4. CHOW
5. Validation 6. Complaint
7. On-Site Visit 9. Other
8. Full Survey After Complaint

FECTIVE DATE CHANGE OF OWNERSHIP
(L9)

DATE OF SURVEY 10/21/2011 (L34)

ACCREDITATION STATUS: 1 (L10)

0 NOT ACCREDITED 1 JC 3 DNV

7. PROVIDER/SUPPLIER CATEGORY 01 (L7)

01 Hospital	05 HHA	09 ESRD	13 PTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	15 ASC
04 SNF	08 OPT/SP	12 RHC	16 HOSPICE

FISCAL YEAR ENDING DATE: (L35)
09/30

LTC PERIOD OF CERTIFICATION
From (a):
To (b):

2. Total Facility Beds 597 (L18)

3. Total Certified Beds 597 (L17)

10. THE FACILITY IS CERTIFIED AS:

A. In Compliance With Program Requirements Compliance Based On:
___1. Acceptable POC

And/Or Approved Waivers Of The Following Requirements:
___2. Technical Personnel
___3. 24 Hour RN
___4. 7-Day RN (Rural SNF)
___5. Life Safety Code
___6. Scope of Services Limit
___7. Medical Director
___8. Patient Room Size
___9. Beds/Room

B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: (L12)

LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
	597			
(L37)	(L38)	(L39)	(L42)	(L43)

15. FACILITY MEETS
1861 (e) (1) or 1861 (j) (1): (L15)

5. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):

An unannounced onsite complaint survey was conducted on October 17-21, 2011. An Immediate Jeopardy was identified on October 21, 2011 at 1000 as a result of events that occured on April 17, 2011 at 2115. The Immediate Jeopardy was not removed and is ongoing. The State Agency recommends condition level deficiencies in 482.12 Governing Body, 482.13 Patients' Rights, 482.21 Quality Assessment/Performance Improvement, and 482.23 Nursing Services and recommends a 23 day termination. NC00076070

7. SURVEYOR SIGNATURE Date: 10/26/2011 (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 10/31/2011 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

9. DETERMINATION OF ELIGIBILITY
___ 1. Facility is Eligible to Participate
___ 2. Facility is not Eligible
(L21)

20. COMPLIANCE WITH CIVIL RIGHTS ACT:

21. 1. Statement of Financial Solvency (HCFA-2572)
2. Ownership/Control Interest Disclosure Stmt (HCFA-1513)
3. Both of the Above:

2. ORIGINAL DATE OF PARTICIPATION (L24)

23. LTC AGREEMENT BEGINNING DATE (L41)

24. LTC AGREEMENT ENDING DATE (L25)

26. TERMINATION ACTION: (L30)

VOLUNTARY 00
01-Merger, Closure
02-Dissatisfaction W/ Reimbursement
03-Risk of Involuntary Termination
04-Other Reason for Withdrawal

INVOLUNTARY
05-Fail to Meet Health/Safety
06-Fail to Meet Agreement

OTHER
07-Provider Status Change
00-Active

5. LTC EXTENSION DATE: (L27)

27. ALTERNATIVE SANCTIONS
A. Suspension of Admissions: (L44)
B. Rescind Suspension Date: (L45)

3. TERMINATION DATE: (L28)

29. INTERMEDIARY/CARRIER NO. 00000 (L31)

30. REMARKS

RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 10/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

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A000	INITIAL COMMENTS A complaint investigation was conducted October 17-21, 2011 to determine the hospital's compliance with the Medicare Conditions of Participation. The investigation resulted in the identification of an Immediate Jeopardy (IJ) to patients' health and safety beginning on April 17, 2011 related to the failure of hospital staff in the ED to implement restraints in accordance with safe and appropriate restraint techniques and without adequate nursing supervision to ensure the patient's safety; resulting in harm to the patient. The hospital's administrative staff was notified on October 21, 2011 at 1000 of the identification of the Immediate Jeopardy. Findings of the investigation revealed on 04/17/2011 at 2115 Patient #5, a 27 year-old behavioral health patient, was physically restrained on the floor of his ED room by two hospital contracted Company Police Officers, who were not trained in patient deescalation or therapeutic hold techniques, and two hospital contracted Security Officers, without adequate nursing supervision to ensure the patient's safety, resulting in harm to the patient. The patient went into cardiopulmonary arrest immediately following the restraint, with unsuccessful resuscitative efforts by hospital staff. The patient died on 04/17/2011 at 2211. An autopsy was completed by the Office of the Chief Medical Examiner, who determined the cause of death to be "asphyxia due to restraint". The hospital failed to ensure staff were trained in safe and appropriate restraint techniques and failed to ensure staff monitored restrained patients to ensure safety. Review of hospital documentation presented	A000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Michael Mazowski — TITLE: CEO — (X6) DATE: 11/02/2011

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 000	Continued From page 1 October 20, 2011 at 1000, revealed an immediate corrective action plan implemented by the hospital that included the following actions: Educate all clinical ED staff regarding the RN's ultimate responsibility for the clinical care and safety of the patient, review of the restraint policy and related forms. - to be completed with all staff during each shift change, began on 10/19/2011 at 1900 and is ongoing. Each RN assigned to psychiatric ED must be NCI trained and must never leave a patient during escalation. Only NCI trained personnel are allowed to utilize a therapeutic hold - began on 10/19/2011 at 1900 Supervisor or ED Resource Nurse to conduct 100% concurrent review of all ED restraints, including therapeutic holds, each shift. - began on 10/19/2011 at 1900 Further immediate corrective action plan implemented by the hospital and presented on October 21, 2011 at 1540 included: Only NCI trained staff, including Company Police Officers, can implement therapeutic holds. Interview on 10/21/2011 at 1540 with the Vice President of Post Acute Care Services revealed, "Non NCI trained staff cannot touch patients. They (Company Police Officers) were told that last night." - began on the evening of 10/20/2011 Consequently, the hospital failed to provide care in a safe setting, promote patients' rights, and ensure nursing staff supervised patient care by failing to ensure hospital staff in the ED implemented restraints in accordance with safe and appropriate restraint techniques and failing to ensure adequate nursing supervision of a restrained patient to prevent harm to the patient.	A 000		

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A 000	Continued From page 2 Based on evaluation of the immediate corrective action plan, the Immediate Jeopardy was determined to be ongoing.	A 000		
A 043	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, personnel file review, hospital investigation report review, restraint log review, and adverse event report review, the hospital's Governing Body failed to provide oversight and have systems in place to ensure the protection of patients' rights, an effective quality assessment and performance improvement program, and an organized nursing service to ensure the safety of patients. The findings include: 1. The hospital failed to promote and protect patients' rights by failing to ensure: a safe setting for patient care, implementation of restraints in accordance with safe and appropriate techniques, physicians' orders for restraints, restrained patients were monitored by trained staff to ensure safety, least restrictive measures were used for restrained patients, safe application of restraints by trained staff, and appropriate staff were trained in the use of nonphysical intervention skills.	A 043	Cape Fear Valley Health System (CFVHS) maintains an organizational chart that demonstrates clear delineation for leadership responsibilities up to and including the Board of Trustees (BOT) (see CFVHS Organizational Chart "attachment 1"). Administrative oversight for health system operations includes direction of processes to maintain a safe and secure environment for our patients as well as to provide quality care. After the Oct. 17-21, 2011, DHSR visit, preliminary findings were reviewed at the Board of Trustees (BOT) meeting on October 26, 2011 by the Chief Executive Officer (CEO). The BOT directed the management staff to develop a full action plan for correcting all identified deficiencies. **The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** A training and education program is being provided to the Emergency Department (ED) staff at the beginning of each shift for ED employees on a daily basis until further notice in order to comply with the Health Systems' policies and procedures for the behavioral health/psychiatric patients (see Staff Education for Behavioral Health/Psychiatric Patients "attachment 2" and Questions for Staff Interviews "attachment 2A"). The training and education consists of education on the:	

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A 043	Continued From page 3 ~cross refer to 482.13 Patient Rights' Condition: Tag A0115 2. The hospital failed to implement and maintain an effective quality assessment and performance improvement program to ensure the safety of patients. ~cross refer to 482.21 Quality Assessment/Performance Improvement Condition: Tag A0263 3. The hospital failed to have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care and ensure nursing staff were trained and competent to ensure the safe and appropriate physical restraint of patients. ~cross refer to 482.23 Nursing Services Condition: Tag A0385	A 043	1) Restraint policy (see Restraints, Seclusions and Safety Devices policy "attachment 3", Restraint/Seclusion Assessment & Monitoring Flow Sheet "attachment 3A", and Restraint/Seclusion Orders "attachment 3B") which includes all types of restraints such as the therapeutic hold 2) least restrictive measures are to be utilized first on the behavioral health/psychiatric patient when needed 3) recognition of the role of the registered nurse (RN) so all members of the health care team understand the registered nurse is always in charge of the clinical care of the patient and the provision of a safe and secure environment for the patient 4) the forms that accompany the restraint policy such as the physician order form, the monitoring and flow sheet for the restrained patient 5) computer process for ordering the restraints including the therapeutic hold 6) emphasis on patient safety at all times including during any type of patient escalation the nurse never leaves the patient and the nurse is always able to complete a physical assessment of her patient 7) required nursing and physician documentation. Application of restraints and restraint training is an annual training requirement for ED staff. Information has also been shared with the ED providers by the ED Medical Director as well as the psychiatrists that work in the ED. Periodic report related to implementation will be given to the BOT.	

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A 043	Continued from page 4	A 043	Non-violent crisis intervention (NCI) training is an annual requirement for ED nursing staff. The nursing staff will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the nurse will not be assigned to the behavioral health/psychiatric patient. Non-violent crisis intervention (NCI) training is an annual requirement for security officers. The security officers will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the security officer will not be assigned to the behavioral health/psychiatric patient. The company police officers will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. In the case of a non-current NCI certification the company police officers will not be assigned to the behavioral health/psychiatric patient. The nursing supervisors will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. Restraint training is required for ED staff that provides direct care to patients. A portion of the training includes review of the hospital policy "Restraints, Seclusions and Safety Devices" (see **"attachment 3", 3A", and 3B"**). It is also required for the security officers and company police officers. Security officers and company police officers will receive restraint training from the Training and Development Department of CFVHS. Part of the education for the security officers and company police officers is to ensure their understanding of taking direction from the clinical nurse in how to assist with the behavioral health/psychiatric patient.	

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A 043	Continued from page 4A	A 043	**Monitoring:** The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff. **Responsibility:** Vice President of Nursing, Chief Operating Officer, Chief Executive Officer, Board of Trustees	11/07/2011

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A 043	Continued from 4B	A04.	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** With the appropriate order entry in the computer for restraints, a daily restraint log is available. The restraint log is provided on a daily basis to the Nursing Supervisors, Nurse Managers, members of Nursing Performance Improvement and ED leadership. This assists the resource nurse/supervisor in the ED to be knowledgeable at all times as to which patients are in restraints. The ED nursing staff have been instructed to notify the resource nurse/supervisor in the ED upon a physician order for any type of restraint. The resource nurse/supervisor is to respond to the patient with the order for restraints immediately or as soon as possible in case of other patient type emergencies. The resource nurse/supervisor in the ED is to review the patient to ensure the patient is receiving safe care as well as ensuring the least restrictive means of restraint are being used first; physician orders, nursing documentation, and safety attendants (sitters) are assigned per policy. The concurrent quality assessment and performance improvement program consists of an audit check list for restraint monitoring that is completed by the resource nurse/supervisor for each shift to ensure policies and procedures are followed. They are submitted to the Director of the ED for review. Currently the Nursing Performance Improvement nurses have been assigned to check the restraints on a daily basis to assist with compliance. The house Nursing Supervisors also has the restraint log and they are an additional resource for ED Leadership when needed. There will be a monthly restraint quality review that is reported to Nursing Oversight Committee and up to Patient Safety Committee quarterly. Periodic reports related to implementation will be given to the BOT.	

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A 043	Continued from page 4C	A 043	**Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see Restraint Log "attachment 4" and Restraint Audit Tool "attachment 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing, Chief Operating Officer, Chief Executive Officer, Board of Trustees	11/07/2011

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A 043	Continued from 4D	A 043	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** Performance Improvement (PI) implemented a new process for review of all Quality Care Control Reports (QCCs), Security Reports and Company Police Reports. This process is outlined in the policy entitled "PI Review of Event Reports" **(see "attachment 5).** This process will be reviewed with the BOT. All Quality Care Control Reports (QCCs), Security Reports and Company Police Reports will be reviewed by a Performance Improvement/Patient Safety Coordinator daily. Friday, Saturday and Sunday reports will be reviewed on Monday. A Patient Safety Response Team (PSRT) **(see "attachment 6")** is activated prior to Monday if the event warrants. For all other occurrences PI will perform an initial screening/analysis considering severity and frequency of the occurrence. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) algorithm **(see "attachment 7")** will be the tool used to assign a severity score to all occurrences. PI will identify whether immediate investigation, Event Response Team (ERT) activation, or further review and analysis is warranted. Please see Sentinel Events and Root Cause Analysis policy **(see "attachment 8")** for composition of the ERT. The ERT will determine whether the occurrence is a sentinel event or serious near miss/close call and whether an RCA should be conducted. If further review and analysis by the involved department is warranted the staff conducting the analysis may be requested to document on a PSRT Form **(see "attachment 9").** PI and Risk Management (RM) will also track these reports and identify trends.	

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A 043	Continued from page 4E	A 043	Individual PSRTs, ERT activations, Root Cause Analyses (RCA), Failure Mode Effects Analyses (FMEA) and system issues, as well as trending of incidents over time are reported to the Harm Events Analysis Team (HEAT). Individual events that are resolved during an ERT are documented on the ERT form, are attached to the QCC and saved for future potential trending. HEAT provides periodic reports to the Quality Council, Patient Safety Committee, the Medical Executive Committee and the Board Quality and Patient Safety Committee. Identified trends will be considered for further statistical analysis or FMEA. **Monitoring:** The monitoring system will involve a second review by another PI/Patient Safety coordinator. A weekly random sample review of 2 of each type of report will be conducted. The initial assignment of error will be blinded to the second reviewer in order to establish inter-rater reliability. Results of this review will be discussed in PI department meetings and reported to the HEAT. Periodic reports related to implementation will be given to the BOT. **Responsibility:** Chief Medical Officer, Chief Executive Officer, Board of Trustees	11/07/2011

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A 043	Continued from page 4F	A 043	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** There is a resource nurse/supervisor assigned each shift in the ED. The resource/nursing supervisor is to be called to the patient area as soon as the restraint is ordered by the physician. The clinical nurse is not to leave the patient during any type of escalation of the behavioral health/psychiatric patient until the patient's condition stabilizes or the clinical nurse is relieved by another clinical nurse. The resource nurse/supervisor in the ED is to ensure there is enough nursing staff available to gather items needed for the behavioral health/psychiatric patient such as medication, restraints etc. This is part of the training and education provided to the nursing staff ongoing at shift change. There is a team leader in most zones of the ED to assist with patient care and oversight. There is also a Director of the ED that is responsible for the overall patient care provided to the ED patients (see Nursing Organizational Chart "attachment 10"). Also there is a house Nursing Supervisor on duty 24 hours per day, 7 days per week that is also responsible for overseeing the ED as part of the supervisor responsibility. The Director of the ED reports directly to the Vice President of Nursing, who reports to the Chief Operating Officer. **Monitoring:** The Director of the ED oversees the staffing and scheduling of the ED to ensure there is a resource nurse/supervisor in the ED 24 hours per day, 7 days per week. There is also a house nursing supervisor scheduled 24 hours per day, 7 days per week that has oversight responsibility for the entire hospital. **Responsibility:** Vice President of Nursing, Chief Operating Officer, Chief Executive Officer, Board of Trustees	11/07/2011

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A 115	Continued From page 4G 482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, personnel file review, and hospital investigation report review, the hospital failed to promote and protect patients' rights by failing to ensure: a safe setting for patient care, implementation of restraints in accordance with safe and appropriate techniques, physicians' orders for restraints, restrained patients were monitored by trained staff to ensure safety, least restrictive measures were used for restrained patients, safe application of restraints by trained staff, and appropriate staff were trained in the use of nonphysical intervention skills. Findings include: 1. The hospital failed to ensure care in a safe setting by failing to ensure restraints were applied by trained and competent staff and failing to ensure patients in restraint were monitored by trained and competent staff to assure patient safety. ~ cross refer to 482.13(c)(2) Patient Rights' Standard: Tag 0144 2. The hospital failed to ensure physical restraint was implemented in accordance with safe and appropriate techniques. ~ cross refer to 482.13(e)(4)(ii) Patient Rights' Standard: Tag 0167	A 115	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: A training and education program is being provided to the Emergency Department (ED) staff at the beginning of each shift for ED employees on a daily basis until further notice in order to comply with the Health Systems' policies and procedures for the behavioral health/psychiatric patients (see "attachment 2" and 2A"). The training and education consists of but is not limited to education on the 1) Restraint policy (see "attachment 3, 3A and 3B") which includes all types of restraints such as the therapeutic hold 2) least restrictive measures are to be utilized first on the behavioral health/psychiatric patient when needed 3) recognition of the role of the registered nurse (RN) so all members of the health care team understand the registered nurse is always in charge of the clinical care of the patient and the provision of a safe and secure environment for the patient 4) the forms that accompany the restraint policy such as the physician order form, the monitoring and flow sheet for the restrained patient 5) computer process for ordering the restraints including the therapeutic hold 6) emphasis on patient safety at all times including during any type of patient escalation the nurse never leaves the patient and the nurse is always able to complete a physical assessment of her patient 7) required nursing and physician documentation. Application of restraints and restraint training is an annual training requirement for ED staff. Information has also been shared with the ED providers by the ED Medical Director as well as the psychiatrists that work in the ED.	

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A 115	Continued From page 5 3. The hospital failed to ensure a physician's order for physical restraint. ~ cross refer to 482.13(e)(5) Patient Rights' Standard: Tag 0168 4. The hospital failed to ensure restrained patients were monitored by trained staff. ~ cross refer to 482.13(e)(10) Patient Rights' Standard: Tag 0175 5. The hospital failed to ensure staff attempted the use of least restrictive interventions prior to restraint. ~ cross refer to 482.13(e)(16)(iii) Patient Rights' Standard: Tag 0186 6. The hospital failed to ensure safe implementation of restraint by trained staff. ~ cross refer to 482.13(f) Patient Rights' Standard: Tag 0194 7. The hospital failed to ensure Emergency Department and Contracted Security staff were trained in the use of nonphysical intervention skills. ~ cross refer to 482.13(f)(2)(ii) Patient Rights' Standard: Tag 0200	A 115	Non-violent crisis intervention (NCI) training is an annual requirement for ED nursing staff. The nursing staff will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the nurse will not be assigned to the behavioral health/psychiatric patient. Non-violent crisis intervention (NCI) training is an annual requirement for security officers. The security officers will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the security officer will not be assigned to the behavioral health/psychiatric patient. The company police officers will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. In the case of a non-current NCI certification the company police officers will not be assigned to the behavioral health/psychiatric patient. The nursing supervisors will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. Restraint training is required for ED staff that provides direct care to patients. A portion of the training include Restraints, Seclusions and Safety Devices" (see "attachment 3", 3A, and 3B"). It is also required for the security officers and company police officers. Security officers and company police officers will receive restraint training from the Training and Development Department of CFVHS. Part of the education for the security officers and company police officers is to ensure their understanding of taking direction from the clinical nurse in how to assist with the behavioral health/psychiatric patient.	

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A 115	Continued from page 5A	A 115	Education has been completed for the ED physicians and psychiatrists on the need for the order for restraint. There is a "Restraint/Seclusion Order" set (see "attachment 3B") to be completed by physician. Physicians have been reminded of the need to include this form and the need to complete for a patient that is in need of restraints. Additional education was done specific to therapeutic hold restraints. Nursing staff and medical staff have been trained that the therapeutic hold is a restraint and it is to be ordered on the physician order form as well as be ordered in the computer so the quality assessment and performance improvement review can be completed. Per the restraint policy anyone who assists with restraints must have restraint training. Therefore as listed above the ED nursing staff, security officers and company police officers are being trained on restraints. They are also being instructed that the nurse is in charge of the patient clinically as well as providing a safe and secure environment for the behavioral health/psychiatric patient. **Monitoring:** The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system on site. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff.	11/07/2011

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A 115	Continued from page 5B	A 115	The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	

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A 144	Continued from page 5C 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, personnel file review, and hospital investigation report review, the hospital failed to ensure care in a safe setting by failing to ensure restraints were applied by trained and competent staff and failing to ensure patients in restraint were monitored by trained and competent staff to assure patient safety for 3 of 11 sampled patients that were restrained (Patients #5, #2, and #7). The findings include:	A 144	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** A training and education program is being provided to the Emergency Department (ED) staff at the beginning of each shift for ED employees on a daily basis until further notice in order to comply with the Health Systems' policies and procedures for the behavioral health/psychiatric patients. The training and education consists of education on the 1) Restraint policy (see "attachment 3", 3A", and 3B") which includes all types of restraints such as the therapeutic hold 2) least restrictive measures are to be utilized first on the behavioral health/psychiatric patient when needed 3) recognition of the role of the registered nurse (RN) so all members of the health care team understand the registered nurse is always in charge of the clinical care of the patient and the provision of a safe and secure environment for the patient 4) the forms that accompany the restraint policy such as the physician order form, the monitoring and flow sheet for the restrained patient 5) computer process for ordering the restraints including the therapeutic hold 6) emphasis on patient safety at all times including during any type of patient escalation the nurse never leaves the patient and the nurse is always able to complete a physical assessment of her patient 7) required nursing and physician documentation. Application of restraints and restraint training is an annual training requirement for ED staff. Information has also been shared with the ED providers by the ED Medical Director as well as the psychiatrists that work in the ED.	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/28/2011
FORM APPROVED
OMB NO. 0938-0391

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A 144	Continued From page 6 Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm. Restraints...are used in a manner that attempts to prevent harm, physical discomfort, embarrassment, or pain to the patient....DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely....5. THERAPEUTIC HOLD - The brief physical holding of a patient in a manner that restricts his/her movement for the purpose of calming or providing physical safety to the patient , other patients, staff members or others. A therapeutic hold is used only by individuals trained in therapeutic hold techniques, and only when less restrictive measures have been attempted and have been determined to be ineffective. 6. FORENSIC RESTRAINTS - A locking restraint required by legal authorities when a person needs to be restrained to provide for safety or detention by legal authorities for legal reasons when that person is in custody of legal authorities or is under arrest/police hold in accordance with Federal and State laws and regulations....Forensic restraint mechanisms (...handcuffs,...)are not health care restraint interventions and are not applied by the staff of (Name of Hospital)....PROCEDURES:...2. TRAINING: Hospital staff involved in meeting the patient's needs are educated upon hire before they participate in the use of seclusion/restraint	A 144	Non-violent crisis intervention (NCI) training is an annual requirement for ED nursing staff. The nursing staff will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the nurse will not be assigned to the behavioral health/psychiatric patient. Non-violent crisis intervention (NCI) training is an annual requirement for security officers. The security officers will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the security officer will not be assigned to the behavioral health/psychiatric patient. The company police officers will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. In the case of a non-current NCI certification the company police officers will not be assigned to the behavioral health/psychiatric patient. The nursing supervisors will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. Restraint training is required for ED staff that provides direct care to patients. A portion of the training includes review of the hospital policy "Restraints, Seclusions and Safety Devices" **(see "attachment 3", 3A", and 3B")**. It is also required for the security officers and company police officers. Security officers and company police officers will receive restraint training from the Training and Development Department of CFVHS. Part of the education for the security officers and company police officers is to ensure their understanding of taking direction from the clinical nurse in how to assist with the behavioral health/psychiatric patient.	

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A 144	Continued From page 7 and annually thereafter. Training can be completed via didactic class or online self-study with successful completion of a post-test and competency. Hospital staff includes personnel from the following areas: Nursing,...Security,....Training Requirements include: a. The underlying causes of threatening behavior. b. Less restrictive alternative. c. Proper and safe application/removal...of restraints. d. Monitoring patient's physical/psychological status....7. INITIATION & ASSESSMENT: A qualified licensed staff member with established competencies may initiate seclusion or apply restraint. Assessment of the patient who has new onset or worsening of confusion/agitation is done by an RN (registered nurse) prior to or within 30 minutes of application of a restraint....11. RESTRAINT/SECLUSION MONITORING:...Behavioral Seclusion/Restraint: Staff provides continuous face-to-face observation of the patient in rigid limb restraint(s) and maintains documentation on the Restraint Flowsheet (excluding therapeutic holds less than 15 minutes) and on the Special Observation Flowsheet....At the initiation of seclusion or restraint, and every 15 minutes, a staff member monitors the patient with the intent to prevent ha rm and maintain well-being....15. DOCUMENTATION: Documentation in the patient's record is to indicate a clear progression in how techniques were implemented with less intrusive restrictive intervention attempted or considered prior to the introduction of more restrictive measures. Only hospital personnel, who have received training and demonstrated competency are to document information related to the use of restraints within the scope of their license. Each episode of restraint/seclusion use	A 144	The restraint policy states that in order to assist with restraints the person has to have restraint training. Since the security officers and company police officers may be requested by the nurse to assist with the restraints for the behavioral health/psychiatric patient they will receive training on restraints. The least restrictive measure for de-escalation will be used prior to any type of restraint and the security officer or company police officer will take direction from the nurse in charge of the patient. **Monitoring:** The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff.	11/07/2011

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A 144	Continued From page 8 is recorded in the medical record. Documentation includes: a. The circumstances that led to their use; b. Consideration or failure of non-physical less restrictive interventions; c. Medical conditions or physical disability that would place the patient at greater risk....d. The rationale for the type of physical intervention selected; e. The type of restraint used,...vital signs, circulation to extremities,...patient response to treatment, patient rights, dignity and privacy maintained, and time released....g. Written orders for use; h. Behavior criteria for release...; i. Informing the patient of behavior criteria for release from restraint...; l. Injuries that are sustained and treatment received for these injuries; and m. Deaths...." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638. Review of EMS documentation prior to arrival to hospital revealed, "Patient presented to ems very anxious, paranoid actions and behavior. Family member advised that patient had stopped taking Risperdal (antipsychotic medication) when the packaging came in different form. Patient also been hearing voices with hallucination. Patient non violent at this present time but very quiet and with paranoid tendencies. Patient cooperated with ems to go to hospital." Record review revealed upon arrival the patient was placed in Room 65 (within the locked psychiatric area of the ED). Review of triage nursing assessment at 1645 revealed, "Chief Complaint: Not taking medications." Review of nurse's notes revealed, "ER Physician Eval....Completed at: 04/17/2011 16:50 by:	A 144	The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	11/07/2011

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A 144	Continued From page 9 (Physician #1 - ED physician) evaluate patient." Review of nurse's notes at 1707 revealed, "Patient calm cooperative, no respiratory distress, pt (patient) ambulatory to bathroom gait steady...." Record review revealed RN #2 completed a psychiatric nursing evaluation of the patient at 1720. Review of RN #2's psychiatric assessment revealed, "Pt not sure why he is here. Confused. Paranoid + restless. Pacing around room. Said he had an outburst at home. Slow to respond to questions. Denies SI/HI (suicidal/homicidal ideations) + hallucinations. Angry at his mother....appears to be responding to internal stimuli....Lives c (with) mother....Drinks occasionally.) (no - denies) drugs. Got upset. Had an outburst - taking medication...." Record review revealed at 1751 Physician #1 ordered a psychiatric evaluation and psychiatric precautions. Review of nurse's notes at 1758 revealed, "Psychiatric Precautions....pt . denies homicidal idealations, pt denies suicidal idealations...calm and cooperative, makes eye contact when communicating, alert and oriented X 3. Assessment: cooperative at this time. Interventions: Clothing removed, initiate psych packet and armband." Record review revealed Physician #2 (psychiatrist) evaluated the patient. Review of Physician #2's orders at 1842 revealed, "Medication Orders: Risperdal M-tab 2 mg (milligrams) Note: give 4 mg po (by mouth) now." Review of RN #2's notes at 1845 revealed, "(Physician #2) completed evaluation. Pt to be diverted to 1st accepting facility. IVC (involuntary commitment) papers initiated at 1845. Primary nurse and security made aware). Record review revealed documentation at 1850 the patient was administered Risperdal M-tab 4 mg by mouth. Record review revealed documentation at 1910	A 144		

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A 144	Continued From page 10 RN #1 assumed care of the patient. Review of RN #1's note at 1929 revealed, "Assumed patient care. Patient awake and alert, breathing even and unlabored. Patient stares at RN, nonverbal. No response to questions or requests. Patient is INVOL(untary)." Review of RN #1's note at 1951 revealed, "Patient more verbal at this time, answering questions. Patient requested water; provided. patient continues to refuse to change into gown." Review of RN #1's note at 2017 revealed, "Patient continued to refuse gown, now stating ' I want my momma. I'm not putting on no mother (expletive) gown'. Patient more active in room, pacing. Patient multiple trips back and forth to bathroom; not following directions of security or nurse. CPO (Company Police Officer) and security to bedside; patient medicated." Record review revealed documentation at 2018 the patient was administered Ativan (anti-anxiety medication) 2 mg and and Geodon (antipsychotic medication) 20 mg via intramuscular injection (IM) per Physician #2's orders. Review of RN #1's note at 2053 revealed, "Patient refusing labs and urine at this time; continues to appear agitated and paces in room at times. Patient now more lucid asking where is and how he got here. Patient reoriented." Review of RN #1's note at 2110 revealed, "Patient pacing in hallway, appears to becoming more agitated. Refusing to stay in room, becoming aggressive with staff. (RN #2) from Psych ED aware of patients increasing agitation; will inform (Physician #2)." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff	A 144		

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A 144	Continued From page 11 member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Review of RN #1's note at 0141 revealed, "Addendum to documentation charted at 2120. --As security was transferring patient to stretcher rigid restraints were being placed on limbs. Limb devices were placed around ankles and wrists, but at no time were they secured to stretcher/bed. Patient was not restrained with the limb devices at any point." Review of Physician #2's note dictated on 04/18/2011 at 0136 revealed, "HISTORY OF PRESENT ILLNESS....has a history of schizophrenia. He was actually discharged from the emergency department by this physician about a week ago. At that time, he was paranoid about a new form of the Risperdal M-Tab; however, at that time he took his medication and agreed to continue to take his medication, stayed overnight, and was reasonable. He reports that over the last week he has not taken his medication for about 4 days....He says his mother is out to get him; his	A 144		

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A 144	Continued From page 12 mother is trying to get rid of him because of some kind of money....Although the patient was having a great (deal) of trouble attending and concentrating, he did report that he would stay in the hospital for treatment and agreed to taking his medication, which he did without any difficulty....He was involuntarily committed because of his paranoia, delusions, and his not taking medications....He became agitated around 8 p.m. and he received 20 mg of the Geodon IM and 2 mg of Ativan IM. This physician was with other patients actually at the time this was happening and he received the medication. He was not compliant with taking his clothes off or letting blood draws happen. It appears that about one-quarter past the hour the patient became more agitated after initially calming down. He was very thirsty. He was drinking some water and then he threw the water either at someone or on the floor and then started to be verbally abusive. He told the officer, 'Let's go,' and evidently took a swing. He was restrained at that period of time. He was on the ground being held by a number of nurses and CPO and so forth. Approximately five minutes into the incident, he urinated on himself and started breathing in erratic way. He was brought up to the gurney where a nurse recognized that he was not breathing appropriately and wanted him to go to the resuscitation room and resuscitation started. The whole incident happened over about an 8 minute period of time. After the code was run the patient expired. The patient's mother reports that, in fact, the patient has been compliant with his medication for the past week. She has been giving it to him....and...has watched him take the mediation every day. She reports that he jumped out a two-story window today and there was no	A 144		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDERS PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 13 indication in the E-stat (medical record) or any report that this patient suffered a two-story fall. The patient's mother reports that there were indentations in the ground where his feet landed from this jump....The patient's mother reported that he was confused at the scene and did not necessarily know who she was, and could not remember what was going on. Once again, none of that information was available at the time the patient was evaluated....There is no known history of drug or alcohol use....LABORATORY AND DIAGNOSTIC DATA 1. Toxicology screen negative...." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/06/2011 and signed by a physician from the Medical Examiner's office revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....He was being involuntarily committed and was at the local hospital when his death occurred. He was agitated and attempting to leave his room when he was physically restrained by multiple individuals. Video of the events show one person placing an arm around his neck prior to him being taken to the ground. The neck restraint appears to be maintained as several other individuals restrain his body. His respiratory function would have been further compromised if overlay occurred on the chest and/or abdomen. The decedent appears unresponsive immediately following the restraint. Significant findings at autopsy include small, multifocal and thin subarachnoid hemorrhages, hemorrhages in the tongue and laryngeal mucosa and chronic active hepatitis of unknown etiology. Toxicology studies are positive for therapeutic concentrations of Risperidone (Risperdol) in aorta	A 144		

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A 144	Continued From page 14 blood. Benzodiazepines, cocaine, ethanol, opiates, organic bases, ziprasidone and haloperidol are not detected. Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the camera angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed the following events at the noted times: 21:13:00 - Patient #5 in room with lights off. CPO #1 and CPO #2 go into patient's room and turn lights on. One Security Officer (SO) in room and another SO at the patient's doorway looking into room (SO #1 and SO #2). RN #1 and RN #2 outside of and looking into room. 21:13:14 - RN #1 goes into room. SO #1 and SO #2 in room and CPO #1 and CPO #2 standing in doorway of room. Patient not in view. 21:13:26 - Patient walks into view in front of bed (which is against the back wall). All staff looking at patient. Patient sits on bed. 21:13:53 - Patient stands up off of bed with a cup in his hand. 21:14:16 - Patient throws water from cup onto a Security Officer (unable to determine which one). CPO reaches for cup.	A 144		

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A 144	Continued From page 15 21:14:22 - RN #1 goes out of room and out of view. RN #2 in doorway looking into room. Patient not in view, but can see 2 Security Officers and 1 CPO in room (other CPO is in room out of view). 21:14:34 - Patient stands in view with CPO #1 in front of him. Patient then sits in a chair to left side of room. The 2 Security Officers are now outside of the room, one of them wipes off his glasses. 21:14:54 - RN #1 stands in doorway of room. 21:14:55 - Patient stands up. CPO #1 standing in front of patient and CPO #2 on the right side of room. RN #2 walks away from room and out of view. 21:15:15 - Security Officer in hall wipes his pants off with a towel and RN #1 steps away from patient's door and helps him. Patient visible standing in room with CPO #1 standing in front of him. 21:15:21 - Patient moves towards door and CPO #1 moves in front of him (between patient and door). SO #1 and SO #2 outside of and looking into room. RN #1 walks towards room while wiping her shirt with a towel. 21:15:22 - CPO #2 walks towards patient (from right side of room) with arms reached out towards patient. 21:15:23 - SO #1 and SO #2 move into the patient's doorway. Patient is facing doorway with CPO #1 on his right side and CPO #2 on his left side (both CPOs positioned towards the front of the patient). 21:15:25 - RN #1 turns away from the patient's room and walks down the hall. The 2 CPOs are holding the patient's arms, one on each side. 21:15:26 - Patient lifts up slightly and sits on bed (CPOs still beside of and with hands on the	A 144		

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A 144	Continued From page 16 patient). 21:15:28 - RN #1 looks over shoulder then turns around and faces the patient's room. SO #1 and SO #2 head into room. CPO #1 leans down towards bed. CPO #2 not in view. 21:15:29 - RN #1 turns back away from and continues to walk away from room. Patient is visible standing and facing towards the right side of the room. CPO #1 goes behind the patient. CPO #1 lifts his right arm out with elbow bent and moves it towards the patient. 21:15:30 - CPO #1's arm not visible. CPO #1 is leaning forward or bending down. Patient not visible. SO #1 and SO #2 in doorway looking in. CPO #1 and patient go backwards (towards left side of room) together. CPO #2 comes into view with in front of patient with his arms extended, but hands not visible. RN #1 looks back towards room again, then turns and continues to walk away from room. 21:15:31 - Patient's right hand is in the doorway, holding onto the door jam. The 2 Security Officers are still in the doorway. Both CPOs face the doorway as they and the patient are going down. 21:15:32 - Patient down and out of view. CPO #1 (who was behind patient) is not visible. CPO #2 in front of patient and leaning towards floor. SO #1 and SO #2 enter room and are on the right side of the patient, with their backs towards the camera. The Security Officer closest to the patient's legs is leaning down. 21:15:35 - CPO #2 leaning down towards patient and out of view. Both Security Officers leaning towards patient, the one near the top of the patient is standing and the one near the patient's legs is leaning towards patient with his (officers) legs extended to the side.	A 144		

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A 144	Continued From page 17 21:15:38 - CPO #1 and patient remain out of view. CPO #2 and both Security Officers are leaning towards the left, over the patient. 21:15:44 - The Two Security Officers stand, but still lean over the patient. 21:15:46 - One of the Security Officers goes around to the patient's other (left) side. 21:15:49 - CPO #1 and patient remain out of view. CPO #2 appears to be on the patient's legs. 21:15:52 - CPO #2 is up on his toes with his legs extended behind him. The top of his body is positioned towards the patient, but the view is blocked by the back of the Security Officer that is positioned on the patient's right side. 21:15:53 - Patient's right leg goes up, then down. Security Officer on right side of patient appears to hold it. 21:16:03 to 21:16:12 - The footage jumps and there is no footage available during this period of time. 21:16:12 - The Security Officer on the right side of the patient and CPO #2, now located near the patient's legs on the right side, are both leaning over the patient with their backs to the door. No one else in the room is visible. 21:16:27 - Security Officers and CPOs visible on floor, no apparent struggling at this point. 21:16:30 - RN #2 and RN #3 (a male psychiatric ED nurse) go to the doorway of the patient's room and look in. 21:16:35 - RN #2 goes into room 21:16:38 - RN #3 goes into room 21:16:42 - RN #3 leans toward patient's feet. CPO #1 now visible and near the top of and to the right of the patient. A Security Officer is visible on each side of the patient. 21:16:48 - RN #1 walks to door, drops restraints	A 144		

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A 144	Continued From page 18 on the floor in the hall near the door, and turns and walks away from room. RN #2 goes into room and goes to the left side of the room. 21:16:54 - Both Security Officers now standing and leaning over patient. CPO #1 is near the top of the patient and is leaning over patient, either on his knees or with his legs extended. 21:16:55 - RN #2 leaning over the patient, near his head and to the left of CPO #1, then standing up. 21:16:59 - 2 EMS staff and ED Tech(nician) #1 arrive and enter into room. 21:17:02 - 1 of the EMS staff goes towards the patient's head and looks down. 21:17:04 - RN #2 comes out of room. 21:17:10 - 2 EMS staff and ED Tech #1 come out of room. 21:17:22 - Licensed Practical Nurse (LPN) #1 (an ED nurse) enters room, followed by 1 EMS staff and ED Tech #1. RN #1 is standing in the doorway with restraints in her hand. 21:17:35 - Second EMS staff goes into room. 21:17:41 - A staff member inside room (unable to determine which one) is seen putting a sheet on the bed. 21:17:48 - Security Officers and other staff are standing looking towards the patient on the floor. 21:17:50 - Several staff (unable to determine who or how many) lift the patient from the floor to the bed. 21:17:52 - Patient is on bed. Staff, including SO #1, SO #2, and CPO #2, surround the patient. CPO #1 is standing in the doorway. 21:17:54 - RN #1 goes into room with restraints in hand. 21:17:58 - CPO #1 goes out of room and rubs his head. 21:18:30 - Physician #2 (psychiatrist) walks	A 144		

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A 144	Continued From page 19 towards room and stops and talks to CPO #1 in the hall on the way. 21:18:37 - Physician #2 stands in patient's doorway, leans on doorway, and looks into room. (Does not go into room). 21:18:42 - RN #4 (psychiatric nurse) walks towards room and talks to CPO #1 in hall. 21:18:49 - RN #3 is standing in room and looking down. 21:18:55 - Physician #2 walks away from room. 1 EMS staff exits room. RN #3 mops floor with towel. 21:19:02 - Patient is seen laying on bed. Patient is not moving and his clothes are off (can see naked right side). 21:19:08 - RN #2 exits room and talks to Physician #2 in hall. 21:19:34 - RN #3 exits room and talks to Physician #2 in hall. Other EMS staff exits room. RN #2 goes back into room. 21:19:49 - RN #3 and CPO #1 go into room. 21:19:56 - RN #3 exits room. RN #1, RN #2, and LPN #1 are in room near the patient's head. Patient is not moving. 21:20:15 - RN #3 goes into room with BP (blood pressure) machine. 21:20:36 - Security Supervisor goes to and looks into room. 21:23:26 - Someone takes BP cuff off of patient's arm. 21:23:33 - Staff roll patient out of room on bed. He is naked with a sheet laying over his groin. Restraints are visible on his ankles (cannot see his clearly see his wrists). Patient is not moving. Interview on 10/19/2011 at 1100 with Security Officer (SO) #1 revealed the officer was posted in the psychiatric area of the ED on 04/17/2011 from	A 144		

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A 144	Continued From page 20 4 PM to Midnight. Interview revealed when Patient #5 arrived to Room 65 "staff decided he didn't need to change (into gown) right away. That was their call....I wanded him", Interview revealed SO #2 walked through the psychiatric area of the ED to see if SO #1 needed any assistance. Further interview revealed, "He (The patient) was calm at first. The longer he sat he got more agitated. (SO #2) decided to stay with me due to his agitation. We don't usually let patients walk in the halls (in the psychiatric area of the ED), but in this occasion I let him walk in the hall. It seemed to calm him. He went back and forth to the bathroom and his room. We kept our distance and kept an eye on him. He didn't say a lot. He had this white stuff around the outside of his mouth. We told the nurse about it because we have seen patients that have been doing spice or something (illicit substances) like that. Its just an observation we had noticed in the past. He was muttering stuff like he wanted to go home." Interview revealed the patient became more agitated and began hitting the bed and wall. Interview revealed SO #1 called Company Police for assistance once before the end of the 0700-1900 shift and CPO #2 came to psychiatric area. Interview revealed, "They came and hung around for a little bit and then left." Interview revealed, "I think he was given a pill before (dayshift nurse) left at 7 PM. It seemed like it made him worse. He really started to hit the walls and bed. (He had) muttered talking, not making any sense. He would come out (of his room) a little bit and we'd ask him to go back and he would eventually go back. (RN #1) came on and I told her about his behavior. I don't remember if she went in to see the patient. I called Company Police again and (CPO #2) came and saw the	A 144		

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A 144	Continued From page 21 patients behavior and called (CPO #1) to come." Interview revealed at this point the patient's behavior had escalated and "it looked like he was about to act out severely". Interview revealed, "I think the nurse came and tried to speak to him. He didn't calm down. The two Company Policy Officers came into his room and told me and (SO #2) to step back. They took charge." Interview revealed at that point the two security officers went out of the patient's room and stood in the doorway. Interview revealed, "They (The CPOs) told the patient medical staff needed to take care of him, take blood or whatever. He (The patient) went at (CPO #1), swung and knocked (CPO #1) against the wall. (CPO #1) and (CPO #2) got him to the ground....I didn't see anyone grab his neck or shoulders, basically just his legs....(When the patient was on the ground) I grabbed his legs and then moved to his arm, I think on the right side. I think the Company Police Officers were on his arms and upper body. As far as I could tell they were leaning on his chest....They had their back to us, so I don't remember if I could see his (the patient's) face or neck." Further interview revealed the officer thought he had to call, by waving his arm so as to be seen on video monitor at the ED desk, to get a nurse in the room. Interview revealed the officer thought someone had pushed the panic button (initiated an emergency response) because "so many" staff showed up. Further interview revealed, "We moved him to the bed. He was still struggling and urinating on himself (when on the floor and the bed). He was moving his arms and legs, trying to get up. He was muttering some stuff....They gave him some shots and tried to put restraints on because he was fighting pretty hard. Before putting restraints on him, they tried to get his	A 144		

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A 144	Continued From page 22 clothes off and put a gown on him. I think they got a gown on him, but I'm not sure. Restraints were placed on his arms and legs by medical staff, I'm not sure who...a couple of females and a male. Sometime during that point he quit moving a lot, because they had given him the shots, it usually works pretty quick. That's when the nurse noticed there seems to be something wrong, seems like he's not breathing. She told (RN #2) to go get the bag (BVM). A male nurse checked the pulse and said it was weak. They got him out of there and to the resuscitation room." Interview was requested with and declined by CPO #1. Review of hospital investigation documents revealed documentation of an interview on 05/19/2011 of CPO #1 by Root Cause Analysis team members. Review of the interview revealed CPO #1 first responded on 04/17/2011 at 2000 and talked with the patient, who appeared to be afraid, and held the patient for a shot. Review of the interview revealed at 2100 CPO #1 was called back to the psychiatric area, at which time the patient was walking out of his room. Review of the interview revealed the patient was completely different and was more agitated and asking for water. Review revealed the patient had white chalk around his mouth that the CPO didn't notice previously. Review revealed the patient threw water and CPO #1 grabbed hold of him. Review revealed the patient grabbed the CPO's badge, and the CPO grabbed his wrist to get him to release it. Review revealed the patient grabbed the badge again and tried to push the CPO out of the room. Review revealed, "Officer (CPO #1) slipped, pulled patient on top of him with shirt. Hit head on wall. (CPO #1)	A 144		

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A 144	Continued From page 23 thinking about rolling fingers under jaw, can't remember if he did it or not." Review revealed Security Officers held the patient's arms and legs. Review revealed, "(CPO #1) got out from under him, laid on his (the patient's) shoulder. Review revealed, when CPO #1 was asked if anything about this case concerned him, he responded the patient had received only one injection, that had more medications than usual in the syringe, and nurses don't know how to apply leather restraints, officers used to apply leathers, now they don't. Review revealed, when CPO #1 was asked who has authority to place a patient in physical restraints, he responded officers not allowed, nurses don't know how. Review revealed, when CPO #1 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the interviewer as "Put arms across jaw to keep his head turned away. Patient blubbering, blowing foam and spit. Patient quit moving. Patient still breathing. Moved to stretcher. Put restraints on legs. Moved to arms and LPN noticed he wasn't breathing. Patient arched back and took one big breath. Training: soft hands - pain compliance; no marks left but cause pain; wrist lock; and nerve under jaw. hard hands - punches". Personnel file review for CPO #1 revealed no documentation the CPO had completed NCI (Nonviolent Crisis Intervention - training program that teaches de-escalation and therapeutic patient hold techniques). File review revealed no documentation the CPO had received hospital based restraint training. Interview was requested with and declined by	A 144		

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A 144	Continued From page 24 CPO #2. Review of hospital investigation documents revealed documentation of an interview on 05/12/2011 of CPO #2 by Root Cause Analysis team members. Review of the interview revealed CPO #2 received a call from SO #1, saying they were trying to get the patient in a gown, at around 2000 on 04/17/2011. Review revealed CPO #2 responded and stayed with the patient, SO #1, and SO #2. Review revealed after about 1 hour the patient kept asking where he was where his mother was. Review revealed CPO #2 said his sixth sense told him to stay in the room with the patient. Review revealed CPO #2 said he thought several people need to stay. Review of interview revealed, "They kept telling patient to stay in room, but he kept going to the bathroom and as the hour progressed he got more and more agitated. They heard him strike the wall one time. They called (CPO #1) to ask him to come to patient's room. Patient sat on bed (not sure if voluntary or if they asked him to). Patient asked for some water, which (CPO #1) gave him and the patient 'sprinkled' water on them. (CPO #1) told him to stop and he did. Then they had to tell him again. (CPO #1) was standing directly in front of patient. 2 security guards standing behind them in hallway. Patient put his hands on (CPO #1). States as a natural reaction to protect themselves (CPO #1) got behind him and had him by his midsection. Both (CPO #1) and patient fell against wall and then to the floor. Then the 2 security guards joined in to help. (SO #2) had patients left arm. (SO #1) had (unable to read). (CPO #2) in front of him. Brought patient under control through physical restraint. Patient put on the bed. When on bed, (CPO #2) restrained left arm, (CPO #1) his feet and medical staff attended	A 144		

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A 144	Continued From page 25 patient. Heard them talk about patient's breathing and doctor was going to take him to the resuscitation room....When (CPO #1) first came they gave him (patient) meds and patient was not fighting or confrontational." Review revealed CPO #2 asked, "Did meds make him escalate?" Review revealed, when CPO #2 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the interviewer as "Training: No department training. As Police Officer get: hand cuff training, unarmed self-defense training (how to grab wrists and arms to gain control), painful force training, and training to de-escalate situation includes verbal, soft hands, equipment to include pepper spray and use of baton (depends on how it escalates)". Review revealed, when CPO #2 was asked who has authority to place a patient in physical restraints, he responded that he now knew, based on an email that recently came out, that medical staff (nurses and physicians) can place leather restraints. Personnel file review for CPO #2 revealed no documentation the CPO had completed NCI (Nonviolent Crisis Intervention - training program that teaches deescalation and therapeutic patient hold techniques). File review revealed no documentation the CPO had received hospital based restraint training. Interview was requested with RN #1. Administrative staff informed surveyor RN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of a "Witness Statement" for RN #1 dated 04/17/2011. Review	A 144		

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A 144	Continued From page 26 of the statement revealed the following: The patient was IVC and began making attempts to leave the facility. He began pacing, cursing, and became physically violent with staff. CPO and security staff were at bedside and intervened when the patient made attempt to leave department and began assaulting staff. While CPO and security were attempting to calm patient, he threw water on staff members and the floor. He then lunged at the CPO and had to be restrained. RN #1 left the area at that time to inform the psychiatrist of the patient's status and events. Upon returning to the area, the patient had stopped resisting CPO and security and was placed on the stretcher. Patient then began to have ineffective breathing and was taken to the resuscitation room. Personnel file review for RN #1 revealed no documentation the nurse had completed NCI. Interview on 10/19/2011 at 0915 with RN #3 revealed the male nurse was a psychiatric nurse that worked in the ED. Interview revealed when the nurse arrived to the patient's room on 04/17/2011 the patient was on the floor with at least 4 security officers (including security officers and CPOs). Interview revealed, "(CPO #1) was up at the head on the patient's right side helping hold him down. He was holding his chest or head....was in a position to hold the top part of the body. Another person (unsure who) was on the patient's right side holding his right leg. (CPO #2) was on the left side holding his leg or thigh. A security officer...was semi-squatting over (CPO #2)....I held his left foot. A police or security officer was at the top of the left shoulder area. I couldn't see what he was holding. I was just	A 144		

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A 144	Continued From page 27 seeing (other staffs') backsides....I think his primary nurse was in the room...but that might have been when I went back and we got him on the stretcher." Interview revealed the nurse wasn't sure what staff monitored the patient's condition during the physical restraint. Interview revealed, "I couldn't see him at all really. He was kicking and fussing and trying to be violent and all of that. I couldn't see his face....All I am seeing is back and arms. They would basically have to be holding him on the chest. He was a big fellow and was doing some pretty good struggling to start with...I could only see him from the knees down because they pretty much had him covered up with their bodies....I stopped holding his foot when he stopped fighting and I went out of the room to get the vital signs machine....I came back in with the vital signs machine and they (staff) were standing up and he didn't look like he was breathing. He had quit fighting. I think (LPN #1) said, 'Let's get him to the stretcher.'...After he was on the stretcher his breathing was very, very shallow....I don't remember his clothes coming off....One (restraint) got put on his leg....There's no point in doing that because he's not breathing right....Everybody's trying to look ahead and get him tied down in case that's what's needed. I got out of the way and they rolled him to the resuscitation room." Interview was requested with LPN #1. Administrative staff informed surveyor LPN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of an interview on 05/18/2011 of LPN #1 by Root Cause Analysis team members. Review of the interview revealed the interviewer documented	A 144		

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A 144	Continued From page 28 the nurse's response as, "(RN #1) asked for help with restraints. When I got to the patient's room, he was still on the floor being restrained, but not longer resisting. We got him up on the stretcher, we were getting him straight and trying to get the restraints on and I didn't like his breathing. So, I repositioned his head, still didn't like his breathing. So I asked for a nasal airway. That didn't help, his respirations were decreased, agonal-like. The psych nurse brought the ambu (BVM) bag, but I was concerned about his poor respirations and I said 'We need to go' and we took him to the resuscitation room." Review revealed, when asked was there anything that caused the nurse concern about the case, the interviewer documented the nurse's response as, "I thought they were a little forceful while restraining him and I didn't like them holding him near his head and neck." Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CIT training did not include training for therapeutic patient holds. Interview revealed neither CPO #1 nor CPO #2 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use law enforcement training for	A 144		

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A 144	Continued From page 29 physical holds." Further interview revealed CPO staff do not receive hospital restraint training. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI (Nonviolent Crisis Intervention training) is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview revealed, "They come in with stated experience and competency in all ED and critical care areas. That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation techniques, NCI, or therapeutic holds. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #1 received NCI training during her employment at the hospital. Further interview on 10/20/2011 at 1130 with the Vice President of Nursing during video taped footage review of the physical restraint of Patient #5 on 04/17/2011 confirmed nursing staff was not continuously present and did not continuously supervise the restraint. Interview confirmed nursing staff did not continuously monitor the patient to ensure safety during the physical restraint. 2. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review revealed the patient had a history of Schizophrenia and multiple mental health hospitalizations. Record	A 144		

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A 144	Continued From page 30 review revealed patient #2 was placed in Room 66 of the psychiatric Red Zone (a locked unit) at 0206. Record review of Nurse #5's notes dated 04/24/2011 at 0433 revealed "PT (patient) pacing about room wringing hands shouting...verbal de(e)scalation unsuccessful. MD (ED physician) and PIC (On Call Psychiatrist) notified for assistance. No orders given at this time." Record review of Nurse # 5's notes dated 04/24/2011 at 0456 revealed "...PT continues to be very agitated and begin(n)ing to self inflict. slapping slef (self) over body and arms...No orders given..." Record review revealed ED physician #3 ordered "Restraints-Mechanical...Leather 4 point" on 04/24/2011 at 0501 and "Ziprasidone (medication for short term control of severe agitation) 10 mg inj (injection)" and "Lorazepam (medication used to calm and treat anxiety) 2 mg IM (intramuscular injection) " on 04/24/2011 at 0502. Record review of " Restraint/Seclusion Orders," dated 04/24/2011 at 0511, revealed the following types of restraints were ordered by the physician: "Side Rails intended to restrict bed exit...Chemical...RUE (Right Upper Extremity) (rigid), LUE (Left Upper Extremity) (rigid), LLE (Left Lower Extremity) (rigid), RLE (Right Lower Extremity) (rigid)..." Record review of Unit Secretary's note dated 04/24/2011 at 0524 revealed the patient was moved to bed "Blue 26 South" (outside locked Psych Unit). Record review revealed Ziprasidone and Lorazepam, chemical restraints, were administered at 0528 and 0529, respectively, by nurse #6. Record review revealed the 4 point (bilateral wrists and ankles) leather (rigid) restraints were initiated at 0529. Record review of Unit Secretary's note dated 04/24/2011 at 0539 revealed Patient #2 was moved to "RED 63 South" (outside locked	A 144		

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A 144	Continued From page 31 Psych Unit). Record review of Nurse #6's notes dated 04/24/2011 at 0551 revealed "Pt moved to room 63 from 29 on stretcher, in 4 point restraints. Pt on cardiac monitor, nibp (blood pressure) cuff and spo2 (Oxygen) monitor. Pt still rocking back in forth in bed from side to side and shaking his legs. Pt sinus tach (tachycardia -elevated heart rate) in 140's - 150's on monitor. (Physician #3) aware." Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing (throwing) his body against the doors tot he (of the) unit. With assistance of (Security Guard # 3) and (Company Police Officer # 2) PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "...(Nurse #5) HEAD STRUCK WALL DURING PHYSICAL ALTERCATION (with Patient #2)..." Report review revealed a narrative stating "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient. Further review of report revealed narrative continued stating "...(Patient	A 144		

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A 144	Continued From page 32 #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with (Security Officer #3), (Nurse #5), and (Security Officer #4) used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was restrained and under control I placed my handcuffs onto the patient so that (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us. Medical staff arrived and administered medication...by giving him an injection in his left arm and left buttocks that would help calm him down...walked the patient back to room 66 until a stretcher arrived so that four point's restraints could be placed on the patient by medical staff... (Patient #2)'s vitals and heart rate were monitored after the incident by medical staff...(Patient #2) had an elevated heart rate and was moved out of the Psych area into treatment room 29 so that he could be monitored more closely. (Nurse #5) fell against the wall striking his head during the physical altercation." Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2. Interview with Nurse #5 on 10/19/2011 at 0950 revealed "The patient (#2) was throwing himself against the doors...to prevent harm I, security, and a CPO tried to get him to the floor. I ended up under all 3 and the patient...the BCH (psych) nurse pulled on my leg to get me." Interview further revealed "I don't have any current training in deescalation, CPI (Crisis Prevention Institute) or NCI (Nonviolent Crisis Intervention), it was	A 144		

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A 144	Continued From page 33 many years ago. I've never had any CPI, NCI at this hospital, they offer training but I've never had training at this hospital." Interview revealed nursing staff were distracted from directing security staff and monitoring the patient during the therapeutic hold and handcuffing of the patient. Interview with Security Officer #4 on 10/21/2011 at 0930 revealed "When I responded the patient (#2) was wrestling (staff). I went in and observed (Patient #2) was trying to assault staff. (I) grab him around the waist to calm him down." Interview revealed the staff involved in the restraint of Patient #2 were Nurse #5, Security Officers #3, #4 and CPO #2. Interview revealed "(Patient #2) went to the floor as I arrived, CPO and Security had his arms, I grabbed his waist so he wouldn't get hurt. (Nurse #5) was on the floor in the mist of everything, he went down first...he was off to the side rolling holding his head...The psych nurse was checking on (Nurse #5). I (Security #4) was down on the ground with the patient. (Security #3) and (CPO #2) were standing over talking to the patient while he was down. We picked him up, he walked on his own, we escorted him back to the room. The psych nurse was checking on (Nurse #5)...I don't know who put restraints on the patient, he ended up being transported to another room, I don't know why he was transported out of psych..." Interview revealed there was no nursing staff directing security or monitoring the patient during the therapeutic hold or handcuffing of the patient. Interview with Security Officer #3 on 10/21/2011 at 1130 revealed "I was posted in the Red Zone...When (Patient #2) was brought in he was	A 144		

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A 144	Continued From page 34 anxious and after about an hour or hour and a half he got worse." Interview revealed Patient #2 attempted to leave the unit by running into the doors. Interview revealed Security Officer #3 grabbed the patient by the shoulder and Security Officers #4 grabbed the patient by the waist and took him to the floor. Interview revealed there were 2 CPOs in the psych unit, standing at the nurses station. Interview revealed "the CPOs came quickly...I didn't know (Nurse #5) was hurt, we held him (patient #2) down and they (CPO) hand cuffed the patient. Personnel file review for Nurse #5 revealed this nurse was a contracted agency nurse assigned to the ED. File review revealed no documentation of current training in deescalation of behavioral patients, NCI or CPI. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview revealed, "They come in with stated experience and competency in all ED and critical care areas. That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation techniques, NCI, or therapeutic holds. Personnel file review for CPO #2 revealed no documentation the CPO had completed NCI. File review revealed no documentation the CPO had received hospital based restraint training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the	A 144		

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A 144	Continued From page 35 CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CIT training did not include training for therapeutic patient holds. Interview revealed CPO #2 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training. 3. Closed medical record review for patient #7 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via private transportation on 06/29/2011 at 2011 with complaints of neck and back pain. Record review revealed the patient was discharged on 06/30/2011 at 1451 with diagnoses UTI (Urinary Tract Infection) and alcohol intoxication. Record review of Nurse #7's notes dated 06/30/2011 at 0848 revealed "...Pt (patient #7) found to have attempted to leave the ED. Pt escorted back to room 31...Pt stated he wanted to leave and smoke. Pt began swinging and acting out in the lobby. pt had to be taken to the floor by room 31 by security and panic alarm sounded by staff. Pt then proceeded to head butt the glass door of room 31..." Record review of physician #4 note dated 06/30/2011 at 0851 revealed "Pt got up, angry, verbally abusive and started to walk out of	A 144		

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A 144	Continued From page 36 ED. I explained he could not leave due to ETOH (Alcohol) level. I told him not to leave or I would have to involuntarily commit him until legally sober. Pt came back in with staff escort, then tried to leave again and became combative. Pt now will be involuntarily committed until MBA (Alcohol Level) comes down." Review of hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #4 and dated 06/30/2011 revealed "...Patient (#7) was combative, resistant and attempted to grab equipment on officers duty belt..." Review of document revealed a narrative of the incident by Security Officer #5 stating, "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone number 31 in reference to an involuntarily committed combative white male patient." Review of document revealed a narrative by CPO #4 stating, "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone room #31 in reference to an involuntarily committed white male (patient #7)...attempting to leave by fighting with Security Personnel and Medical staff. When I arrived on scene Security Officer's and Medical staff were laying on (Patient #7) in an attempt to gain control. I was informed by (Nurse #8) that (Patient #7) was involuntarily committed and may still be intoxicated. I told (Patient #7) he needed to allow medical staff to help him and that he could not leave. (Patient #7) became verbally uncooperative but got up off the floor and went into his room and sat down on his bed. (Security Officer #5) and I were standing outside the room obtaining information...when (Patient #7) jumped off his bed throwing his body and arms into the	A 144		

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A 144	Continued From page 37 glass door of his room and sat back down on the bed. Approximately three or four minutes later (Patient #7) came out of his room and said "arrest me I want you to (expletive) arrest me." I informed (Patient #7) he was not under arrest but could not leave due to being involuntarily committed and attempted to walk him back to his room. I asked (Patient #7) to sit down and relax on his bed. (Patient #7) out his finger in my face and stated "(expletive) you get out of my face and my (expletive) room". Once again I told (Patient #7) to relax. (Patient #7) pushed my chest and said "(expletive) you make me lay the (expletive) down and pushed me again. I attempted to gain control of (Patient #7)'s hands to keep from being pushed again when he became combative and resistant to my commands. Security Officer #5 entered the room along with Nurse #8 to assist me in gaining control of (Patient #7). (Patient #7) started thrashing and attempted to grab my handcuffs to prevent being handcuffed to the bed putting nicks and cuts on my fingers. Approximately ten to twelve minutes later I told (Patient #7) I would take him out of handcuffs if he agreed to cooperate with medical staff. (Patient #7) agreed. I took (Patient #7) out of handcuffs without further incident." Further medical record review for Patient #7 revealed no documentation of how long the patient was on the floor, how the patient was held on the floor, what security staff where involved in the hold, or of the use of handcuffs by CPO staff to restrain the patient. Record review revealed no documentation of least restrictive measures implemented prior to the physical restraint and handcuff restraint of the patient. Record review revealed patient #7's vital signs were not	A 144		

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A 144	Continued From page 38 reassessed until 0952 on 06/30/2011 (1 hour and 4 mins after held to floor and subsequently handcuffed to the bed). Record review revealed no documentation of an assessment of the patient's wrists. Interview on 10/21/2011 at 1000 with Security Officer #5 revealed this officer and another security officer received a radio call to go to the Blue Zone, room 31. Interview revealed "...Everything happened at the nurses station, nurses and techs were there...the patient was in the hall...verbally abusive and threatening staff...we needed him back in the room....he was intoxicated and swinging at the officer (CPO)...We grabbed both arms, the (ED) tech grabbed his legs...the nurse and the doctor came to talk to him...They told him to relax and comply with staff...the patient was on the floor...once we got him back up to his feet we escorted him back to the room and everyone let go...we were holding him one on each side...The CPO did not touch him...after we left I'm not sure what happened." Interview on 10/21/2011 at 1200 with nurse #8 revealed, "The patient was trying to leave, (Physician #4) said 'you can't leave I'm going to IVC you'...we did have to do a therapeutic hold...I think I was at the waist, he was taken to the floor and he started to fight...there were 3 or 4 people, maybe, I don't remember...he was down about 20 seconds...I'm not 100% sure if the CPO put hand cuffs on him...we helped him to stand and walked him back to his room...Physician #4 was there and saw the patient before and after (the hold)..I don't remember (patient #7) head butting the glass..." Interview revealed "...Hand cuffs are	A 144		

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A 144	Continued From page 39 restraints when used by duly swore officers, but it is the ultimate responsibility of the nurse to monitor the patient...there are ways to walk a patient back without cuffs...I don't remember him being cuffed to the bed...there was a nurse in the room when I left..." Interview on 10/21/2011 at 1300 with CPO #4 revealed "(Patient #7) was back in his room when I saw him...he was running into the glass, attempting to hit, biting, spitting, oursing and threatening staff...(Nurse #8) and (Security #5) were not going to take action..." Interview revealed Nurse #8 and Security Officer #5 were in the patient's room when CPO #4 handcuffed the patient. Interview revealed "When he attempted to assault me, that was the end of it." Interview revealed CPO #4 placed a handcuff on the patient and with the other cuff secured the patient to the bed. Personnel file review for CPO #4 revealed no documentation the CPO had received NCI or hospital based restraint training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training. Interview revealed when CPO staff is hired, a supervisor or experienced field training officer goes through the orientation checklist and	A 144		

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A 144	Continued From page 40 verbally addresses each item with the officer. Interview revealed the supervisor or training officer typically informs the CPO when they assist with a patient's restraint, they don't apply the restraints, but rather hospital staff does. Interview revealed CPO staff are instructed to hold the patient's limb and help at the direction of staff.	A 144		
A167	482.13(e)(4)(ii) PATIENT RIGHTS: RESTRAINT OR SECLUSION [The use of restraint or seclusion must be--] (ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law. This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, personnel file review, and hospital investigation document review, the hospital failed to ensure physical restraint was implemented in accordance with safe and appropriate techniques for 2 of 3 sampled patients that were physically restrained by staff (Patients #5 and #2). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm. Restraints...are used in a manner that attempts to prevent harm, physical discomfort, embarrassment, or pain to the	A167	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: Based on the hospital procedure it is mandatory for ED nurses to have a current certification in NCI as well as annual restraint training. It is also mandatory for security officers to have a current certification in NCI as well as restraint training. Company Police Officers will receive NCI training and restraint training. If there is an ED nurse, security officer, or company police officer that is not current in NCI certification or restraint training this person is to be reassigned as to prevent them from being assigned to a psychiatric patient or in the case of security officers or company policy officers not assigned to the ED locations until NCI certification and restraint training is completed. This training and education is to ensure the provision of safe and appropriate care for our patients by providing the least restrictive measures prior to any type of restraint. When restraint is necessary the ED nursing staff, security officers and company police officers have the knowledge for following correct policy and procedure.	

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A 167	Continued From page 41 patient....DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely....5. THERAPEUTIC HOLD - The brief physical holding of a patient in a manner that restricts his/her movement for the purpose of calming or providing physical safety to the patient , other patients, staff members or others. A therapeutic hold is used only by individuals trained in therapeutic hold techniques, and only when less restrictive measures have been attempted and have been determined to be ineffective. 6. FORENSIC RESTRAINTS - A locking restraint required by legal authorities when a person needs to be restrained to provide for safety or detention by legal authorities for legal reasons when that person is in custody of legal authorities or is under arrest/police hold in accordance with Federal and State laws and regulations....Forensic restraint mechanisms (...handcuffs,...)are not health care restraint interventions and are not applied by the staff of (Name of Hospital)....PROCEDURES:....2. TRAINING: Hospital staff involved in meeting the patient's needs are educated upon hire before they participate in the use of seclusion/restraint and annually thereafter. Training can be completed via didactic class or online self-study with successful completion of a post-test and competency. Hospital staff includes personnel from the following areas: Nursing,...Security,....Training Requirements Include: a. The underlying causes of threatening behavior. b. Less restrictive alternative. c. Proper and safe application/removal...of restraints. d. Monitoring patient's	A 167	**Monitoring:** The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff.	11/07/2011

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A 167	Continued From page 42 physical/psychological status....7. INITIATION & ASSESSMENT: A qualified licensed staff member with established competencies may initiate seclusion or apply restraint. Assessment of the patient who has new onset or worsening of confusion/agitation is done by an RN (registered nurse) prior to or within 30 minutes of application of a restraint....11. RESTRAINT/SECLUSION MONITORING:...Behavioral Seclusion/Restraint: Staff provides continuous face-to-face observation of the patient in rigid limb restraint(s) and maintains documentation on the Restraint Flowsheet (excluding therapeutic holds less than 15 minutes) and on the Special Observation Flowsheet....At the initiation of seclusion or restraint, and every 15 minutes, a staff member monitors the patient with the intent to prevent harm and maintain well-being....15. DOCUMENTATION: Documentation in the patient's record is to indicate a clear progression in how techniques were implemented with less intrusive restrictive intervention attempted or considered prior to the introduction of more restrictive measures. Only hospital personnel, who have received training and demonstrated competency are to document information related to the use of restraints within the scope of their license. Each episode of restraint/seclusion use is recorded in the medical record. Documentation includes: a. The circumstances that led to their use; b. Consideration or failure of non-physical less restrictive interventions; c. Medical conditions or physical disability that would place the patient at greater risk....d. The rationale for the type of physical intervention selected; e. The type of restraint used,...vital signs, circulation to extremities,...patient response to treatment, patient rights, dignity and	A 167	The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	11/07/2011

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A 167	Continued From page 43 privacy maintained, and time released....g. Written orders for use; h. Behavior criteria for release...; i. Informing the patient of behavior criteria for release from restraint...; l. Injuries that are sustained and treatment received for these injuries; and m. Deaths...." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638. Review of EMS documentation prior to arrival to hospital revealed, "Patient presented to ems very anxious, paranoid actions and behavior. Family member advised that patient had stopped taking Risperdal (antipsychotic medication) when the packaging came in different form. Patient also been hearing voices with hallucination. Patient non violent at this present time but very quiet and with paranoid tendencies. Patient cooperated with ems to go to hospital." Record review revealed upon arrival the patient was placed in Room 65 (within the locked psychiatric area of the ED). Review of triage nursing assessment at 1645 revealed, "Chief Complaint: Not taking medications." Review of nurse's notes revealed, "ER Physician Eval....Completed at: 04/17/2011 16:50 by: (Physician #1 - ED physician) evaluate patient." Review of nurse's notes at 1707 revealed, "Patient calm cooperative, no respiratory distress, pt (patient) ambulatory to bathroom gait steady...." Record review revealed RN #2 completed a psychiatric nursing evaluation of the patient at 1720. Review of RN #2's psychiatric assessment revealed, "Pt not sure why he is here. Confused. Paranoid + restless. Pacing around room. Said he had an outburst at home.	A 167		

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A 167	Continued From page 44 Slow to respond to questions. Denies SI/HI (suicidal/homicidal ideations) + hallucinations. Angry at his mother....appears to be responding to internal stimuli....Lives c (with) mother....Drinks occasionally.) (no - denies) drugs. Got upset. Had an outburst - taking medication...." Record review revealed at 1751 Physician #1 ordered a psychiatric evaluation and psychiatric precautions. Review of nurse's notes at 1758 revealed, "Psychiatric Precautions....pt . denies homicidal idealations, pt denies suicidal idealations...calm and cooperative, makes eye contact when communicating, alert and oriented X 3. Assessment: cooperative at this time. Interventions: Clothing removed, initiate psych packet and armband." Record review revealed Physician #2 (psychiatrist) evaluated the patient. Review of Physician #2's orders at 1842 revealed, "Medication Orders: Risperdal M-tab 2 mg (milligrams) Note: give 4 mg po (by mouth) now." Review of RN #2's notes at 1845 revealed, "(Physician #2) completed evaluation. Pt to be diverted to 1st accepting facility. IVC (involuntary commitment) papers initiated at 1845. Primary nurse and security made aware). Record review revealed documentation at 1850 the patient was administered Risperdal M-tab 4 mg by mouth. Record review revealed documentation at 1910 RN #1 assumed care of the patient. Review of RN #1's note at 1929 revealed, "Assumed patient care. Patient awake and alert, breathing even and unlabored. Patient stares at RN, nonverbal. No response to questions or requests. Patient is INVOL(untary)." Review of RN #1's note at 1951 revealed, "Patient more verbal at this time, answering questions. Patient requested water; provided. patient continues to refuse to change into gown." Review of RN #1's note at 2017	A 167		

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A 167	Continued from page 45 revealed, "Patient continued to refuse gown, now stating ' I want my momma. I'm not putting on no mother (expletive) gown'. Patient more active in room, pacing. Patient multiple trips back and forth to bathroom; not following directions of security or nurse. CPO (Company Police Officer) and security to bedside; patient medicated." Record review revealed documentation at 2018 the patient was administered Ativan (anti-anxiety medication) 2 mg and and Geodon (antipsychotic medication) 20 mg via intramuscular injection (IM) per Physician #2's orders. Review of RN #1's note at 2053 revealed, "Patient refusing labs and urine at this time; continues to appear agitated and paces in room at times. Patient now more lucid asking where is and how he got here. Patient reoriented." Review of RN #1's note at 2110 revealed, "Patient pacing in hallway, appears to becoming more agitated. Refusing to stay in room, becoming aggressive with staff. (RN #2) from Psych ED aware of patients increasing agitation; will inform (Physician #2)." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to	A 167		

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A 167	Continued From page 46 resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Review of RN #1's note at 0141 revealed, "Addendum to documentation charted at 2120. --As security was transferring patient to stretcher rigid restraints were being placed on limbs. Limb devices were placed around ankles and wrists, but at not time were they secured to stretcher/bed. Patient was not restrained with the limb devices at any point." Review of Physician #2's note dictated on 04/18/2011 at 0136 revealed, "HISTORY OF PRESENT ILLNESS....has a history of schizophrenia. He was actually discharged from the emergency department by this physician about a week ago. At that time, he was paranoid about a new form of the Risperdal M-Tab; however, at that time he took his medication and agreed to continue to take his medication, stayed overnight, and was reasonable. He reports that over the last week he has not taken his medication for about 4 days....He says his mother is out to get him; his mother is trying to get rid of him because of some kind of money....Although the patient was having a great (deal) of trouble attending and concentrating, he did report that he would stay in the hospital for treatment and agreed to taking his medication, which he did without any difficulty....He was involuntarily committed because of his paranoia, delusions, and his not taking medications....He became agitated around 8 p.m. and he received 20 mg of the Geodon IM	A 167		

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A 167	Continued From page 47 and 2 mg of Ativan IM. This physician was with other patients actually at the time this was happening and he received the medication. He was not compliant with taking his clothes off or letting blood draws happen. It appears that about one-quarter past the hour the patient became more agitated after initially calming down. He was very thirsty. He was drinking some water and then he threw the water either at someone or on the floor and then started to be verbally abusive. He told the officer, 'Let's go,' and evidently took a swing. He was restrained at that period of time. He was on the ground being held by a number of nurses and CPO and so forth. Approximately five minutes into the incident, he urinated on himself and started breathing in erratic way. He was brought up to the gurney where a nurse recognized that he was not breathing appropriately and wanted him to go to the resuscitation room and resuscitation started. The whole incident happened over about an 8 minute period of time. After the code was run the patient expired. The patient's mother reports that, in fact, the patient has been compliant with his medication for the past week. She has been giving it to him....and...has watched him take the mediation every day. She reports that he jumped out a two-story window today and there was no indication in the E-stat (medical record) or any report that this patient suffered a two-story fall. The patient's mother reports that there were indentations in the ground where his feet landed from this jump....The patient's mother reported that he was confused at the scene and did not necessarily know who she was, and could not remember what was going on. Once again, none of that information was available at the time the patient was evaluated....There is no known	A 167		

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A 167	Continued From page 48 history of drug or alcohol use....LABORATORY AND DIAGNOSTIC DATA 1. Toxicology screen negative...." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/06/2011 and signed by a physician from the Medical Examiner's office revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....He was being involuntarily committed and was at the local hospital when his death occurred. He was agitated and attempting to leave his room when he was physically restrained by multiple individuals. Video of the events show one person placing an arm around his neck prior to him being taken to the ground. The neck restraint appears to be maintained as several other individuals restrain his body. His respiratory function would have been further compromised if overlay occurred on the chest and/or abdomen. The decedent appears unresponsive immediately following the restraint. Significant findings at autopsy include small, multifocal and thin subarachnoid hemorrhages, hemorrhages in the tongue and laryngeal mucosa and chronic active hepatitis of unknown etiology. Toxicology studies are positive for therapeutic concentrations of Risperidone (Risperdol) in aorta blood. Benzodiazepines, cocaine, ethanol, opiates, organic bases, ziprasidone and haloperidol are not detected. Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and	A 167		

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A 167	Continued From page 49 beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the cameral angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed the following events at the noted times: 21:13:00 - Patient #5 in room with lights off. CPO #1 and CPO #2 go into patient's room and turn lights on. One Security Officer (SO) in room and another SO at the patient's doorway looking into room (SO #1 and SO #2). RN #1 and RN #2 outside of and looking into room. 21:13:14 - RN #1 goes into room. SO #1 and SO #2 in room and CPO #1 and CPO #2 standing in doorway of room. Patient not in view. 21:13:26 - Patient walks into view in front of bed (which is against the back wall). All staff looking at patient. Patient sits on bed. 21:13:53 - Patient stands up off of bed with a cup in his hand. 21:14:16 - Patient throws water from cup onto a Security Officer (unable to determine which one). CPO reaches for cup. 21:14:22 - RN #1 goes out of room and out of view. RN #2 in doorway looking into room. Patient not in view, but can see 2 Security Officers and 1 CPO in room (other CPO is in room out of view). 21:14:34 - Patient stands in view with CPO #1 in front of him. Patient then sits in a chair to left side of room. The 2 Security Officers are now outside of the room, one of them wipes off his glasses.	A 167		

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A 167	Continued From page 50 21:14:54 - RN #1 stands in doorway of room. 21:14:55 - Patient stands up. CPO #1 standing in front of patient and CPO #2 on the right side of room. RN #2 walks away from room and out of view. 21:15:15 - Security Officer in hall wipes his pants off with a towel and RN #1 steps away from patient's door and helps him. Patient visible standing in room with CPO #1 standing in front of him. 21:15:21 - Patient moves towards door and CPO #1 moves in front of him (between patient and door). SO #1 and SO #2 outside of and looking into room. RN #1 walks towards room while wiping her shirt with a towel. 21:15:22 - CPO #2 walks towards patient (from right side of room) with arms reached out towards patient. 21:15:23 - SO #1 and SO #2 move into the patient's doorway. Patient is facing doorway with CPO #1 on his right side and CPO #2 on his left side (both CPOs positioned towards the front of the patient). 21:15:25 - RN #1 turns away from the patient's room and walks down the hall. The 2 CPOs are holding the patient's arms, one on each side. 21:15:26 - Patient lifts up slightly and sits on bed (CPOs still beside of and with hands on the patient). 21:15:28 - RN #1 looks over shoulder then turns around and faces the patient's room. SO #1 and SO #2 head into room. CPO #1 leans down towards bed. CPO #2 not in view. 21:15:29 - RN #1 turns back away from and continues to walk away from room. Patient is visible standing and facing towards the right side of the room. CPO #1 goes behind the patient. CPO #1 lifts his right arm out with elbow bent and	A 167		

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A 167	Continued From page 51 moves it towards the patient. 21:15:30 - CPO #1's arm not visible. CPO #1 is leaning forward or bending down. Patient not visible. SO #1 and SO #2 in doorway looking in. CPO #1 and patient go backwards (towards left side of room) together. CPO #2 comes into view with in front of patient with his arms extended, but hands not visible. RN #1 looks back towards room again, then turns and continues to walk away from room. 21:15:31 - Patient's right hand is in the doorway, holding onto the door jam. The 2 Security Officers are still in the doorway. Both CPOs face the doorway as they and the patient are going down. 21:15:32 - Patient down and out of view. CPO #1 (who was behind patient) is not visible. CPO #2 in front of patient and leaning towards floor. SO #1 and SO #2 enter room and are on the right side of the patient, with their backs towards the camera. The Security Officer closest to the patient's legs is leaning down. 21:15:35 - CPO #2 leaning down towards patient and out of view. Both Security Officers leaning towards patient, the one near the top of the patient is standing and the one near the patient's legs is leaning towards patient with his (officers) legs extended to the side. 21:15:38 - CPO #1 and patient remain out of view. CPO #2 and both Security Officers are leaning towards the left, over the patient. 21:15:44 - The Two Security Officers stand, but still lean over the patient. 21:15:46 - One of the Security Officers goes around to the patient's other (left) side. 21:15:49 - CPO #1 and patient remain out of view. CPO #2 appears to be on the patient's legs.	A 167		

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A 167	Continued From page 52 21:15:52 - CPO #2 is up on his toes with his legs extended behind him. The top of his body is positioned towards the patient, but the view is blocked by the back of the Security Officer that is positioned on the patient's right side. 21:15:53 - Patient's right leg goes up, then down. Security Officer on right side of patient appears to hold it. 21:16:03 to 21:16:12 - The footage jumps and there is no footage available during this period of time. 21:16:12 - The Security Officer on the right side of the patient and CPO #2, now located near the patient's legs on the right side, are both leaning over the patient with their backs to the door. No one else in the room is visible. 21:16:27 - Security Officers and CPOs visible on floor, no apparent struggling at this point. 21:16:30 - RN #2 and RN #3 (a male psychiatric ED nurse) go to the doorway of the patient's room and look in. 21:16:35 - RN #2 goes into room 21:16:38 - RN #3 goes into room 21:16:42 - RN #3 leans toward patient's feet. CPO #1 now visible and near the top of and to the right of the patient. A Security Officer is visible on each side of the patient. 21:16:48 - RN #1 walks to door, drops restraints on the floor in the hall near the door, and turns and walks away from room. RN #2 goes into room and goes to the left side of the room. 21:16:54 - Both Security Officers now standing and leaning over patient. CPO #1 is near the top of the patient and is leaning over patient, either on his knees or with his legs extended. 21:16:55 - RN #2 leaning over the patient, near his head and to the left of CPO #1, then standing up.	A 167		

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A 167	Continued From page 53 21:16:59 - 2 EMS staff and ED Tech(nician) #1 arrive and enter into room. 21:17:02 - 1 of the EMS staff goes towards the patient's head and looks down. 21:17:04 - RN #2 comes out of room. 21:17:10 - 2 EMS staff and ED Tech #1 come out of room. 21:17:22 - Licensed Practical Nurse (LPN) #1 (an ED nurse) enters room, followed by 1 EMS staff and ED Tech #1. RN #1 is standing in the doorway with restraints in her hand. 21:17:35 - Second EMS staff goes into room. 21:17:41 - A staff member inside room (unable to determine which one) is seen putting a sheet on the bed. 21:17:48 - Security Officers and other staff are standing looking towards the patient on the floor. 21:17:50 - Several staff (unable to determine who or how many) lift the patient from the floor to the bed. 21:17:52 - Patient is on bed. Staff, including SO #1, SO #2, and CPO #2, surround the patient. CPO #1 is standing in the doorway. 21:17:54 - RN #1 goes into room with restraints in hand. 21:17:58 - CPO #1 goes out of room and rubs his head. 21:18:30 - Physician #2 (psychiatrist) walks towards room and stops and talks to CPO #1 in the hall on the way. 21:18:37 - Physician #2 stands in patient's doorway, leans on doorway, and looks into room. (Does not go into room). 21:18:42 - RN #4 (psychiatric nurse) walks towards room and talks to CPO #1 in hall. 21:18:49 - RN #3 is standing in room and looking down. 21:18:55 - Physician #2 walks away from room. 1	A 167		

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A 167	Continued From page 54 EMS staff exits room. RN #3 mops floor with towel. 21:19:02 - Patient is seen laying on bed. Patient is not moving and his clothes are off (can see naked right side). 21:19:08 - RN #2 exits room and talks to Physician #2 in hall. 21:19:34 - RN #3 exits room and talks to Physician #2 in hall. Other EMS staff exits room. RN #2 goes back into room. 21:19:49 - RN #3 and CPO #1 go into room. 21:19:56 - RN #3 exits room. RN #1, RN #2, and LPN #1 are in room near the patient's head. Patient is not moving. 21:20:15 - RN #3 goes into room with BP (blood pressure) machine. 21:20:36 - Security Supervisor goes to and looks into room. 21:23:26 - Someone takes BP cuff off of patient's arm. 21:23:33 - Staff roll patient out of room on bed. He is naked with a sheet laying over his groin. Restraints are visible on his ankles (cannot see his clearly see his wrists). Patient is not moving. Interview on 10/19/2011 at 1100 with Security Officer (SO) #1 revealed the officer was posted in the psychiatric area of the ED on 04/17/2011 from 4 PM to Midnight. Interview revealed when Patient #5 arrived to Room 65 "staff decided he didn't need to change (into gown) right away. That was their call....I wanded him". Interview revealed SO #2 walked through the psychiatric area of the ED to see if SO #1 needed any assistance. Further interview revealed, "He (The patient) was calm at first. The longer he sat he got more agitated. (SO #2) decided to stay with me due to his agitation. We don't usually let	A 167		

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A 167	Continued From page 55 patients walk in the halls (in the psychiatric area of the ED), but in this occasion I let him walk in the hall. It seemed to calm him. He went back and forth to the bathroom and his room. We kept our distance and kept an eye on him. He didn't say a lot. He had this white stuff around the outside of his mouth. We told the nurse about it because we have seen patients that have been doing spice or something (illicit substances) like that. Its just an observation we had noticed in the past. He was muttering stuff like he wanted to go home." Interview revealed the patient became more agitated and began hitting the bed and wall. Interview revealed SO #1 called Company Police for assistance once before the end of the 0700-1900 shift and CPO #2 came to psychiatric area. Interview revealed, "They came and hung around for a little bit and then left." Interview revealed, "I think he was given a pill before (dayshift nurse) left at 7 PM. It seemed like it made him worse. He really started to hit the walls and bed. (He had) muttered talking, not making any sense. He would come out (of his room) a little bit and we'd ask him to go back and he would eventually go back. (RN #1) came on and I told her about his behavior. I don't remember if she went in to see the patient. I called Company Police again and (CPO #2) came and saw the patient's behavior and called (CPO #1) to come." Interview revealed at this point the patient's behavior had escalated and "it looked like he was about to act out severely". Interview revealed, "I think the nurse came and tried to speak to him. He didn't calm down. The two Company Policy Officers came into his room and told me and (SO #2) to step back. They took charge." Interview revealed at that point the two security officers went out of the patient's room and stood in the	A 167		

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A 167	Continued From page 56 doorway. Interview revealed, "They (The CPOs) told the patient medical staff needed to take care of him, take blood or whatever. He (The patient) went at (CPO #1), swung and knocked (CPO #1) against the wall. (CPO #1) and (CPO #2) got him to the ground....I didn't see anyone grab his neck or shoulders, basically just his legs....(When the patient was on the ground) I grabbed his legs and then moved to his arm, I think on the right side. I think the Company Police Officers were on his arms and upper body. As far as I could tell they were leaning on his chest....They had their back to us, so I don't remember if I could see his (the patient's) face or neck." Further interview revealed the officer thought he had to call, by waving his arm so as to be seen on video monitor at the ED desk, to get a nurse in the room. Interview revealed the officer thought someone had pushed the panic button (initiated an emergency response) because "so many" staff showed up. Further interview revealed, "We moved him to the bed. He was still struggling and urinating on himself (when on the floor and the bed). He was moving his arms and legs, trying to get up. He was muttering some stuff....They gave him some shots and tried to put restraints on because he was fighting pretty hard. Before putting restraints on him, they tried to get his clothes off and put a gown on him. I think they got a gown on him, but I'm not sure. Restraints were placed on his arms and legs by medical staff, I'm not sure who...a couple of females and a male. Sometime during that point he quit moving a lot, because they had given him the shots, it usually works pretty quick. That's when the nurse noticed there seems to be something wrong, seems like he's not breathing. She told (RN #2) to go get the bag (BVM). A male nurse	A 167		

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A 167	Continued From page 57 checked the pulse and said it was weak. They got him out of there and to the resuscitation room." Interview was requested with and declined by CPO #1. Review of hospital investigation documents revealed documentation of an interview on 05/19/2011 of CPO #1 by Root Cause Analysis team members. Review of the interview revealed CPO #1 first responded on 04/17/2011 at 2000 and talked with the patient, who appeared to be afraid, and held the patient for a shot. Review of the interview revealed at 2100 CPO #1 was called back to the psychiatric area, at which time the patient was walking out of his room. Review of the interview revealed the patient was completely different and was more agitated and asking for water. Review revealed the patient had white chalk around his mouth that the CPO didn't notice previously. Review revealed the patient threw water and CPO #1 grabbed hold of him. Review revealed the patient grabbed the CPO's badge, and the CPO grabbed his wrist to get him to release it. Review revealed the patient grabbed the badge again and tried to push the CPO out of the room. Review revealed, "Officer (CPO #1) slipped, pulled patient on top of him with shirt. Hit head on wall. (CPO #1) thinking about rolling fingers under jaw, can't remember if he did it or not." Review revealed Security Officers held the patient's arms and legs. Review revealed, "(CPO #1) got out from under him, laid on his (the patient's) shoulder. Review revealed, when CPO #1 was asked if anything about this case concerned him, he responded the patient had received only one injection, that had more medications than usual in the syringe, and nurses don't know how to apply leather restraints,	A 167		

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A 167	Continued From page 58 officers used to apply leathers, now they don't. Review revealed, when CPO #1 was asked who has authority to place a patient in physical restraints, he responded officers not allowed, nurses don't know how. Review revealed, when CPO #1 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the interviewer as "Put arms across jaw to keep his head turned away. Patient blubbering, blowing foam and spit. Patient quit moving. Patient still breathing. Moved to stretcher. Put restraints on legs. Moved to arms and LPN noticed he wasn't breathing. Patient arched back and took one big breath. Training: soft hands - pain compliance; no marks left but cause pain; wrist lock; and nerve under jaw. hard hands - punches". Personnel file review for CPO #1 revealed no documentation the CPO had completed NCI (Nonviolent Crisis Intervention training program that teaches deescalation and therapeutic patient hold techniques). File review revealed no documentation the CPO had received hospital based restraint training. Interview was requested with and declined by CPO #2. Review of hospital investigation documents revealed documentation of an interview on 05/12/2011 of CPO #2 by Root Cause Analysis team members. Review of the interview revealed CPO #2 received a call from SO #1, saying they were trying to get the patient in a gown, at around 2000 on 04/17/2011. Review revealed CPO #2 responded and stayed with the patient, SO #1, and SO #2. Review revealed after about 1 hour the patient kept	A 167		

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A 167	Continued From page 59 asking where he was where his mother was. Review revealed CPO #2 said his sixth sense told him to stay in the room with the patient. Review revealed CPO #2 said he thought several people need to stay. Review of interview revealed, "They kept telling patient to stay in room, but he kept going to the bathroom and as the hour progressed he got more and more agitated. They heard him strike the wall one time. The called (CPO #1) to ask him to come to patient's room. Patient sat on bed (not sure if voluntary or if they asked him to). Patient asked for some water, which (CPO #1) gave him and the patient 'sprinkled ' water on them. (CPO #1) told him to stop and he did. Then they had to tell him again. (CPO #1) was standing directly in front of patient. 2 security guards standing behind them in hallway. Patient put his hands on (CPO #1). States as a natural reaction to protect themselves (CPO #1) got behind him and had him by his mid-section. Both (CPO #1) and patient fell against wall and then to the floor. Then the 2 security guards joined in to help. (SO #2) had patients left arm. (SO #1) had (unable to read text). (CPO #2) in front of him. Brought patient under control through physical restraint. Patient put on the bed. When on bed, (CPO #2) restrained left arm, (CPO #1) his feet and medical staff attended patient. Heard them talk about patient's breathing and doctor was going to take him to the resuscitation room....When (CPO #1) first came they gave him (patient) meds and patient was not fighting or confrontational." Review revealed CPO #2 asked, "Did meds make him escalate?" Review revealed, when CPO #2 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the	A 167		

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A 167	Continued From page 60 interviewer as "Training: No department training. As Police Officer get: hand cuff training, unarmed self-defense training (how to grab wrists and arms to gain control), painful force training, and training to de-escalate situation includes verbal, soft hands, equipment to include pepper spray and use of baton (depends on how it escalates)". Review revealed, when CPO #2 was asked who has authority to place a patient in physical restraints, he responded that he now knew, based on an e-mail that recently came out, that medical staff (nurses and physicians) can place leather restraints. Personnel file review for CPO #2 revealed no documentation the CPO had completed NCI. File review revealed no documentation the CPO had received hospital based restraint training. Interview was requested with RN #1. Administrative staff informed surveyor RN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of a "Witness Statement" for RN #1 dated 04/17/2011. Review of the statement revealed the following: The patient was IVC and began making attempts to leave the facility. He began pacing, cursing, and became physically violent with staff. CPO and security staff were at bedside and intervened when the patient made attempt to leave department and began assaulting staff. While CPO and security were attempting to calm patient, he threw water on staff members and the floor. He then lunged at the CPO and had to be restrained. RN #1 left the area at that time to inform the psychiatrist of the patient's status and events. Upon returning to the area, the patient	A 167		

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A 167	Continued From page 61 had stopped resisting CPO and security and was placed on the stretcher. Patient then began to have ineffective breathing and was taken to the resuscitation room. Personnel file review for RN #1 revealed no documentation the nurse had completed NCI. Interview on 10/19/2011 at 0915 with RN #3 revealed the male nurse was a psychiatric nurse that worked in the ED. Interview revealed when the nurse arrived to the patient's room on 04/17/2011 the patient was on the floor with at least 4 security officers (including security officers and CPOs). Interview revealed, "(CPO #1) was up at the head on the patient's right side helping hold him down. He was holding his chest or head....was in a position to hold the top part of the body. Another person (unsure who) was on the patient's right side holding his right leg. (CPO #2) was on the left side holding his leg or thigh. A security officer...was semi-squatting over (CPO #2)....I held his left foot. A police or security officer was at the top of the left shoulder area. I couldn't see what he was holding. I was just seeing (other staffs') backsides....I think his primary nurse was in the room...but that might have been when I went back and we got him on the stretcher." Interview revealed the nurse wasn't sure what staff monitored the patient's condition during the physical restraint. Interview revealed, "I couldn't see him at all really. He was kicking and fussing and trying to be violent and all of that. I couldn't see his face....All I am seeing is back and arms. They would basically have to be holding him on the chest. He was a big fellow and was doing some pretty good struggling to start with...I could only see him from the knees	A 167		

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A 167	Continued From page 62 down because they pretty much had him covered up with their bodies....I stopped holding his foot when he stopped fighting and I went out of the room to get the vital signs machine....I came back in with the vital signs machine and they (staff) were standing up and he didn't look like he was breathing. He had quit fighting. I think (LPN #1) said, 'Let's get him to the stretcher.'...After he was on the stretcher his breathing was very, very shallow....I don't remember his clothes coming off....One (restraint) got put on his leg....There's no point in doing that because he's not breathing right....Everybody's trying to look ahead and get him tied down in case that's what's needed. I got out of the way and they rolled him to the resuscitation room." Interview was requested with LPN #1. Administrative staff informed surveyor LPN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of an interview on 05/18/2011 of LPN #1 by Root Cause Analysis team members. Review of the interview revealed the interviewer documented the nurse's response as, "(RN #1) asked for help with restraints. When I got to the patient's room, he was still on the floor being restrained, but not longer resisting. We got him up on the stretcher, we were getting him straight and trying to get the restraints on and I didn't like his breathing. So, I repositioned his head, still didn't like his breathing. So I asked for a nasal airway. That didn't help, his respirations were decreased, agonal-like. The psych nurse brought the ambu (BVM) bag, but I was concerned about his poor respirations and I said 'We need to go' and we took him to the resuscitation room." Review	A 167		

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A 167	Continued From page 63 revealed, when asked was there anything that caused the nurse concern about the case, the interviewer documented the nurse's response as, "I thought they were a little forceful while restraining him and I didn't like them holding him near his head and neck." Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CIT training did not include training for therapeutic patient holds. Interview revealed CPO #1 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview revealed, "They come in with stated experience and competency in all ED and critical care areas. That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation	A 167		

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A 167	Continued From page 64 techniques, NCI, or therapeutic holds. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #1 received NCI training during her employment at the hospital. Further interview on 10/20/2011 at 1130 with the Vice President of Nursing during video taped footage review of the physical restraint of Patient #5 on 04/17/2011 confirmed nursing staff was not continuously present and did not continuously supervise the restraint. Interview confirmed nursing staff did not continuously monitor the patient to ensure safety during the physical restraint. 2. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review revealed the patient had a history of Schizophrenia and multiple mental health hospitalizations. Record review revealed patient #2 was placed in Room 66 of the psychiatric Red Zone (a locked unit) at 0206. Record review of Nurse #5's notes dated 04/24/2011 at 0433 revealed "PT (patient) pacing about room wringing hands shouting...verbal de(e)scalation unsuccessful. MD (ED physician) and PIC (On Call Psychiatrist) notified for assistance. No orders given at this time." Record review of Nurse # 5's notes dated 04/24/2011 at 0456 revealed "...PT continues to be very agitated and begin(n)ing to self inflict, slapping slef (self) over body and arms...No orders given..." Record review revealed ED physician #3 ordered "Restraints-Mechanical...Leather 4 point" on 04/24/2011 at 0501 and "Ziprasidone (medication	A 167		

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A 167	Continued From page 65 for short term control of severe agitation) 10 mg inj (injection)" and "Lorazepam (medication used to calm and treat anxiety) 2 mg IM (intramuscular injection) " on 04/24/2011 at 0502. Record review of " Restraint/Seclusion Orders, " dated 04/24/2011 at 0511, revealed the following types of restraints were ordered by the physician: "Side Rails intended to restrict bed exit...Chemical...RUE (Right Upper Extremity) (rigid), LUE (Left Upper Extremity) (rigid), LLE (Left Lower Extremity) (rigid), RLE (Right Lower Extremity) (rigid)..." Record review of Unit Secretary's note dated 04/24/2011 at 0524 revealed the patient was moved to bed "Blue 26 South" (outside locked Psych Unit). Record review revealed Ziprasidone and Lorazepam, chemical restraints, were administered at 0528 and 0529, respectively, by nurse #6. Record review revealed the 4 point (bilateral wrists and ankles) leather (rigid) restraints were initiated at 0529. Record review of Unit Secretary's note dated 04/24/2011 at 0539 revealed Patient #2 was moved to "RED 63 South" (outside locked Psych Unit). Record review of Nurse #6's notes dated 04/24/2011 at 0551 revealed "Pt moved to room 63 from 29 on stretcher, in 4 point restraints. Pt on cardiac monitor, nibp (blood pressure) cuff and spo2 (Oxygen) monitor. Pt sill rocking back in forth in bed from side to side and shaking his legs. Pt sinus tach (tachycardia -elevated heart rate) in 140's - 150's on monitor. (Physician #3) aware." Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing	A 167		

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A 167	Continued From page 66 (throwing) his body against the doors tot he (of the) unit. With assistance of (Security Guard # 3) and CPO (Company Police Officer # 2) PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "...(Nurse #5) HEAD STRUCK WALL DURING PHYSICAL ALTERCATION (with Patient #2)..." Report review revealed a narrative stating "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient. Further review of report revealed narrative continued stating "...(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with (Security Officer #3), (Nurse #5), and (Security Officer #4) used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was restrained and under control I placed my handcuffs onto the patient so that (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us. Medical staff arrived and administered medication...by giving him an injection in his left arm and left buttocks that would help calm him down...walked the patient back to room 66 until a	A 167		

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A 167	Continued From page 67 stretcher arrived so that four point's restraints could be placed on the patient by medical staff... (Patient #2)'s vitals and heart rate were monitored after the incident by medical staff...(Patient #2) had an elevated heart rate and was moved out of the Psych area into treatment room 29 so that he could be monitored more closely. (Nurse #5) fell against the wall striking his head during the physical altercation." Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2. Interview with Nurse #5 on 10/19/2011 at 0950 revealed "The patient (#2) was throwing himself against the doors...to prevent harm I, security, and a CPO tried to get him to the floor. I ended up under all 3 and the patient...the BCH (psych) nurse pulled on my leg to get me." Interview further revealed "I don't have any current training in deescalation, CPI (Crisis Prevention Institute) or NCI (Nonviolent Crisis Intervention), it was many years ago. I've never had any CPI, NCI at this hospital, they offer training but I've never had training at this hospital." Interview revealed nursing staff were distracted from directing security staff and monitoring the patient during the therapeutic hold and handcuffing of the patient. Interview with Security Officer #4 on 10/21/2011 at 0930 revealed "When I responded the patient (#2) was wrestling (staff). I went in and observed (Patient #2) was trying to assault staff. (I) grab him around the waist to calm him down." Interview revealed the staff involved in the restraint of Patient #2 were Nurse #5, Security	A 167		

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A 167	Continued From page 68 Officers #3, #4 and CPO #2. Interview revealed "(Patient #2) went to the floor as I arrived, CPO and Security had his arms, I grabbed his waist so he wouldn't get hurt. (Nurse #5) was on the floor in the mist of everything, he went down first...he was off to the side rolling holding his head...The psych nurse was checking on (Nurse #5). I (Security #4) was down on the ground with the patient. (Security #3) and (CPO #2) were standing over talking to the patient while he was down. We picked him up, he walked on his own, we escorted him back to the room. The psych nurse was checking on (Nurse #5)...I don't know who put restraints on the patient, he ended up being transported to another room, I don't know why he was transported out of psych..." Interview revealed there was no nursing staff directing security or monitoring the patient during the therapeutic hold or handcuffing of the patient. Interview with Security Officer #3 on 10/21/2011 at 1130 revealed "I was posted in the Red Zone...When (Patient #2) was brought in he was anxious and after about an hour or hour and a half he got worse." Interview revealed Patient #2 attempted to leave the unit by running into the doors. Interview revealed Security Officer #3 grabbed the patient by the shoulder and Security Officers #4 grabbed the patient by the waist and took him to the floor. Interview revealed there were 2 CPOs in the psych unit, standing at the nurses station. Interview revealed "the CPOs came quickly...I didn't know (Nurse #5) was hurt, we held him (patient #2) down and they (CPO) hand cuffed the patient." Personnel file review for Nurse #5 revealed this nurse was a contracted agency nurse assigned to	A 167		

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A 167	Continued From page 69 the ED. File review revealed no documentation of current training in deescalation of behavioral patients, NCI or CPI. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview revealed, "They come in with stated experience and competency in all ED and critical care areas. That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation techniques, NCI, or therapeutic holds. Personnel file review for CPO #2 revealed no documentation the CPO had completed NCI. File review revealed no documentation the CPO had received hospital based restraint training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CIT training did not include training for therapeutic patient holds. Interview revealed CPO #2 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use	A 167		

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A 167	Continued From page 70 law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training.	A 167		
A168	482.13(e)(5) PATIENT RIGHTS: RESTRAINT OR SECLUSION The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law. This STANDARD is not met as evidenced by: Based on policy review, medical record review, and staff interview, the hospital failed to ensure a physician's order for physical restraint for 3 of 3 sampled patients that were physically restrained by staff (Patients #5, #2, and #7). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm. Restraints...are used in a manner that attempts to prevent harm, physical discomfort, embarrassment, or pain to the patient....DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely...PROCEDURES:...8. TIME LIMITED	A168	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** It has been educated to ED providers, psychiatrists and nursing staff there has to always be a physician order for restraint and the order must be placed in the computer for quality monitoring. In the case of a therapeutic hold, providers and staff have been educated and will continue to be educated that this is a restraint and it has to be ordered as a restraint (see "3B"). Based on the "Restraint, Seclusion and Safety Devices" (see "attachment 3, 3A and 3B") policy there has to be a physician order within 30 minutes and a face to face assessment within 60 minutes of the time the restraint was applied. This has also been educated to the ED nursing staff. Physician education was provided to the ED medical staff by the ED Medical Director. **Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on	11/07/2011

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A 168	Continued From page 71 ORDERS: A verbal or telephone order is obtained from the physician within 30 minutes of the placement of restraints...15. DOCUMENTATION:...Documentation includes:...g. Written orders for use..." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638. Review of triage nursing assessment at 1645 revealed, "Chief Complaint: Not taking medications." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation...." Review of Physician #2's note dictated on 04/18/2011 at 0136 revealed, "...He became agitated around 8 p.m. and he received 20 mg of the Geodon (anti-psychotic mediation) IM (intramuscularly) and 2 mg of Ativan (anti-anxiety medication) IM. This physician was with other patients actually at the time this was happening and he received the medication....It appears that about one-quarter past the hour the patient became more agitated after initially calming down....he threw the water either at someone or on the floor and then started to be verbally abusive. He told the officer, 'Let's go,' and	A 168	restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. Responsibility: Vice President of Nursing	

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A 168	Continued From page 72 evidently took a swing. He was restrained at that period of time. He was on the ground being held by a number of nurses and CPO and so forth...." Further record review revealed no documentation of a physician's order for restraint. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed a physical hold was a restraint and therefore required a physician's order. Interview revealed if the restraint is a physical hold that does not progress to mechanical restraint "I do not believe a physician's order is always obtained, because it is a rapid situation that deescalated". Interview revealed, "it is required to get an order and the physician should evaluate the patient within 1 hour." Further interview with the Director at 1400 confirmed there was no available documentation of a physician's order for the physical restraint of the patient on 04/17/2011. 2. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services (EMS) on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review of "Restraint/Seclusion Orders," dated 04/24/2011 at 0511, revealed the following types of restraints were ordered by the physician; "Side Rails intended to restrict bed exit...Chemical...RUE (Right Upper Extremity) (rigid), LUE (Left Upper Extremity) (rigid), LLE (Left Lower Extremity) (rigid), RLE (Right Lower Extremity) (rigid)..." Record review revealed the check box for Therapeutic Hold (physical restraint) was not checked. Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely)	A 168		

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A 168	Continued From page 73 agitated unable to verbally deescalate....With assistance of Security Guard # 3 and CPO (Company Police Officer) # 2 PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed no physician order for a therapeutic hold. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed a physical hold was a restraint and therefore required a physician's order. Interview revealed if the restraint is a physical hold that does not progress to mechanical restraint "I do not believe a physician's order is always obtained, because it is a rapid situation that deescalated". Interview revealed, "It is required to get an order and the physician should evaluate the patient within 1 hour." Further interview with the Director at 1400 confirmed there was no available documentation of a physician's order for the physical restraint of the patient on 04/24/2011. 3. Closed medical record review for patient #7 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via private transportation on 06/29/2011 at 2011 with complaints of neck and back pain. Record review revealed the patient was discharged on 06/30/2011 at 1451 with diagnoses UTI (Urinary Tract Infection) and alcohol intoxication. Record review of Nurse #7 notes dated 06/30/2011 at 0848 revealed "...Pt (patient #7) found to have attempted to leave the ED. Pt escorted back to room 31...Pt stated he wanted to leave and smoke. Pt began swinging and acting out in the lobby, pt had to be taken to the floor by room 31 by security and panic alarm sounded by staff. Pt	A 168		

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A 168	Continued From page 74 then proceeded to head butt the glass door of room 31..." Record review of physician #4 note dated 06/30/2011 at 0851 revealed "Pt got up, angry, verbally abusive and started to walk out of ED. I explained he could not leave due to ETOH (Alcohol) level. I told him not to leave or I would have to involuntarily commit him until legally sober. Pt came back in with staff escort, then tried to leave again and became combative. Pt now will be involuntarily committed until MBA (Alcohol Level) comes down." Record review revealed no physician order for the physical restraint (therapeutic hold) placed on the patient. Record review revealed no physician order for the physical restraint (therapeutic hold) placed on the patient. Interview on 10/19/2011 at 1345 with physician #4 revealed the physician did not write an order for restraint or therapeutic hold of patient #7. Interview revealed physician #4 felt initiating the involuntary commitment paper was sufficient. Interview confirmed an order for the use of a therapeutic hold, physical restraint, was not written. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed a physical hold was a restraint and therefore required a physician's order. Interview revealed if the restraint is a physical hold that does not progress to mechanical restraint "I do not believe a physician's order is always obtained, because it is a rapid situation that deescalated". Interview revealed, "It is required to get an order and the physician should evaluate the patient within 1 hour." Further interview with the Director at 1400 confirmed there was no available documentation	A 168		

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A 168	Continued From page 75 of a physician's order for the physical restraint of the patient on 06/30/2011.	A 168		
A175	482.13(e)(10) PATIENT RIGHTS: RESTRAINT OR SECLUSION The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, and hospital investigation document review, the hospital failed to ensure restrained patients were monitored by trained staff for 3 of 11 sampled patients that were restrained by staff (Patients #5, #7, and #2). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm....DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely....7. INITIATION & ASSESSMENT: A qualified licensed staff member with established competencies may initiate seclusion or apply restraint. Assessment of the patient who has new onset or worsening of	A175	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: A training and education program is being provided to the Emergency Department (ED) staff at the beginning of each shift for ED employees on a daily basis until further notice in order to comply with the Health Systems' policies and procedures for the behavioral health/psychiatric patients (see "attachment 2" and 2A"). The training and education consists of education on the 1) Restraint policy (see "attachment 3", 3A", and 3B") which includes all types of restraints such as the therapeutic hold 2) least restrictive measures are to be utilized first on the behavioral health/psychiatric patient when needed 3) recognition of the role of the registered nurse (RN) so all members of the health care team understand the registered nurse is always in charge of the clinical care of the patient and the provision of a safe and secure environment for the patient 4) the forms that accompany the restraint policy such as the physician order form, the monitoring and flow sheet for the restrained patient 5) computer process for ordering the restraints including the therapeutic hold 6) emphasis on patient safety at all times including during any type of patient escalation the nurse never leaves the patient and the nurse is always able to complete a physical assessment of her patient	

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A 175	Continued From page 76 confusion/agitation is done by an RN (registered nurse) prior to or within 30 minutes of application of a restraint....11. RESTRAINT/SECLUSION MONITORING:...Behavioral Seclusion/Restraint: Staff provides continuous face-to-face observation of the patient in rigid limb restraint(s) and maintains documentation on the Restraint Flowsheet (excluding therapeutic holds less than 15 minutes) and on the Special Observation Flowsheet....At the initiation of seclusion or restraint, and every 15 minutes, a staff member monitors the patient with the intent to prevent harm and maintain well-being....15. DOCUMENTATION:...Each episode of restraint/seclusion use is recorded in the medical record. Documentation includes: a. The circumstances that led to their use; b. Consideration or failure of non-physical less restrictive interventions; c. Medical conditions or physical disability that would place the patient at greater risk....d. The rationale for the type of physical intervention selected; e. The type of restraint used,...vital signs, circulation to extremities,...patient response to treatment, patient rights, dignity and privacy maintained, and time released....h. Behavior criteria for release...; i. Informing the patient of behavior criteria for release from restraint...; l. Injuries that are sustained and treatment received for these injuries; and m. Deaths...." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638 with complaints of not taking his medicine. Record review revealed upon arrival the patient was placed in Room 65 (within	A 175	7) required nursing and physician documentation. Application of restraints and restraint training is an annual training requirement for ED staff. Information has also been shared with the ED providers by the ED Medical Director as well as the psychiatrists that work in the ED. Non-violent crisis intervention (NCI) training is an annual requirement for ED nursing staff. The nursing staff will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the nurse will not be assigned to the behavioral health/psychiatric patient. Non-violent crisis intervention (NCI) training is an annual requirement for security officers. The security officers will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the security officer will not be assigned to the behavioral health/psychiatric patient. The company police officers will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. In the case of a non-current NCI certification the company police officers will not be assigned to the behavioral health/psychiatric patient. The nursing supervisors will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. Restraint training is required for ED staff that provides direct care to patients. A portion of the training includes review of the hospital policy "Restraints, Seclusions and Safety Devices" (see "attachment 3", 3A", and 3B"). It is also required for the	

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A 175	Continued From page 77 the locked psychiatric area of the ED). Record review revealed the psychiatrist evaluated the patient and he was then involuntarily committed (IVC). Review of RN #1's note at 1929 revealed, "Assumed patient care. Patient awake and alert, breathing even and unlabored. Patient stares at RN, nonverbal. No response to questions or requests. Patient is INVOL(untary)." Review of RN #1's note at 1951 revealed, "Patient more verbal at this time, answering questions. Patient requested water; provided. patient continues to refuse to change into gown." Review of RN #1's note at 2017 revealed, "Patient continued to refuse gown, now stating ' I want my momma. I'm not putting on no mother (expletive) gown'. Patient more active in room, pacing. Patient multiple trips back and forth to bathroom; not following directions of security or nurse. CPO (Company Police Officer) and security to bedside; patient medicated." Review of RN #1's note at 2110 revealed, "Patient pacing in hallway, appears to becoming more agitated. Refusing to stay in room, becoming aggressive with staff. (RN #2) from Psych ED aware of patients increasing agitation; will inform (Physician #2)." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security	A 175	security officers and company police officers. Security officers and company police officers will receive restraint training from the Training and Development Department of CFVHS. Part of the education for the security officers and company police officers is to ensure their understanding of taking direction from the clinical nurse in how to assist with the behavioral health/psychiatric patient. Security officers and company police officers will be aware that in addition to doing what is in the best interest of the patient they also have the responsibility of the protection of other patients and staff. Monitoring: The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff.	11/07/2011

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A 175	Continued From page 78 states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/08/2011 and signed by a physician from the Medical Examiner's office revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....He was being involuntarily committed and was at the local hospital when his death occurred. He was agitated and attempting to leave his room when he was physically restrained by multiple individuals. Video of the events show one person placing an arm around his neck prior to him being taken to the ground. The neck restraint appears to be maintained as several other individuals restrain his body. His respiratory function would have been further compromised if overlay occurred on the chest and/or abdomen. The decedent appears unresponsive immediately following the restraint. Significant findings at autopsy include small, multifocal and thin subarachnoid hemorrhages, hemorrhages in the tongue and laryngeal mucosa and chronic active hepatitis of unknown etiology. Toxicology studies are positive for therapeutic concentrations of Risperidone (Risperdal) in aorta blood. Benzodiazepines, cocaine, ethanol,	A 175	The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	11/07/2011

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A 175	Continued From page 79 opiates, organic bases, ziprasidone and haloperidol are not detected. Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the camera angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed the following events at the noted times: 21:13:00 - Patient #5 in room with lights off. CPO #1 and CPO #2 go into patient's room and turn lights on. One Security Officer (SO) in room and another SO at the patient's doorway looking into room (SO #1 and SO #2). RN #1 and RN #2 outside of and looking into room. (No nurse in room). 21:13:14 - RN #1 goes into room. SO #1 and SO #2 in room and CPO #1 and CPO #2 standing in doorway of room. Patient not in view. 21:13:26 - Patient walks into view in front of bed (which is against the back wall). All staff looking at patient. Patient sits on bed. 21:13:53 - Patient stands up off of bed with a cup in his hand. 21:14:16 - Patient throws water from cup onto a Security Officer (unable to determine which one). CPO reaches for cup.	A 175		

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A 175	Continued From page 80 21:14:22 - RN #1 goes out of room and out of view, RN #2 in doorway looking into room. Patient not in view, but can see 2 Security Officers and 1 CPO in room (other CPO is in room out of view). No nurse in room. 21:15:21 - Patient moves towards door and CPO #1 moves in front of him (between patient and door). SO #1 and SO #2 outside of and looking into room. RN #1 walks towards room while wiping her shirt with a towel. 21:15:22 - CPO #2 walks towards patient (from right side of room) with arms reached out towards patient. 21:15:23 - SO #1 and SO #2 move into the patient's doorway. Patient is facing doorway with CPO #1 on his right side and CPO #2 on his left side (both CPOs positioned towards the front of the patient). 21:15:25 - RN #1 turns away from the patient's room and walks down the hall. The 2 CPOs are holding the patient's arms, one on each side. (No nurse in room as physical restraint is initiated by CPOs). 21:15:26 - Patient lifts up slightly and sits on bed (CPOs still beside of and with hands on the patient). 21:15:28 - RN #1 looks over shoulder then turns around and faces the patient's room. SO #1 and SO #2 head into room. CPO #1 leans down towards bed. CPO #2 not in view. 21:15:29 - RN #1 turns back away from and continues to walk away from room. Patient is visible standing and facing towards the right side of the room. CPO #1 goes behind the patient. CPO #1 lifts his right arm out with elbow bent and moves it towards the patient. 21:15:30 - CPO #1's arm not visible. CPO #1 is leaning forward or bending down. Patient not	A 175		

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A 175	Continued From page 81 visible. SO #1 and SO #2 in doorway looking in. CPO #1 and patient go backwards (towards left side of room) together. CPO #2 comes into view with in front of patient with his arms extended, but hands not visible. RN #1 looks back towards room again, then turns and continues to walk away from room. 21:15:31 - Patient's right hand is in the doorway, holding onto the door jam. The 2 Security Officers are still in the doorway. Both CPOs face the doorway as they and the patient are going down. 21:15:32 - Patient down and out of view. CPO #1 (who was behind patient) is not visible. CPO #2 in front of patient and leaning towards floor. SO #1 and SO #2 enter room and are on the right side of the patient, with their backs towards the camera. The Security Officer closest to the patient's legs is leaning down. (No nurse in room) 21:15:35 - CPO #2 leaning down towards patient and out of view. Both Security Officers leaning towards patient, the one near the top of the patient is standing and the one near the patient's legs is leaning towards patient with his (officers) legs extended to the side. 21:15:38 - CPO #1 and patient remain out of view. CPO #2 and both Security Officers are leaning towards the left, over the patient. 21:15:44 - The Two Security Officers stand, but still lean over the patient. 21:15:46 - One of the Security Officers goes around to the patient's other (left) side. 21:15:49 - CPO #1 and patient remain out of view. CPO #2 appears to be on the patient's legs. 21:15:52 - CPO #2 is up on his toes with his legs extended behind him. The top of his body is	A 175		

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A 175	Continued From page 82 positioned towards the patient, but the view is blocked by the back of the Security Officer that is positioned on the patient's right side. (No nurse in room) 21:15:53 - Patient's right leg goes up, then down. Security Officer on right side of patient appears to hold it. 21:16:03 to 21:16:12 - The footage jumps and there is no footage available during this period of time. 21:16:12 - The Security Officer on the right side of the patient and CPO #2, now located near the patient's legs on the right side, are both leaning over the patient with their backs to the door. No one else in the room is visible. 21:16:27 - Security Officers and CPOs visible on floor, no apparent struggling at this point. (No nurse in room) 21:16:30 - RN #2 and RN #3 (a male psychiatric ED nurse) go to the doorway of the patient's room and look in. 21:16:35 - RN #2 goes into room (first time a nurse has been in room since CPOs put hands on patient at 21:15:26). 21:16:38 - RN #3 goes into room 21:16:42 - RN #3 leans toward patient's feet. CPO #1 now visible and near the top of and to the right of the patient. A Security Officer is visible on each side of the patient. 21:16:48 - RN #1 walks to door, drops restraints on the floor in the hall near the door, and turns and walks away from room. RN #2 goes into room and goes to the left side of the room. 21:16:54 - Both Security Officers now standing and leaning over patient. CPO #1 is near the top of the patient and is leaning over patient, either on his knees or with his legs extended. 21:16:55 - RN #2 leaning over the patient, near	A 175		

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A 175	Continued From page 83 his head and to the left of CPO #1, then standing up. 21:17:04 - RN #2 comes out of room. 21:17:22 - Licensed Practical Nurse (LPN) #1 (an ED nurse) enters room, followed by 1 EMS staff and ED Tech #1. RN #1 is standing in the doorway with restraints in her hand. 21:17:48 - Security Officers and other staff are standing looking towards the patient on the floor. 21:17:50 - Several staff (unable to determine who or how many) lift the patient from the floor to the bed. 21:17:52 - Patient is on bed. Staff, including SO #1, SO #2, and CPO #2, surround the patient. CPO #1 is standing in the doorway. 21:17:54 - RN #1 goes into room with restraints in hand. 21:17:58 - CPO #1 goes out of room and rubs his head. 21:18:30 - Physician #2 (psychiatrist) walks towards room and stops and talks to CPO #1 in the hall on the way. 21:18:37 - Physician #2 stands in patient's doorway, leans on doorway, and looks into room. (Does not go into room). 21:18:42 - RN #4 (psychiatric nurse) walks towards room and talks to CPO #1 in hall. 21:18:49 - RN #3 is standing in room and looking down. 21:18:55 - Physician #2 walks away from room. RN #3 mops floor with towel. 21:19:02 - Patient is seen laying on bed. Patient is not moving and his clothes are off (can see naked right side). 21:19:08 - RN #2 exits room and talks to Physician #2 in hall. 21:19:34 - RN #3 exits room and talks to Physician #2 in hall. RN #2 goes back into room.	A 175		

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A 175	Continued From page 84 21:19:49 - RN #3 and CPO #1 go into room. 21:19:56 - RN #3 exits room. RN #1, RN #2, and LPN #1 are in room near the patient's head. Patient is not moving. 21:20:15 - RN #3 goes into room with BP (blood pressure) machine. 21:23:26 - Someone takes BP cuff off of patient's arm. 21:23:33 - Staff roll patient out of room on bed. He is naked with a sheet laying over his groin. Restraints are visible on his ankles (cannot see his clearly see his wrists). Patient is not moving. Interview on 10/19/2011 at 1100 with Security Officer (SO) #1 revealed the officer was posted in the psychiatric area of the ED on 04/17/2011 from 4 PM to Midnight and was involved in the physical restraint of Patient #5. Interview revealed, "(When the patient was on the ground) I grabbed his legs and then moved to his arm, I think on the right side. I think the Company Police Officers (CPOs) were on his arms and upper body. As far as I could tell they were leaning on his chest....They had their back to us, so I don't remember if I could see his (the patient's) face or neck." Further interview revealed the officer thought he had to call, by waving his arm so as to be seen on video monitor at the ED desk, to get a nurse in the room. Interview revealed the officer thought someone had pushed the panic button (initiated an emergency response) because "so many" staff showed up. Further interview revealed, "We moved him to the bed. He was still struggling and urinating on himself (when on the floor and the bed). He was moving his arms and legs, trying to get up. He was muttering some stuff....They gave him some shots and tried to put restraints on because he was fighting pretty hard.	A 175		

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A 175	Continued From page 85 Before putting restraints on him, they tried to get his clothes off and put a gown on him. I think they got a gown on him, but I'm not sure. Restraints were placed on his arms and legs by medical staff, I'm not sure who...a couple of females and a male. Sometime during that point he quit moving a lot, because they had given him the shots, it usually works pretty quick. That's when the nurse noticed there seems to be something wrong, seems like he's not breathing. She told (RN #2) to go get the bag (BVM). A male nurse checked the pulse and said it was weak. They got him out of there and to the resuscitation room." Interview was requested with RN #1. Administrative staff informed surveyor RN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of a "Witness Statement" for RN #1 dated 04/17/2011. Review of the statement revealed the following: The patient was IVC and began making attempts to leave the facility. He began pacing, cursing, and became physically violent with staff. CPO and security staff were at bedside and intervened when the patient made attempt to leave department and began assaulting staff. While CPO and security were attempting to calm patient, he threw water on staff members and the floor. He then lunged at the CPO and had to be restrained. RN #1 left the area at that time to inform the psychiatrist of the patient's status and events. Upon returning to the area, the patient had stopped resisting CPO and security and was placed on the stretcher. Patient then began to have ineffective breathing and was taken to the resuscitation room.	A 175		

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A 175	Continued From page 86 Interview on 10/18/2011 at 1515 with RN #2 revealed, "The patient made a move towards (CPO #2) so they called the other CPO (#1). I went to his room and he threw water towards staff....I'm not sure if his nurse was in the room. He backed up and said he was sorry and sat on his bed. I went to tell (Physician#2), but he was with another patient. I came back after I told (RN #3) what had happened. I went to the room and he was on the floor on his back...with a CPO towards the upper part of his body on his right side. Somebody had his feet....I don't know who, it was more than one person....He was struggling....I tried to tell him to calm down. I told him we'd let him up if he'd calm down and stop struggling. He was breathing and sweaty, but he was sweaty when he got there. I stepped out and was at the doorway and he stopped struggling. They were in the process of getting him up on the bed. He was a heavy boy....He was making raspy sounds on the bed....They determined he wasn't breathing. The ED nurse told me to go get the bag/mask....When I got back with the bag/mask they called a code and rushed him to the resuscitation room." Further interview revealed the psychiatric nurse works in the ED and also on the behavioral health unit. Interview revealed during a hold a patient should be monitored for breathing and safety. Interview revealed, "If we do a hold on behavioral health (unit) we document on the restraint form. They document differently in the ED." Interview on 10/19/2011 at 0915 with RN #3 revealed the male nurse was a psychiatric nurse that worked in the ED. Interview revealed when the nurse arrived to the patient's room on	A 175		

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A 175	Continued From page 87 04/17/2011 the patient was on the floor with at least 4 security officers (including security officers and CPOs). Interview revealed, "(CPO #1) was up at the head on the patient's right side helping hold him down. He was holding his chest or head....was in a position to hold the top part of the body. Another person (unsure who) was on the patient's right side holding his right leg. (CPO #2) was on the left side holding his leg or thigh. A security officer...was semi-squatting over (CPO #2)....I held his left foot. A police or security officer was at the top of the left shoulder area. I couldn't see what he was holding. I was just seeing (other staffs') backsides....I think his primary nurse was in the room...but that might have been when I went back and we got him on the stretcher." Interview revealed the nurse wasn't sure what staff monitored the patient's condition during the physical restraint. Interview revealed, "I couldn't see him at all really. He was kicking and fussing and trying to be violent and all of that. I couldn't see his face....All I am seeing is back and arms. They would basically have to be holding him on the chest. He was a big fellow and was doing some pretty good struggling to start with...I could only see him from the knees down because they pretty much had him covered up with their bodies....I stopped holding his foot when he stopped fighting and I went out of the room to get the vital signs machine....I came back in with the vital signs machine and they (staff) were standing up and he didn't look like he was breathing. He had quit fighting. I think (LPN #1) said, 'Let's get him to the stretcher.'...After he was on the stretcher his breathing was very, very shallow....I don't remember his clothes coming off....One (restraint) got put on his leg....There's no point in doing that because he's not breathing	A 175		

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A 175	Continued From page 88 right....Everybody's trying to look ahead and get him tied down in case that's what's needed. I got out of the way and they rolled him to the resuscitation room." Interview on 10/20/2011 at 1245 with ED Technician #1 revealed during April 2011 the staff member worked as an ED Tech(nician), but starting in May 2011 he joined EMS as an Emergency Medical Technician (EMT). Interview revealed on 04/17/2011 the ED Tech went to the patient's room after he heard a radio call for security assistance. Interview revealed, "I went to see what was going on...The patient was standing and there were 2 Company Police Officers telling him to calm down. The patient was cursing and was trying to get out of his room. I left...and later went back over to see if the situation had calmed down. He (the patient) was on the floor. He was kicking and combative. I went to the right, to his feet....I couldn't see his face. They were around him so I couldn't see him....I never heard him say get off me or you're hurting me. He didn't say anything....The only parts (of him) I saw was the legs. I think 3 officers were at the top, I couldn't tell what position or what they were trying to hold....After he calmed down, he was still breathing. I helped lift him to the bed. He was calm and peaceful on the bed. They brought the vital signs machine in and took his vital signs. Then he started going down. Respirations didn't seem right...slow and thready respirations....I left to clear the hallway to move him and to get the resuscitation room ready....I don't remember taking his clothes off or putting restraints on him. He never struggled or fought when he was on the bed. (LPN #1) was at the head of the bed and was directing people....	A 175		

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A 175	Continued From page 89 (RN #1) was in the doorway." Interview was requested with LPN #1. Administrative staff informed surveyor LPN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of an interview on 05/18/2011 of LPN #1 by Root Cause Analysis team members. Review of the interview revealed the interviewer documented the nurse's response as, "(RN #1) asked for help with restraints. When I got to the patient's room, he was still on the floor being restrained, but no longer resisting. We got him up on the stretcher, we were getting him straight and trying to get the restraints on and I didn't like his breathing. So, I repositioned his head, still didn't like his breathing. So I asked for a nasal airway. That didn't help, his respirations were decreased, agonal-like. The psych nurse brought the ambu (BVM) bag, but I was concerned about his poor respirations and I said 'We need to go' and we took him to the resuscitation room." Review revealed, when asked was there anything that caused the nurse concern about the case, the interviewer documented the nurse's response as, "I thought they were a little forceful while restraining him and I didn't like them holding him near his head and neck." Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed physical restraints in the ED are usually rapid and temporary, not lasting more than a few minutes, until a patient either calms down or is placed in mechanical restraints. Interview revealed, "The nurse is with the patient the entire time that is happening. A tech can assist, at time security	A 175		

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A 175	Continued From page 90 can assist, but we try not to use them. They follow the direction of nursing staff. The nurse should be clinically directing and overseeing that (the physical restraint). (The physically restrained patient) is monitored more often. A behavioral health emergency is the same as a medical emergency. Interview on 10/20/2011 at 1130 with the Vice President of Nursing during video taped footage review of the physical restraint of Patient #5 on 04/17/2011 confirmed nursing staff was not continuously present and did not continuously supervise the restraint. Further interview confirmed nursing staff did not continuously monitor the patient to ensure safety during the physical restraint. 2. Closed medical record review for patient #7 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via private transportation on 06/29/2011 at 2011 with complaints of neck and back pain. Record review revealed the patient was discharged on 06/30/2011 at 1451 with diagnoses UTI (Urinary Tract Infection) and alcohol intoxication. Record review of Nurse #7's notes dated 06/30/2011 at 0848 revealed "...Pt (patient #7) found to have attempted to leave the ED. Pt escorted back to room 31...Pt stated he wanted to leave and smoke. Pt began swinging and acting out in the lobby. pt had to be taken to the floor by room 31 by security and panic alarm sounded by staff. Pt then proceeded to head butt the glass door of room 31..." Record review of physician #4 note dated 06/30/2011 at 0851 revealed "Pt got up, angry, verbally abusive and started to walk out of ED. I explained he could not leave due to ETOH (Alcohol) level. I told him not to leave or I would	A 175		

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A 175	Continued From page 91 have to involuntarily commit him until legally sober. Pt came back in with staff escort, then tried to leave again and became combative. Pt now will be involuntarily committed until MBA (Alcohol Level) comes down." Review of hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO (Company Police Officer) #4 and dated 06/30/2011 revealed "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone room #31 in reference to an involuntarily committed white male (patient #7)...attempting to leave by fighting with Security Personnel and Medical staff.... (Patient #7) became verbally uncooperative but got up off the floor and went into his room and sat down on his bed. (Security Officer #5) and I were standing outside the room obtaining information...when (Patient #7) jumped off his bed throwing his body and arms into the glass door of his room and sat back down on the bed. Approximately three or four minutes later (Patient #7) came out of his room and said 'arrest me I want you to (expletive) arrest me.' I informed (Patient #7) he was not under arrest but could not leave due to being involuntarily committed and attempted to walk him back to his room. I asked (Patient #7) to sit down and relax on his bed. (Patient #7) out his finger in my face and stated '(expletive) you get out of my face and my (expletive) room'. Once again I told (Patient #7) to relax. (Patient #7) pushed my chest and said '(expletive) you make me lay the (expletive) down and pushed me again. I attempted to gain control of (Patient #7)'s hands to keep from being pushed again when he became combative and resistant to my commands. Security Officer #5	A 175		

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A 175	Continued From page 92 entered the room along with Nurse #8 to assist me in gaining control of (Patient #7). (Patient #7) started thrashing and attempted to grab my handcuffs to prevent being handcuffed to the bed putting nicks and cuts on my fingers. Approximately ten to twelve minutes later I told (Patient #7) I would take him out of handcuffs if he agreed to cooperate with medical staff. (Patient #7) agreed. I took (Patient #7) out of handcuffs without further incident." Interview on 10/21/2011 at 1200 with nurse #8 revealed, "The patient was trying to leave, (Physician #4) said 'you can't leave I'm going to IVC you'...we did have to do a therapeutic hold...I think I was at the waist, he was taken to the floor and he started to fight...there were 3 or 4 people, maybe, I don't remember...he was down about 20 seconds...I'm not 100% sure if the CPO put hand cuffs on him...we helped him to stand and walked him back to his room...(Physician #4) was there and saw the patient before and after (the hold)..I don't remember (patient #7) head butting the glass..." Interview revealed "...Hand cuffs are restraints when used by duly swore officers, but it is the ultimate responsibility of the nurse to monitor the patient...there are ways to walk a patient back without cuffs...I don't remember him being cuffed to the bed...there was a nurse in the room when I left..." Further medical record review for Patient #7 revealed no documentation of how long the patient was on the floor, the patient's condition while on the floor, how the patient was held on the floor, what security staff where involved in the hold, or of the use of handcuffs by CPO staff to restrain the patient. Record review revealed	A 175		

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A 175	Continued From page 93 patient #7's vital signs were not reassessed until 0952 on 08/30/2011 (1 hour and 4 mins after held to floor and subsequently handcuffed to the bed). Record review revealed no documentation of an assessment of the patient's wrists. Interview on 10/21/2011 at 1445 with administrative nursing staff confirmed nursing did not reassess the patient's vital signs per policy after a physical restraint/hold or after the patient was handcuffed. 3. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review of Nurse # 5's notes dated 04/24/2011 at 0456 revealed "...PT continues to be very agitated and begin(n)ing to self inflict. slapping slef (self) over body and arms...No orders given..." Record review revealed ED physician #3 ordered "Restraints-Mechanical...Leather 4 point" on 04/24/2011 at 0501 and "Ziprasidone (medication for short term control of severe agitation) 10 mg Inj (injection)" and "Lorazepam (medication used to calm and treat anxiety) 2 mg IM (intramuscular injection) " on 04/24/2011 at 0502. Record review of " Restraint/Seclusion Orders," dated 04/24/2011 at 0511, revealed the following types of restraints were ordered by the physician: "Side Rails intended to restrict bed exit...Chemical...RUE (Right Upper Extremity) (rigid), LUE (Left Upper Extremity) (rigid), LLE (Left Lower Extremity) (rigid), RLE (Right Lower Extremity) (rigid)..." Record review of Unit Secretary's note dated 04/24/2011 at 0524	A 175		

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A 175	Continued From page 94 revealed the patient was moved to bed "Blue 26 South" (outside locked Psych Unit). Record review revealed Ziprasidone and Lorazepam, chemical restraints, were administered at 0528 and 0529, respectively, by nurse #6. Record review revealed the 4 point (bilateral wrists and ankles) leather (rigid) restraints were initiated at 0529. Record review of Unit Secretary's note dated 04/24/2011 at 0539 revealed Patient #2 was moved to "RED 63 South" (outside locked Psych Unit). Record review of Nurse #6's notes dated 04/24/2011 at 0551 revealed "Pt moved to room 63 from 29 on stretcher, in 4 point restraints. Pt on cardiac monitor, nibp (blood pressure) cuff and spo2 (Oxygen) monitor. Pt still rocking back in forth in bed from side to side and shaking his legs. Pt sinus tach (tachycardia -elevated heart rate) in 140's - 150's on monitor. (Physician #3) aware." Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing (throwing) his body against the doors tot he (of the) unit. With assistance of Security Guard # 3 and CPO (Company Police Officer) # 2 PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "...(Nurse #5) HEAD	A 175		

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A 175	Continued From page 95 STRUCK WALL DURING PHYSICAL ALTERCATION (with Patient #2)..." Report review revealed a narrative stating "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient." Further review of report revealed narrative continued stating "...(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with (Security Officer #3), (Nurse #5), and (Security Officer #4) used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was restrained and under control I placed my handcuffs onto the patient so that (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us. Medical staff arrived and administered medication...by giving him an injection in his left arm and left buttocks that would help calm him down...walked the patient back to room 66 until a stretcher arrived so that four point's restraints could be placed on the patient by medical staff... (Patient #2)'s vitals and heart rate were monitored after the incident by medical staff...(Patient #2) had an elevated heart rate and was moved out of the Psych area into treatment room 29 so that he could be monitored more closely. (Nurse #5) fell against the wall striking his head during the physical altercation." Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2.	A 175		

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A 175	Continued From page 96 Interview with Security Officer #4 on 10/21/2011 at 0930 revealed "When I responded the patient (#2) was wrestling (staff). I went in and observed (Patient #2) was trying to assault staff. (I) grab him around the waist to calm him down." Interview revealed the staff involved in the restraint of Patient #2 were Nurse #5, Security Officers #3, #4 and CPO #2. Interview revealed "(Patient #2) went to the floor as I arrived, CPO and Security had his arms, I grabbed his waist so he wouldn't get hurt. (Nurse #5) was on the floor in the mist of everything, he went down first...he was off to the side rolling holding his head...The psych nurse was checking on (Nurse #5). I (Security #4) was down on the ground with the patient. (Security #3) and (CPO #2) were standing over talking to the patient while he was down. We picked him up, he walked on his own, we escorted him back to the room. The psych nurse was checking on (Nurse #5)...I don't know who put restraints on the patient, he ended up being transported to another room, I don't know why he was transported out of psych..." Interview revealed there was no nursing staff directing security or monitoring the patient during the therapeutic hold or handcuffing of the patient. Interview with Nurse #5 on 10/19/2011 at 0950 revealed "The patient (#2) was throwing himself against the doors...to prevent harm I, security, and a CPO tried to get him to the floor. I ended up under all 3 and the patient...the BCH (psych) nurse pulled on my leg to get me." Interview further revealed "I don't have any current training in deescalation, CPI (Crisis Prevention Institute) or NCI (Nonviolent Crisis Intervention), it was many years ago. I've never had any CPI, NCI at	A 175		

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A 175	Continued From page 97 this hospital, they offer training but I've never had training at this hospital." Interview revealed nursing staff were distracted from directing security staff and monitoring the patient during the therapeutic hold and handcuffing of the patient.	A 175		
A186	482.13(e)(16)(iii) PATIENT RIGHTS: RESTRAINT OR SECLUSION [there must be documentation in the patient's medical record of] Alternatives or other less restrictive interventions attempted (as applicable); This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, and hospital investigation document review, the hospital failed to ensure staff attempted the use of least restrictive interventions prior to restraint for 3 of 11 sampled patients that were restrained by staff (Patients #5, #7, and #2). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint...is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm,...DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely....5. THERAPEUTIC HOLD - The brief physical holding of a patient in a manner that	A186	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** Training and education has been completed on the "Restraints, Seclusion, and Safety Devices" policy (see "attachment 3", 3A", and 3B") and the NCI for ED nursing staff, security officers and company police officers. Education has also been provided to the ED providers and the psychiatrists. One portion of the education that has been provided is using the least restrictive method with the behavioral health/psychiatric patient when the patient is combative, hostile, out of control etc. The staff has been instructed to use verbal de-escalation/allowing patient to pace etc., then if needed therapeutic hold and then if needed restraints as appropriate. **Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see attachment "attachment 4 and 4A"). Currently there is baseline data for	11/07/2011

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A 186	Continued From page 98 restricts his/her movement for the purpose of calming or providing physical safety to the patient , other patients, staff members or others. A therapeutic hold is used only by individuals trained in therapeutic hold techniques, and only when less restrictive measures have been attempted and have been determined to be ineffective. 6. FORENSIC RESTRAINTS - A locking restraint required by legal authorities when a person needs to be restrained to provide for safety or detention by legal authorities for legal reasons when that person is in custody of legal authorities or is under arrest/police hold in accordance with Federal and State laws and regulations....Forensic restraint mechanisms (...handcuffs,...)are not health care restraint interventions and are not applied by the staff of (Name of Hospital)....PROCEDURES:....4. Less Restrictive Alternatives: Attempts are made to evaluate and/or consider interventions/alternatives such as:...b. Environmental Measures: i. Decrease stimulation; quiet surroundings....c. Comfort Measures:....iv. Gentle touch, soothing voice....f. Diversional Activities: i. Distract patient with videos, TV, photographs, radio, reading materials, engage in conversation....iii. Provide alternative activity for hands, i.e. rubber ball, squeezing devices, etc....h. Interpersonal Skills: i. Pleasant, consistent interaction with patient....ii. Actively listen to patient, calm reassurance....i. Communication/Interpersonal Relationships....iv. Respect a patient's need for personal space....6. CLINICAL JUSTIFICATION:...Behavioral Seclusion/Restraint:...Clinical justification includes: Harmful to self or others, as evidenced by hitting, hair pulling, striking at or biting staff or family, and/or self-mutilation or serious	A 186	compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	

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A 186	Continued From page 99 destruction to unit property, and appropriate alternative measures have been attempted....15. DOCUMENTATION: Documentation in the patient's record is to indicate a clear progression in how techniques were implemented with less intrusive restrictive intervention attempted or considered prior to the introduction of more restrictive measures....Each episode of restraint/seclusion use is recorded in the medical record. Documentation includes: a. The circumstances that led to their use; b. Consideration or failure of non-physical less restrictive interventions....d. The rationale for the type of physical intervention selected.... " 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638. Review of EMS documentation prior to arrival to hospital revealed, "Patient presented to ems very anxious, paranoid actions and behavior. Family member advised that patient had stopped taking Risperdal (antipsychotic medication) when the packaging came in different form. Patient also been hearing voices with hallucination. Patient non violent at this present time but very quiet and with paranoid tendencies. Patient cooperated with ems to go to hospital." Record review revealed upon arrival the patient was placed in Room 65 (within the locked psychiatric area of the ED). Review of nurse's notes at 1707 revealed, "Patient calm cooperative, no respiratory distress, pt (patient) ambulatory to bathroom gait steady...." Record review revealed RN #2 completed a psychiatric nursing evaluation of the patient at 1720. Review of RN #2's psychiatric assessment revealed, "Pt	A 186		

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A 186	Continued From page 100 not sure why he is here. Confused. Paranoid + restless. Pacing around room. Said he had an outburst at home. Slow to respond to questions. Denies SI/HI (suicidal/homicidal ideations) + hallucinations. Angry at his mother....appears to be responding to internal stimuli....Lives c (with) mother....Drinks occasionally. 0 (no - denies) drugs. Got upset. Had an outburst - taking medication...." Record review revealed at 1751 Physician #1 ordered a psychiatric evaluation and psychiatric precautions. Review of nurse's notes at 1758 revealed, "Psychiatric Precautions....pt . denies homicidal idealations, pt denies suicidal idealations...calm and cooperative, makes eye contact when communicating, alert and oriented X 3. Assessment: cooperative at this time...." Record review revealed Physician #2 (psychiatrist) evaluated the patient. Review of Physician #2's orders at 1842 revealed, "Medication Orders: Risperdal M-tab 2 mg (milligrams) Note: give 4 mg po (by mouth) now." Review of RN #2's notes at 1845 revealed, "(Physician #2) completed evaluation. Pt to be diverted to 1st accepting facility. IVC (involuntary commitment) papers initiated at 1845. Primary nurse and security made aware). Record review revealed documentation at 1850 the patient was administered Risperdal M-tab 4 mg by mouth. Review of RN #1's note at 1929 revealed, "Assumed patient care. Patient awake and alert, breathing even and unlabored. Patient stares at RN, nonverbal. No response to questions or requests. Patient is INVOL(untary)." Review of RN #1's note at 1951 revealed, "Patient more verbal at this time, answering questions. Patient requested water; provided. patient continues to refuse to change into gown." Review of RN #1's note at 2017 revealed, "Patient continued to	A 186		

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A 186	Continued From page 101 refuse gown, now stating ' I want my momma. I'm not putting on no mother (expletive) gown'. Patient more active in room, pacing. Patient multiple trips back and forth to bathroom; not following directions of security or nurse. CPO (Company Police Officer) and security to bedside; patient medicated." Record review revealed documentation at 2018 the patient was administered Ativan (anti-anxiety medication) 2 mg and Geodon (antipsychotic medication) 20 mg via intramuscular injection (IM) per Physician #2's orders. Review of RN #1's note at 2053 revealed, "Patient refusing labs and urine at this time; continues to appear agitated and paces in room at times. Patient now more lucid asking where is and how he got here. Patient reoriented." Review of RN #1's note at 2110 revealed, "Patient pacing in hallway, appears to becoming more agitated. Refusing to stay in room, becoming aggressive with staff. (RN #2) from Psych ED aware of patients increasing agitation; will inform (Physician #2)." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to	A 186		

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A 186	Continued From page 102 resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Review of RN #1's note at 0141 revealed, "Addendum to documentation charted at 2120. --As security was transferring patient to stretcher rigid restraints were being placed on limbs. Limb devices were placed around ankles and wrists, but at not time were they secured to stretcher/bed. Patient was not restrained with the limb devices at any point." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/06/2011 and signed by a physician from the Medical Examiner's office revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....He was being involuntarily committed and was at the local hospital when his death occurred. He was agitated and attempting to leave his room when he was physically restrained by multiple individuals. Video of the events show one person placing an arm around his neck prior to him being taken to the ground. The neck restraint appears to be maintained as several other individuals restrain his body. His respiratory function would have been further compromised if overlay occurred on the chest and/or abdomen. The decedent appears unresponsive immediately following the restraint. Significant findings at autopsy include small, multifocal and thin subarachnoid hemorrhages, hemorrhages in the tongue and laryngeal mucosa	A 186		

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A 186	Continued From page 103 and chronic active hepatitis of unknown etiology. Toxicology studies are positive for therapeutic concentrations of Risperidone (Risperdal) in aorta blood. Benzodiazepines, cocaine, ethanol, opiates, organic bases, ziprasidone and haloperidol are not detected. Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the cameral angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed the following events at the noted times: 21:13:00 - Patient #5 in room with lights off. CPO #1 and CPO #2 go into patient's room and turn lights on. One Security Officer (SO) in room and another SO at the patient's doorway looking into room (SO #1 and SO #2). RN #1 and RN #2 outside of and looking into room. 21:13:14 - RN #1 goes into room. SO #1 and SO #2 in room and CPO #1 and CPO #2 standing in doorway of room. Patient not in view. 21:13:26 - Patient walks into view in front of bed (which is against the back wall). All staff looking at patient. Patient sits on bed. 21:13:53 - Patient stands up off of bed with a cup in his hand.	A 186		

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A 186	Continued From page 104 21:14:16 - Patient throws water from cup onto a Security Officer (unable to determine which one). CPO reaches for cup. 21:14:22 - RN #1 goes out of room and out of view. RN #2 in doorway looking into room. Patient not in view, but can see 2 Security Officers and 1 CPO in room (other CPO is in room out of view). 21:14:34 - Patient stands in view with CPO #1 in front of him. Patient then sits in a chair to left side of room. The 2 Security Officers are now outside of the room, one of them wipes off his glasses. 21:14:54 - RN #1 stands in doorway of room. 21:14:55 - Patient stands up. CPO #1 standing in front of patient and CPO #2 on the right side of room. RN #2 walks away from room and out of view. 21:15:15 - Security Officer in hall wipes his pants off with a towel and RN #1 steps away from patient's door and helps him. Patient visible standing in room with CPO #1 standing in front of him. 21:15:21 - Patient moves towards door and CPO #1 moves in front of him (between patient and door). SO #1 and SO #2 outside of and looking into room. RN #1 walks towards room while wiping her shirt with a towel. 21:15:22 - CPO #2 walks towards patient (from right side of room) with arms reached out towards patient. 21:15:23 - SO #1 and SO #2 move into the patient's doorway. Patient is facing doorway with CPO #1 on his right side and CPO #2 on his left side (both CPOs positioned towards the front of the patient). 21:15:25 - RN #1 turns away from the patient's room and walks down the hall. The 2 CPOs are	A 186		

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A 186	Continued From page 105 holding the patient's arms, one on each side. 21:15:26 - Patient lifts up slightly and sits on bed (CPOs still beside of and with hands on the patient). 21:15:28 - RN #1 looks over shoulder then turns around and faces the patient's room. SO #1 and SO #2 head into room. CPO #1 leans down towards bed. CPO #2 not in view. 21:15:29 - RN #1 turns back away from and continues to walk away from room. Patient is visible standing and facing towards the right side of the room. CPO #1 goes behind the patient. CPO #1 lifts his right arm out with elbow bent and moves it towards the patient. 21:15:30 - CPO #1's arm not visible. CPO #1 is leaning forward or bending down. Patient not visible. SO #1 and SO #2 in doorway looking in. CPO #1 and patient go backwards (towards left side of room) together. CPO #2 comes into view with in front of patient with his arms extended, but hands not visible. RN #1 looks back towards room again, then turns and continues to walk away from room. 21:15:31 - Patient's right hand is in the doorway, holding onto the door jam. The 2 Security Officers are still in the doorway. Both CPOs face the doorway as they and the patient are going down. 21:15:32 - Patient down and out of view. CPO #1 (who was behind patient) is not visible. CPO #2 in front of patient and leaning towards floor. SO #1 and SO #2 enter room and are on the right side of the patient, with their backs towards the camera. The Security Officer closest to the patient's legs is leaning down. 21:15:35 - CPO #2 leaning down towards patient and out of view. Both Security Officers leaning towards patient, the one near the top of the	A 186		

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A 186	Continued From page 106 patient is standing and the one near the patient's legs is leaning towards patient with his (officers) legs extended to the side. 21:15:38 - CPO #1 and patient remain out of view. CPO #2 and both Security Officers are leaning towards the left, over the patient. 21:15:44 - The Two Security Officers stand, but still lean over the patient. 21:15:46 - One of the Security Officers goes around to the patient's other (left) side. 21:15:49 - CPO #1 and patient remain out of view. CPO #2 appears to be on the patient's legs. 21:15:52 - CPO #2 is up on his toes with his legs extended behind him. The top of his body is positioned towards the patient, but the view is blocked by the back of the Security Officer that is positioned on the patient's right side. 21:15:53 - Patient's right leg goes up, then down. Security Officer on right side of patient appears to hold it. 21:16:03 to 21:16:12 - The footage jumps and there is no footage available during this period of time. 21:16:12 - The Security Officer on the right side of the patient and CPO #2, now located near the patient's legs on the right side, are both leaning over the patient with their backs to the door. No one else in the room is visible. 21:16:27 - Security Officers and CPOs visible on floor, no apparent struggling at this point. 21:16:30 - RN #2 and RN #3 (a male psychiatric ED nurse) go to the doorway of the patient's room and look in. 21:16:35 - RN #2 goes into room 21:16:38 - RN #3 goes into room 21:16:42 - RN #3 leans toward patient's feet. CPO #1 now visible and near the top of and to the	A 186		

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A 186	Continued From page 107 right of the patient. A Security Officer is visible on each side of the patient. 21:16:48 - RN #1 walks to door, drops restraints on the floor in the hall near the door, and turns and walks away from room. RN #2 goes into room and goes to the left side of the room. 21:16:54 - Both Security Officers now standing and leaning over patient. CPO #1 is near the top of the patient and is leaning over patient, either on his knees or with his legs extended. 21:16:55 - RN #2 leaning over the patient, near his head and to the left of CPO #1, then standing up. 21:16:59 - 2 EMS staff and ED Tech(nician) #1 arrive and enter into room. 21:17:02 - 1 of the EMS staff goes towards the patient's head and looks down. 21:17:04 - RN #2 comes out of room. 21:17:10 - 2 EMS staff and ED Tech #1 come out of room. 21:17:22 - Licensed Practical Nurse (LPN) #1 (an ED nurse) enters room, followed by 1 EMS staff and ED Tech #1. RN #1 is standing in the doorway with restraints in her hand. 21:17:35 - Second EMS staff goes into room. 21:17:41 - A staff member inside room (unable to determine which one) is seen putting a sheet on the bed. 21:17:48 - Security Officers and other staff are standing looking towards the patient on the floor. 21:17:50 - Several staff (unable to determine who or how many) lift the patient from the floor to the bed. 21:17:52 - Patient is on bed. Staff, including SO #1, SO #2, and CPO #2, surround the patient. CPO #1 is standing in the doorway. 21:17:54 - RN #1 goes into room with restraints in hand.	A 186		

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A 186	Continued From page 108 21:17:58 - CPO #1 goes out of room and rubs his head. 21:18:30 - Physician #2 (psychiatrist) walks towards room and stops and talks to CPO #1 in the hall on the way. 21:18:37 - Physician #2 stands in patient's doorway, leans on doorway, and looks into room. (Does not go into room). 21:18:42 - RN #4 (psychiatric nurse) walks towards room and talks to CPO #1 in hall. 21:18:49 - RN #3 is standing in room and looking down. 21:18:55 - Physician #2 walks away from room. 1 EMS staff exits room. RN #3 mops floor with towel. 21:19:02 - Patient is seen laying on bed. Patient is not moving and his clothes are off (can see naked right side). 21:19:08 - RN #2 exits room and talks to Physician #2 in hall. 21:19:34 - RN #3 exits room and talks to Physician #2 in hall. Other EMS staff exits room. RN #2 goes back into room. 21:19:49 - RN #3 and CPO #1 go into room. 21:19:56 - RN #3 exits room. RN #1, RN #2, and LPN #1 are in room near the patient's head. Patient is not moving. 21:20:15 - RN #3 goes into room with BP (blood pressure) machine. 21:20:36 - Security Supervisor goes to and looks into room. 21:23:26 - Someone takes BP cuff off of patient's arm. 21:23:33 - Staff roll patient out of room on bed. He is naked with a sheet laying over his groin. Restraints are visible on his ankles (cannot see his clearly see his wrists). Patient is not moving.	A 186		

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A 186	Continued From page 109 Interview on 10/19/2011 at 1100 with Security Officer (SO) #1 revealed the officer was posted in the psychiatric area of the ED on 04/17/2011 from 4 PM to Midnight. Interview revealed when Patient #5 arrived to Room 65 "staff decided he didn't need to change (into gown) right away. That was their call....I wanded him.". Interview revealed SO #2 walked through the psychiatric area of the ED to see if SO #1 needed any assistance. Further interview revealed, "He (The patient) was calm at first. The longer he sat he got more agitated. (SO #2) decided to stay with me due to his agitation. We don't usually let patients walk in the halls (in the psychiatric area of the ED), but in this occasion I let him walk in the hall. It seemed to calm him. He went back and forth to the bathroom and his room. We kept our distance and kept an eye on him. He didn't say a lot. He had this white stuff around the outside of his mouth. We told the nurse about it because we have seen patients that have been doing spice or something (illicit substances) like that. Its just an observation we had noticed in the past. He was muttering stuff like he wanted to go home.". Interview revealed the patient became more agitated and began hitting the bed and wall. Interview revealed SO #1 called Company Police for assistance once before the end of the 0700-1900 shift and CPO #2 came to psychiatric area. Interview revealed, "They came and hung around for a little bit and then left." Interview revealed, "I think he was given a pill before (dayshift nurse) left at 7 PM. It seemed like it made him worse. He really started to hit the walls and bed. (He had) muttered talking, not making any sense. He would come out (of his room) a little bit and we'd ask him to go back and he would eventually go back. (RN #1) came on and	A 186		

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A 186	Continued From page 110 I told her about his behavior. I don't remember if she went in to see the patient. I called Company Police again and (CPO #2) came and saw the patients behavior and called (CPO #1) to come." Interview revealed at this point the patient's behavior had escalated and "it looked like he was about to act out severely". Interview revealed, "I think the nurse came and tried to speak to him. He didn't calm down. The two Company Policy Officers came into his room and told me and (SO #2) to step back. They took charge." Interview revealed at that point the two security officers went out of the patient's room and stood in the doorway. Interview revealed, "They (The CPOs) told the patient medical staff needed to take care of him, take blood or whatever. He (The patient) went at (CPO #1), swung and knocked (CPO #1) against the wall. (CPO #1) and (CPO #2) got him to the ground....I didn't see anyone grab his neck or shoulders, basically just his legs....(When the patient was on the ground) I grabbed his legs and then moved to his arm, I think on the right side. I think the Company Police Officers were on his arms and upper body. As far as I could tell they were leaning on his chest....They had their back to us, so I don't remember if I could see his (the patient's) face or neck." Further interview revealed, "We moved him to the bed. He was still struggling and urinating on himself (when on the floor and the bed). He was moving his arms and legs, trying to get up. He was muttering some stuff....They gave him some shots and tried to put restraints on because he was fighting pretty hard. Before putting restraints on him, they tried to get his clothes off and put a gown on him. I think they got a gown on him, but I'm not sure. Restraints were placed on his arms and legs by medical staff, I'm not sure who...a couple of	A 186		

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A 186	Continued From page 111 females and a male. Sometime during that point he quit moving a lot, because they had given him the shots, it usually works pretty quick. That's when the nurse noticed there seems to be something wrong, seems like he's not breathing. She told (RN #2) to go get the bag (BVM). A male nurse checked the pulse and said it was weak. They got him out of there and to the resuscitation room." Interview was requested with and declined by CPO #1. Review of hospital investigation documents revealed documentation of an interview on 05/19/2011 of CPO #1 by Root Cause Analysis team members. Review of the interview revealed CPO #1 first responded on 04/17/2011 at 2000 and talked with the patient, who appeared to be afraid, and held the patient for a shot. Review of the interview revealed at 2100 CPO #1 was called back to the psychiatric area, at which time the patient was walking out of his room. Review of the interview revealed the patient was completely different and was more agitated and asking for water. Review revealed the patient threw water and CPO #1 grabbed hold of him. Review revealed the patient grabbed the CPO's badge, and the CPO grabbed his wrist to get him to release it. Review revealed the patient grabbed the badge again and tried to push the CPO out of the room. Review revealed, "Officer (CPO #1) slipped, pulled patient on top of him with shirt. Hit head on wall. (CPO #1) thinking about rolling fingers under jaw, can't remember if he did it or not." Review revealed Security Officers held the patient's arms and legs. Review revealed, "(CPO #1) got out from under him, laid on his (the patient's) shoulder." Review revealed, when CPO #1 was asked if anything about this	A 186		

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A 186	Continued From page 112 case concerned him, he responded the patient had received only one injection, that had more medications than usual in the syringe, and nurses don't know how to apply leather restraints, officers used to apply leathers, now they don't. Review revealed, when CPO #1 was asked who has authority to place a patient in physical restraints, he responded officers not allowed, nurses don't know how. Review revealed, when CPO #1 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the interviewer as "Put arms across jaw to keep his head turned away. Patient blubbering, blowing foam and spit. Patient quit moving. Patient still breathing. Moved to stretcher. Put restraints on legs. Moved to arms and LPN noticed he wasn't breathing. Patient arched back and took one big breath. Training: soft hands - pain compliance; no marks left but cause pain; wrist lock; and nerve under jaw. hard hands - punches". Interview was requested with and declined by CPO #2. Review of hospital investigation documents revealed documentation of an interview on 05/12/2011 of CPO #2 by Root Cause Analysis team members. Review of the interview revealed CPO #2 received a call from SO #1, saying they were trying to get the patient in a gown, at around 2000 on 04/17/2011. Review revealed CPO #2 responded and stayed with the patient, SO #1, and SO #2. Review revealed after about 1 hour the patient kept asking where he was where his mother was. Review revealed CPO #2 said his sixth sense told him to stay in the room with the patient. Review revealed CPO #2 said he thought several people	A 186		

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A 186	Continued From page 113 need to stay. Review of interview revealed, "They kept telling patient to stay in room, but he kept going to the bathroom and as the hour progressed he got more and more agitated. They heard him strike the wall one time. The called (CPO #1) to ask him to come to patient's room. Patient sat on bed (not sure if voluntary or if they asked him to). Patient asked for some water, which (CPO #1) gave him and the patient 'sprinkled ' water on them. (CPO #1) told him to stop and he did. Then they had to tell him again. (CPO #1) was standing directly in front of patient. 2 security guards standing behind them in hallway. Patient put his hands on (CPO #1). States as a natural reaction to protect themselves (CPO #1) got behind him and had him by his mid-section. Both (CPO #1) and patient fell against wall and then to the floor. Then the 2 security guards joined in to help. (SO #2) had patients left arm. (SO #1) had (unable to read text). (CPO #2) in front of him. Brought patient under control through physical restraint...." Review revealed, when CPO #2 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his resporise was documented by the interviewer as "Training: No department training. As Police Officer get: hand cuff training, unarmed self-defense training (how to grab wrists and arms to gain control), painful force training, and training to de-escalate situation includes verbal, soft hands, equipment to include pepper spray and use of baton (depends on how it escalates)" Interview was requested with RN #1. Administrative staff informed surveyor RN #1 had moved and was no longer employed at the hospital. Review of hospital investigation	A 186		

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A 186	Continued From page 114 documents revealed documentation of a "Witness Statement" for RN #1 dated 04/17/2011. Review of the statement revealed the following: The patient was IVC and began making attempts to leave the facility. He began pacing, cursing, and became physically violent with staff. CPO and security staff were at bedside and intervened when the patient made attempt to leave department and began assaulting staff. While CPO and security were attempting to calm patient, he threw water on staff members and the floor. He then lunged at the CPO and had to be restrained. RN #1 left the area at that time to inform the psychiatrist of the patient's status and events. Upon returning to the area, the patient had stopped resisting CPO and security and was placed on the stretcher. Patient then began to have ineffective breathing and was taken to the resuscitation room. Interview on 10/18/2011 at 1515 with RN #2 revealed, "The patient made a move towards (CPO #2) so they called the other CPO (#1). I went to his room and he threw water towards staff....I'm not sure if his nurse was in the room. He backed up and said he was sorry and sat on his bed. I went to tell (Physician#2), but he was with another patient. I came back after I told (RN #3) what had happened. I went to the room and he was on the floor on his back...with a CPO towards the upper part of his body on his right side. Somebody had his feet....I don't know who, it was more than one person....He was struggling....I tried to tell him to calm down. I told him we'd let him up if he'd calm down and stop struggling. He was breathing and sweaty, but he was sweaty when he got there. I stepped out and was at the doorway and he stopped struggling.	A 186		

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A 186	Continued From page 115 They were in the process of getting him up on the bed. He was a heavy boy....He was making raspy sounds on the bed....They determined he wasn't breathing. The ED nurse told me to go get the bag/mask....When I got back with the bag/mask they called a code and rushed him to the resuscitation room." Interview on 10/19/2011 at 0915 with RN #3 revealed the male nurse was a psychiatric nurse that worked in the ED. Interview revealed when the nurse arrived to the patient's room on 04/17/2011 the patient was on the floor with at least 4 security officers (including security officers and CPOs). Interview revealed, "(CPO #1) was up at the head on the patient's right side helping hold him down. He was holding his chest or head....was in a position to hold the top part of the body. Another person (unsure who) was on the patient's right side holding his right leg. (CPO #2) was on the left side holding his leg or thigh. A security officer...was semi-squatting over (CPO #2)....I held his left foot. A police or security officer was at the top of the left shoulder area. I couldn't see what he was holding. I was just seeing (other staffs') backsides....I think his primary nurse was in the room...but that might have been when I went back and we got him on the stretcher." Interview revealed, "I couldn't see his face....All I am seeing is back and arms. They would basically have to be holding him on the chest. He was a big fellow and was doing some pretty good struggling to start with...I could only see him from the knees down because they pretty much had him covered up with their bodies....I stopped holding his foot when he stopped fighting and I went out of the room to get the vital signs machine....I came back in with the vital signs	A 186		

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A 186	Continued From page 116 machine and they (staff) were standing up and he didn't look like he was breathing. He had quit fighting. I think (LPN #1) said, 'Let's get him to the stretcher.'...After he was on the stretcher his breathing was very, very shallow....I don't remember his clothes coming off....One (restraint) got put on his leg....There's no point in doing that because he's not breathing right....Everybody's trying to look ahead and get him tied down in case that's what's needed. I got out of the way and they rolled him to the resuscitation room." Interview was requested with LPN #1. Administrative staff informed surveyor LPN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of an interview on 05/18/2011 of LPN #1 by Root Cause Analysis team members. Review of the interview revealed the interviewer documented the nurse's response as, "(RN #1) asked for help with restraints. When I got to the patient's room, he was still on the floor being restrained, but not longer resisting. We got him up on the stretcher, we were getting him straight and trying to get the restraints on and I didn't like his breathing. So, I repositioned his head, still didn't like his breathing. So I asked for a nasal airway. That didn't help, his respirations were decreased, agonal-like. The psych nurse brought the ambu (BVM) bag, but I was concerned about his poor respirations and I said 'We need to go' and we took him to the resuscitation room." Review revealed, when asked was there anything that caused the nurse concern about the case, the interviewer documented the nurse's response as, "I thought they were a little forceful while	A 186		

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A 186	Continued From page 117 restraining him and I didn't like them holding him near his head and neck." Interview on 10/20/2011 at 1130 with the Vice President of Nursing during video taped footage review of the physical restraint of Patient #5 on 04/17/2011 revealed there was no evidence less restrictive interventions were tried prior to the patient being physically restrained at 2115 by 2 CPOs and 2 Security Officers. 2. Closed medical record review for patient #7 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via private transportation on 06/29/2011 at 2011 with complaints of neck and back pain. Record review revealed the patient was discharged on 06/30/2011 at 1451 with diagnoses UTI (Urinary Tract Infection) and alcohol intoxication. Record review of Nurse #7's notes dated 06/30/2011 at 0848 revealed "...Pt (patient #7) found to have attempted to leave the ED. Pt escorted back to room 31...Pt stated he wanted to leave and smoke. Pt began swinging and acting out in the lobby. pt had to be taken to the floor by room 31 by security and panic alarm sounded by staff. Pt then proceeded to head butt the glass door of room 31..." Record review of physician #4 note dated 06/30/2011 at 0851 revealed "Pt got up, angry, verbally abusive and started to walk out of ED. I explained he could not leave due to ETOH (Alcohol) level. I told him not to leave or I would have to involuntarily commit him until legally sober. Pt came back in with staff escort, then tried to leave again and became combative. Pt now will be involuntarily committed until MBA (Alcohol Level) comes down."	A 186		

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A 186	Continued From page 118 Review of hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO (Company Police Officer) #4 and dated 06/30/2011 revealed "...Patient (#7) was combative, resistant and attempted to grab equipment on officers duty belt..." Review of document revealed a narrative of the incident by Security Officer #5 stating, "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone number 31 in reference to an involuntarily committed combative white male patient." Review of document revealed a narrative by CPO #4 stating, "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone room #31 in reference to an involuntarily committed white male (patient #7)...attempting to leave by fighting with Security Personnel and Medical staff. When I arrived on scene Security Officer's and Medical staff were laying on (Patient #7) in an attempt to gain control. I was informed by (Nurse #8) that (Patient #7) was involuntarily committed and may still be intoxicated. I told (Patient #7) he needed to allow medical staff to help him and that he could not leave. (Patient #7) became verbally uncooperative but got up off the floor and went into his room and sat down on his bed. (Security Officer #5) and I were standing outside the room obtaining information...when (Patient #7) jumped off his bed throwing his body and arms into the glass door of his room and sat back down on the bed. Approximately three or four minutes later (Patient #7) came out of his room and said "arrest me I want you to (expletive) arrest me." I informed (Patient #7) he was not under arrest but could not leave due to being involuntarily committed and attempted to walk him back to his room. I asked (Patient #7) to sit down and relax	A 186		

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A 186	Continued From page 119 on his bed. (Patient #7) out his finger in my face and stated '(expletive) you get out of my face and my (expletive) room'. Once again I told (Patient #7) to relax. (Patient #7) pushed my chest and said '(expletive) you make me lay the (expletive) down' and pushed me again. I attempted to gain control of (Patient #7)'s hands to keep from being pushed again when he became combative and resistant to my commands. Security Officer #5 entered the room along with Nurse #8 to assist me in gaining control of (Patient #7). (Patient #7) started thrashing and attempted to grab my handcuffs to prevent being handcuffed to the bed putting nicks and cuts on my fingers. Approximately ten to twelve minutes later I told (Patient #7) I would take him out of handcuffs if he agreed to cooperate with medical staff. (Patient #7) agreed. I took (Patient #7) out of handcuffs without further incident." Interview on 10/21/2011 at 1200 with nurse #8 revealed, "The patient was trying to leave, (Physician #4) said 'you can't leave I'm going to IVC you'...we did have to do a therapeutic hold...I think I was at the waist, he was taken to the floor and he started to fight...there were 3 or 4 people, maybe, I don't remember...he was down about 20 seconds...I'm not 100% sure if the CPO put hand cuffs on him...we helped him to stand and walked him back to his room...(Physician #4) was there and saw the patient before and after (the hold)..I don't remember (patient #7) head butting the glass..." Interview revealed "...Hand cuffs are restraints when used by duly sworn officers..." Interview on 10/21/2011 at 1300 with CPO #4 revealed "(Patient #7) was back in his room when I saw him...he was running into the glass,	A 186		

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A 186	Continued From page 120 attempting to hit, biting, spitting, cursing and threatening staff...(Nurse #8) and (Security #5) were not going to take action..." Interview revealed Nurse #8 and Security Officer #5 were in the patient's room when CPO #4 handcuffed the patient. Interview revealed "When he attempted to assault me, that was the end of it." Interview revealed CPO #4 placed a handcuff on the patient and with the other cuff secured the patient to the bed. Further medical record review for Patient #7 revealed no documentation of the use of handcuffs by CPO staff to restrain the patient. Record review revealed no documentation of least restrictive measures implemented prior to the physical restraint and handcuff restraint of the patient. 3. Closed medical record review for patient revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review revealed the patient had a history of Schizophrenia and multiple mental health hospitalizations. Record review revealed patient #2 was placed in Room 68 of the psychiatric Red Zone (a locked unit) at 0206. Record review of Nurse #5's notes dated 04/24/2011 at 0433 revealed "PT (patient) pacing about room wringing hands shouting...verbal de(e)scalation unsuccessful. MD (ED physician) and PIC (On Call Psychiatrist) notified for assistance. No orders given at this time." Record review of Nurse # 5's notes dated 04/24/2011 at 0456 revealed "...PT continues to be very agitated and begin(n)ing to self inflict. slapping slef (self)	A 186		

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A 186	Continued From page 121 over body and arms...No orders given..." Record review revealed ED physician #3 ordered "Restraints-Mechanical...Leather 4 point" on 04/24/2011 at 0501 and "Ziprasidone (medication for short term control of severe agitation) 10 mg inj (injection)" and "Lorazepam (medication used to calm and treat anxiety) 2 mg IM (intramuscular injection) " on 04/24/2011 at 0502. Record review of " Restraint/Seclusion Orders, " dated 04/24/2011 at 0511, revealed the following types of restraints were ordered by the physician: "Side Rails intended to restrict bed exit...Chemical...RUE (Right Upper Extremity) (rigid), LUE (Left Upper Extremity) (rigid), RLE (Right Lower Extremity) (rigid)..." Record review of Unit Secretary's note dated 04/24/2011 at 0524 revealed the patient was moved to bed "Blue 26 South" (outside locked Psych Unit). Record review revealed Ziprasidone and Lorazepam, chemical restraints, were administered at 0528 and 0529, respectively, by nurse #6. Record review revealed the 4 point (bilateral wrists and ankles) leather (rigid) restraints were initiated at 0529. Record review of Nurse #6's notes dated 04/24/2011 at 0551 revealed "Pt moved to room 63 from 29 on stretcher, in 4 point restraints...." Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing (throwing) his body against the doors tot he (of the) unit. With assistance of Security Guard # 3 and CPO (Company Police Officer) # 2 PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the	A 186		

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A 186	Continued From page 122 floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Record review revealed no documentation of the progression of restrictive measures from verbal descalation to therapeutic hold. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "...(Nurse #5) HEAD STRUCK WALL DURING PHYSICAL ALTERCATION (with Patient #2)..." Report review revealed a narrative stating "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient. Further review of report revealed narrative continued stating "...(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with Security Officer #3, Nurse #5, and Security Officer #4 used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was restrained and under control I placed my handcuffs onto the patient so that (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us. Medical staff arrived and administered medication...by giving him an injection in his left arm and left buttocks that would help calm him down...walked the patient back to room 66 until a stretcher arrived so that four point's restraints could be placed on the patient by medical staff...."	A 186		

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A 186	Continued From page 123 Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2. Interview with Nurse #5 on 10/19/2011 at 0950 revealed "The patient (#2) was throwing himself against the doors...to prevent harm I, security, and a CPO tried to get him to the floor. I ended up under all 3 and the patient..." Interview revealed "...There were several incidents (escalating behaviors) prior, I talked to Physician #3 about getting orders...the physician was not responding quickly (about orders)." Interview with Security Officer #3 on 10/21/2011 at 1130 revealed "I was posted in the Red Zone...When (Patient #2) was brought in he was anxious and after about an hour or hour and a half he got worse." Interview revealed Patient #2 attempted to leave the unit by running into the doors. Interview revealed Security Officer #3 grabbed the patient by the shoulder and Security Officers #4 grabbed the patient by the waist and took him to the floor. Interview revealed there were 2 CPOs in the psych unit, standing at the nurses station. Interview revealed "the CPOs came quickly...we held him (patient #2) down and they (CPO) hand cuffed the patient." Interview revealed Security Officer #3 was trained in NCI (Nonviolent Crisis Intervention) and knew how to perform a therapeutic carry. Interview revealed the Security Officers (#3, #4) did not request CPO #2 to place handcuffs on the patient. Interview revealed Security did not attempt a therapeutic carry prior to application of handcuffs. Interview revealed handcuffs were not the least restrictive measure.	A 186		

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A 194	Continued from page 124 482.13(f) PATIENT RIGHTS: RESTRAINT OR SECLUSION Restraint or Seclusion: Staff Training Requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff. This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, personnel file review, staff interview, and hospital investigation document review, the hospital failed to ensure safe implementation of restraint by trained staff for 3 of 11 sampled patients that were restrained by staff (Patients #5, #2, and #7). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm. Restraints...are used in a manner that attempts to prevent harm, physical discomfort, embarrassment, or pain to the patient....DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely....5. THERAPEUTIC HOLD - The brief physical holding of a patient in a manner that restricts his/her movement for the purpose of calming or providing physical safety to the patient, other patients, staff members or others. A therapeutic hold is used only by individuals trained in	A 194	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: A training and education program is being provided to the Emergency Department (ED) staff at the beginning of each shift for ED employees on a daily basis until further notice in order to comply with the Health Systems' policies and procedures for the behavioral health/psychiatric patients (see "attachment 2 and 2A"). The training and education consists of education on the 1) Restraint policy (see "attachment 3, 3A and 3B") which includes all types of restraints such as the therapeutic hold 2) least restrictive measures are to be utilized first on the behavioral health/psychiatric patient when needed 3) recognition of the role of the registered nurse (RN) so all members of the health care team understand the registered nurse is always in charge of the clinical care of the patient and the provision of a safe and secure environment for the patient 4) the forms that accompany the restraint policy such as the physician order form, the monitoring and flow sheet for the restrained patient 5) computer process for ordering the restraints including the therapeutic hold 6) emphasis on patient safety at all times including during any type of patient escalation the nurse never leaves the patient and the nurse is always able to complete a physical assessment of her patient	

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A 194	Continued From page 125 therapeutic hold techniques, and only when less restrictive measures have been attempted and have been determined to be ineffective. 6. FORENSIC RESTRAINTS - A locking restraint required by legal authorities when a person needs to be restrained to provide for safety or detention by legal authorities for legal reasons when that person is in custody of legal authorities or is under arrest/police hold in accordance with Federal and State laws and regulations....Forensic restraint mechanisms (...handcuffs,...)are not health care restraint interventions and are not applied by the staff of (Name of Hospital)....PROCEDURES:....2. TRAINING: Hospital staff involved in meeting the patient's needs are educated upon hire before they participate in the use of seclusion/restraint and annually thereafter. Training can be completed via didactic class or online self-study with successful completion of a post-test and competency. Hospital staff includes personnel from the following areas: Nursing,...Security,....Training Requirements Include: a. The underlying causes of threatening behavior. b. Less restrictive alternative. c. Proper and safe application/removal...of restraints. d. Monitoring patient's physical/psychological status....15. DOCUMENTATION:...Only hospital personnel, who have received training and demonstrated competency are to document information related to the use of restraints within the scope of their license...." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on	A 194	7) required nursing and physician documentation. Application of restraints and restraint training is an annual training requirement for ED staff. Information has also been shared with the ED providers by the ED Medical Director as well as the psychiatrists that work in the ED. Non-violent crisis intervention (NCI) training is an annual requirement for ED nursing staff. The nursing staff will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the nurse will not be assigned to the behavioral health/psychiatric patient. Non-violent crisis intervention (NCI) training is an annual requirement for security officers. The security officers will receive NCI training through the Training and Development Department at CFVHS to ensure a current certification. In the case of a non-current NCI certification the security officer will not be assigned to the behavioral health/psychiatric patient. The company police officers will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification. In the case of a non-current NCI certification the company police officers will not be assigned to the behavioral health/psychiatric patient. The nursing supervisors will receive NCI training through the Training and Development Department of CFVHS to ensure a current certification.	

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A 194	Continued From page 126 04/17/2011 at 1638 with a complaint of not taking his medication. Record review revealed the patient was involuntarily committed by the physician. Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/06/2011 and signed by a physician from the Medical Examiner's office revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....He was being involuntarily committed and was at the local hospital when his death occurred. He was agitated and attempting to leave his room when he was physically	A 194	Restraint training is required for ED staff that provides direct care to patients. A portion of the training includes review of the hospital policy "Restraints, Seclusions and Safety Devices" (see "attachment 3, 3A, and 3B) It is also required for the security officers and company police officers. Security officers and company police officers will receive restraint training from the Training and Development Department of CFVHS. Based on the hospital procedure it is mandatory for ED nurses to have a current certification in NCI as well as annual restraint training. It is also mandatory for security officers to have a current certification in NCI as well as restraint training. Company police officers will receive NCI training and restraint training. If there is an ED nurse, security officer, or company police officer that is not current in NCI certification or restraint training this person is to be reassigned as to prevent them from being assigned to a psychiatric patient or in the case of security officers or company policy officers not assigned to the ED locations until NCI certification and restraint training is completed. This training and education is to ensure the provision of safe and appropriate care for our patients by providing the least restrictive measures prior to any type of restraint. When restraint is necessary the ED nursing staff, security officers and company police officers have the knowledge for following correct policy and procedure.	

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A 194	Continued From page 127 restrained by multiple individuals. Video of the events show one person placing an arm around his neck prior to him being taken to the ground. The neck restraint appears to be maintained as several other individuals restrain his body. His respiratory function would have been further compromised if overlay occurred on the chest and/or abdomen. The decedent appears unresponsive immediately following the restraint. Significant findings at autopsy include small, multifocal and thin subarachnoid hemorrhages, hemorrhages in the tongue and laryngeal mucosa and chronic active hepatitis of unknown etiology. Toxicology studies are positive for therapeutic concentrations of Risperidone (Risperdol) in aorta blood. Benzodiazepines, cocaine, ethanol, opiates, organic bases, ziprasidone and haloperidol are not detected. Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the cameral angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed the patient was physically restrained from 21:15:26 (when CPOs begin to hold the patient by his arms and then go to the floor with the patient	A 194	**Monitoring:** The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff. **Responsibility:** Vice President of Nursing	11/07/2011

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A 194	Continued From page 128 at 21:15:30) until 21:17:50 (when staff lift the patient off of the floor and place him on a stretcher). Video footage review revealed several staff were involved in the physical restraint of the patient, including CPO #1 and CPO #2. Further video footage review revealed RN #1 walked away from the patient's room and did not stay to monitor the patient and supervise the situation when CPO and Security staff placed the patient in a physical restraint. Personnel file review for CPO #1 revealed no documentation the CPO had completed NCI (Nonviolent Crisis Intervention: training program that teaches deescalation and therapeutic patient hold techniques). File review revealed no documentation the CPO had received hospital based restraint training. Interview was requested with and declined by CPO #1. Review of hospital investigation documents revealed documentation of an interview on 05/19/2011 of CPO #1 by Root Cause Analysis team members. Review revealed, when CPO #1 was asked who has authority to place a patient in physical restraints, he responded officers not allowed, nurses don't know how. Review revealed, when CPO #1 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the interviewer as "Put arms across jaw to keep his head turned away. Patient blubbering, blowing foam and spit. Patient quit moving. Patient still breathing. Moved to stretcher. Put restraints on legs. Moved to arms and LPN noticed he wasn't breathing. Patient arched back and took one big breath. Training: soft hands - pain compliance;	A 194		

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A 194	Continued From page 129 no marks left but cause pain; wrist lock; and nerve under jaw. hard hands - punches". Personnel file review for CPO #2 revealed no documentation the CPO had completed NCI. File review revealed no documentation the CPO had received hospital based restraint training. Interview was requested with and declined by CPO #2. Review of hospital investigation documents revealed documentation of an interview on 05/12/2011 of CPO #2 by Root Cause Analysis team members. Review revealed, when CPO #2 was asked what he does when a patient starts to escalate and how he was trained in de-escalating patients, his response was documented by the interviewer as "Training: No department training. As Police Officer get: hand cuff training, unarmed self-defense training (how to grab wrists and arms to gain control), painful force training, and training to de-escalate situation includes verbal, soft hands, equipment to include pepper spray and use of baton (depends on how it escalates)". Review revealed, when CPO #2 was asked who has authority to place a patient in physical restraints, he responded that he now knew, based on an e-mail that recently came out, that medical staff (nurses and physicians) can place leather restraints. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients,	A 194		

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A 194	Continued From page 130 including verbal de-escalation techniques. Interview revealed CIT training did not include training for therapeutic patient holds. Interview revealed CPO #1 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training. Interview revealed when CPO staff is hired, a supervisor or experienced field training officer goes through the orientation checklist and verbally addresses each item with the officer. Interview revealed the supervisor or training officer typically informs the CPO when they assist with a patient's restraint, they don't apply the restraints, but rather hospital staff does. Interview revealed CPO staff are instructed to hold the patient's limb and help at the direction of staff. Personnel file review for RN #1 revealed the staff member was hired on 12/04/2000 and became a registered nurse during 2005 and remained employed at the hospital. File review revealed the nurse worked in the ED until 05/21/2011, at which time she moved and terminated employment. File review revealed no documentation the nurse received NCI training during her employment at the hospital. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI (Nonviolent Crisis Intervention training) is required for all permanent ED staff within a year	A 194		

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A 194	Continued From page 131 of hire. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #1 received NCI training during her employment at the hospital. 2. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing (throwing) his body against the doors tot he (of the) unit. With assistance of Security Guard # 3 and CPO (Company Police Officer) # 2 PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient. Further	A 194		

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A 194	Continued From page 132 review of report revealed narrative continued stating "...(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with Security Officer #3, Nurse #5, and Security Officer #4 used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was restrained and under control I placed my handcuffs onto the patient so that (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us..." Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2. Personnel file review for RN #5 revealed the staff was a contracted agency nurse that began work as a psychiatric nurse in the ED on 02/07/2011. File review revealed the nurse's contract expires on 11/26/2011. File review revealed no documentation the nurse received NCI (Nonviolent Crisis Intervention) training skill training during his employment at the hospital Interview on 10/19/2011 at 0950 with RN #5 revealed the nurse had not received NCI training or other nonphysical intervention skill training in many years. Interview revealed the nurse was aware NCI training was offered at the hospital, but he had not been required to take it. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview	A 194		

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A 194	Continued From page 133 revealed, "They come in with stated experience and competency in all ED and critical care areas. That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation techniques, NCI, or therapeutic holds. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #5 received NCI training during his employment at the hospital. Personnel file review for CPO #2 revealed the CPO was hired on 02/15/2011 by the security company contracted by the hospital and provided police services at the hospital until 09/29/2011, at which time he was reassigned elsewhere by the security company. File review revealed no documentation the CPO had completed NCI. File review revealed no documentation the CPO had received hospital based restraint training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) training in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CIT training did not include training for therapeutic patient holds. Interview revealed CPO #2 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that	A 194		

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A 194	Continued From page 134 (therapeutic patient holds) for Company Police Officers. They use law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training. Interview revealed when CPO staff is hired, a supervisor or experienced field training officer goes through the orientation checklist and verbally addresses each item with the officer. Interview revealed the supervisor or training officer typically informs the CPO when they assist with a patient's restraint, they don't apply the restraints, but rather hospital staff does. Interview revealed CPO staff are instructed to hold the patient's limb and help at the direction of staff. 3. Closed medical record review for patient #7 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) on 06/29/2011 at 2011 with complaints of neck and back pain. Record review revealed the patient was discharged on 06/30/2011 at 1451 with diagnoses UTI (Urinary Tract Infection) and alcohol intoxication. Record review of Nurse #7 notes dated 06/30/2011 at 0848 revealed "...Pt (patient #7) found to have attempted to leave the ED. Pt escorted back to room 31...Pt stated he wanted to leave and smoke. Pt began swinging and acting out in the lobby. pt had to be taken to the floor by room 31 by security and panic alarm sounded by staff. Pt then proceeded to head butt the glass door of room 31..." Record review revealed no documentation of how the patient was "taken to the floor" or who participated in the taking the patient to the floor. Review of hospital's Security Company's document titled "INCIDENT/INVESTIGATION	A 194		

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A 194	Continued From page 135 REPORT" dated 06/30/2011 revealed a narrative by CPO #4 stating, "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone room #31 in reference to an involuntarily committed white male (patient #7)...attempting to leave by fighting with Security Personnel and Medical staff. When I arrived on scene Security Officer's and Medical staff were laying on (Patient #7) in an attempt to gain control...(Patient #7) became verbally uncooperative but got up off the floor and went into his room and sat down on his bed. (Security Officer #5) and I were standing outside the room obtaining information...when (Patient #7) jumped off his bed throwing his body and arms into the glass door of his room and sat back down on the bed. Approximately three or four minutes later (Patient #7) came out of his room and said "arrest me I want you to (expletive) arrest me." I informed (Patient #7) he was not under arrest but could not leave due to being involuntarily committed and attempted to walk him back to his room. I asked (Patient #7) to sit down and relax on his bed. (Patient #7) out his finger in my face and stated "(expletive) you get out of my face and my (expletive) room". Once again I told (Patient #7) to relax. (Patient #7) pushed my chest and said "(expletive) you make me lay the (expletive) down and pushed me again. I attempted to gain control of (Patient #7)'s hands to keep from being pushed again when he became combative and resistant to my commands. Security Officer #5 entered the room along with Nurse #8 to assist me in gaining control of (Patient #7). (Patient #7) started thrashing and attempted to grab my handcuffs to prevent being handcuffed to the bed putting nicks and cuts on my fingers. Approximately ten to twelve minutes later I told (Patient #7) I would	A 194		

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A 194	Continued From page 136 take him out of handcuffs if he agreed to cooperate with medical staff. (Patient #7) agreed. I took (Patient #7) out of handcuffs without further incident." Interview on 10/21/2011 at 1300 with CPO #4 revealed "(Patient #7) was back in his room when I saw him...he was running into the glass, attempting to hit, biting, spitting, cursing and threatening staff...(Nurse #8) and (Security #5) were not going to take action..." Interview revealed Nurse #8 and Security Officer #5 were in the patient's room when CPO #4 handcuffed the patient. Interview revealed "When he attempted to assault me, that was the end of it." Interview revealed CPO #4 placed a handcuff on the patient and with the other cuff secured the patient to the bed. Personnel file review for CPO #4 revealed the CPO was hired on 10/19/2010 by the security company contracted by the hospital and provided police services at the hospital through the present time. File review revealed the CPO attended CIT class on 03/04/2011. File review revealed no documentation the CPO had completed NCI. File review revealed no documentation the CPO had received hospital based restraint training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) training in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CIT training did	A 194		

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A 194	Continued From page 137 not include training for therapeutic patient holds. Further interview revealed CPO staff were not required to and did not receive NCI training. Interview revealed, "Unless they've attended classes in addition to police training, there isn't any specific training for that (therapeutic patient holds) for Company Police Officers. They use law enforcement training for physical holds." Further interview revealed CPO staff do not receive hospital restraint training. Interview revealed when CPO staff is hired, a supervisor or experienced field training officer goes through the orientation checklist and verbally addresses each item with the officer. Interview revealed the supervisor or training officer typically informs the CPO when they assist with a patient's restraint, they don't apply the restraints, but rather hospital staff does. Interview revealed CPO staff are instructed to hold the patient's limb and help at the direction of staff.	A 194		
A200	482.13(f)(2)(ii) PATIENT RIGHTS: RESTRAINT OR SECLUSION [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (ii) The use of nonphysical intervention skills. This STANDARD is not met as evidenced by: Based on policy review, personnel file review, and staff interview, the hospital failed to ensure Emergency Department and Contracted Security staff were trained in the use of nonphysical intervention skills for 5 of 16 sampled Emergency Department and Contracted Security staff (Company Police Officer [CPO] #1, CPO #2,	A200		

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A 200	Continued From page 138 Registered Nurse [RN] #1, RN #5, and RN #6). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "PROCEDURES:....2. TRAINING: Hospital staff involved in meeting the patient's needs are educated upon hire before they participate in the use of seclusion/restraint and annually thereafter. Training can be completed via didactic class or online self-study with successful completion of a post-test and competency. Hospital staff includes personnel from the following areas: Nursing;...Security,....Training Requirements include: a. The underlying causes of threatening behavior. b. Less restrictive alternative. c. Proper and safe application/removal...of restraints. d. Monitoring patient's physical/psychological status....4. Less Restrictive Alternatives: Attempts are made to evaluate and/or consider interventions/alternatives such as:...b. Environmental Measures: i. Decrease stimulation; quiet surroundings....c. Comfort Measures:....iv. Gentle touch, soothing voice....f. Diversional Activities: i. Distract patient with videos, TV, photographs, radio, reading materials, engage in conversation....iii. Provide alternative activity for hands, i.e. rubber ball, squeezing devices, etc....h. Interpersonal Skills: i. Pleasant, consistent interaction with patient....ii. Actively listen to patient, calm reassurance....i, Communication/Interpersonal Relationships....iv. Respect a patient's need for personal space...." 1. Personnel file review for CPO #1 revealed the	A 200	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** Based on the hospital procedure it is mandatory for ED nurses to have a current certification in NCI as well as annual restraint training. It is also mandatory for security officers to have a current certification in NCI as well as restraint training. Company police officers will receive NCI training and restraint training. If there is an ED nurse, security officer, or company police officer that is not current in NCI certification or restraint training this person is to be reassigned as to prevent them from being assigned to a psychiatric patient or in the case of security officers or company policy officers not assigned to the ED locations until NCI certification and restraint training is completed. This training and education is to ensure the provision of safe and appropriate care for our patients by providing the least restrictive measures prior to any type of restraint. When restraint is necessary the ED nursing staff, security officers and company police officers have the knowledge for following correct policy and procedure. **Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource	11/07/2011

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A 200	Continued From page 139 CPO was hired on 01/30/2007 by the security company contracted by the hospital and provided police services at the hospital until 09/29/2011, at which time he was reassigned elsewhere by the security company. File review revealed no documentation the CPO had completed NCI or other nonphysical intervention skill training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques. Interview revealed CPO #1 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. 2. Personnel file review for CPO #2 revealed the CPO was hired on 02/15/2011 by the security company contracted by the hospital and provided police services at the hospital until 09/29/2011, at which time he was reassigned elsewhere by the security company. File review revealed no documentation the CPO had completed NCI or other nonphysical intervention skill training. Interview on 10/18/2011 at 1330 with the Company Police Captain/Supervisor revealed the CPO staff began receiving Crisis Intervention Training (CIT) in the spring of 2011. Interview revealed the purpose of CIT training was to help CPO staff identify mental illnesses and train them in how to respond to mentally ill patients, including verbal de-escalation techniques.	A 200	nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	

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A 200	Continued From page 140 Interview revealed CPO #2 had not yet attended CIT class. Further interview revealed CPO staff were not required to and did not receive NCI training. 3. Personnel file review for RN #1 revealed the staff member was hired on 12/04/2000, became a registered nurse during 2005, and remained employed at the hospital. File review revealed the nurse worked in the ED until 05/21/2011, at which time she moved and terminated employment. File review revealed no documentation the nurse received NCI training or other nonphysical intervention skill training during her employment at the hospital. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #1 received NCI or other nonphysical intervention skill training during her employment at the hospital. 4. Personnel file review for RN #5 revealed the staff was a contracted agency nurse that began work as a psychiatric nurse in the ED on 02/07/2011. File review revealed the nurse's contract expires on 11/26/2011. File review revealed no documentation the nurse received NCI training or other nonphysical intervention skill training during his employment at the hospital. Interview on 10/19/2011 at 0950 with RN #5 revealed the nurse had not received NCI training	A 200		

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A 200	Continued From page 141 or other nonphysical intervention skill training in many years. Interview revealed the nurse was aware NCI training was offered at the hospital, but he had not been required to take it. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview revealed, "They come in with stated experience and competency in all ED and critical care areas. That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation techniques, NCI, or therapeutic holds. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #5 received NCI or other nonphysical intervention skill training during his employment at the hospital. 5. Personnel file review for RN #6 revealed the staff was a contracted agency nurse that began work in the ED in 11/2010. File review revealed nurse is currently working in the ED. File review revealed no documentation the nurse received NCI training or other nonphysical intervention skill training during his employment at the hospital. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI is required for all permanent ED staff within a year of hire. Interview revealed NCI training was not mandatory for agency nursing staff. Interview revealed, "They come in with stated experience and competency in all ED and critical care areas.	A 200		

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A 200	Continued From page 142 That's considered their competencies." Further interview revealed the agency checklist of competencies did not include de-escalation techniques, NCI, or therapeutic holds.	A 200	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: With the appropriate order entry in the computer for restraints, a daily restraint log is available. The restraint log is provided on a daily basis to the Nursing Supervisors, Nurse Managers, members of Nursing Performance Improvement and ED leadership. This assists the resource nurse/supervisor in the ED to be knowledgeable at all times as to which patients are in restraints. The ED nursing staff have been instructed to notify the resource nurse/supervisor in the ED upon a physician order for any type of restraint. The resource nurse/supervisor is to respond to the patient with the order for restraints immediately or as soon as possible in case of other patient type emergencies. The resource nurse/supervisor in the ED is to review the patient to ensure the patient is receiving safe care as well as ensuring the least alternative means of restraint are being used first; physician orders, nursing documentation, and safety attendants (sitters) are assigned per policy. The concurrent quality assessment and performance improvement program consists of an audit check list for restraint monitoring that is completed by the resource nurse/supervisor for each shift to ensure policies and procedures are followed. They are submitted to the Director of the ED for review. Currently the Nursing Performance Improvement nurses have been assigned to check the restraints on a daily basis to assist with compliance. The house Nursing Supervisors also have the restraint log and they have been asked to check patients with restraints as well. There will be a monthly report available for review as well including the compliance with monitoring and documentation. The monthly report on restraint utilization and performance improvement monitoring is presented at the monthly nursing quality meeting known as the "Nursing Oversight Committee". This information is reported at least quarterly to the Patient Safety Committee.	
A263	482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on policy review, restraint log review, staff interview, adverse event report review, and hospital investigative document review, the hospital failed to implement and maintain an effective quality assessment and performance improvement program to ensure the safety of patients. The findings include: 1. The hospital failed to have a system in place to evaluate and analyze the use of physical restraints in the Emergency Department.	A263		

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A 263	Continued From page 143 ~cross refer to 482.21(a)(2) QAPI Standard: Tag A0267 2. The hospital failed to analyze reported incidents of patient restraint by Company Police Officers (CPO) to ensure safe and appropriate patient restraints for 2 of 3 sampled reported incidents of patient restraint by CPO. ~cross refer to 482.21(c)(2) QAPI Standard: Tag A0287 3. The hospital failed to implement actions to improve the safety of patients placed in physical restraints after the hospital's analysis of an incident of patient harm during physical restraint identified areas of needed improvement for 1 of 1 sampled incidents of patient harm during physical restraint. ~cross refer to 482.21(c)(2) QAPI Standard: Tag A0288	A 263	**Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	11/07/2011

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A.263	Continued from page 143A	A 263	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: Performance Improvement (PI) implemented a new process for review of all Quality Care Control Reports (QCCs), Security Reports and Company Police Reports. This process is outlined in the policy entitled "PI Review of Event Reports" (see "attachment 5"). All Quality Care Control Reports (QCCs), Security Reports and Company Police Reports will be reviewed by a Performance Improvement/Patient Safety Coordinator daily. Friday, Saturday and Sunday reports will be reviewed on Monday. A Patient Safety Response Team (PSRT) (see "attachment 6") is activated prior to Monday if the event warrants. For all other occurrences PI will perform an initial screening/analysis considering severity and frequency of the occurrence. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) algorithm (see "attachment 7") will be the tool used to assign a severity score to all occurrences. PI will identify whether immediate investigation, Event Response Team (ERT) activation, or further review and analysis is warranted. Please see Sentinel Events and Root Cause Analysis policy (see "attachment 8") for composition of the ERT. The ERT will determine whether the occurrence is a sentinel event or serious near miss/close call and whether an RCA should be conducted. If further review and analysis by the involved department is warranted the staff conducting the analysis may be requested to document on a PSRT Form (see "attachment 9"). PI and Risk Management (RM) will also track these reports and identify trends.	

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A 263	Continued from page 143B	A 263	Individual PSRTs, ERT activations, Root Cause Analyses (RCA), Failure Mode Effects Analyses (FMEA) and system issues, as well as trending of incidents over time are reported to the Harm Events Analysis Team (HEAT). Individual events that are resolved during an ERT are documented on the ERT form, are attached to the QCC and saved for future potential trending. HEAT provides periodic reports to the Quality Council, Patient Safety Committee, the Medical Executive Committee and the Board Quality and Patient Safety Committee. Identified trends will be considered for further statistical analysis or FMEA. **Monitoring:** The monitoring system will involve a second review by another PI/Patient Safety coordinator. A weekly random sample review of 2 of each type of report will be conducted. The initial assignment of error will be blinded to the second reviewer in order to establish inter-rater reliability. Results of this review will be discussed in PI department meetings and reported to the HEAT. **Responsibility:** Chief Medical Officer **The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** A Root Cause Analysis (RCA) Team was pulled together immediately after the incident. In reviewing the incident, the RCA team issued five (5) key recommendations in June 2011: (1) the Director of the ED, Service Line Director of Psychiatry, and the Director of Security will form an integrated team to function solely in the Red Zone-Psych ED. This team will consist of physicians, nursing, mental health specialists, security and a Licensed Clinical Social Worker who have clearly defined roles and responsibilities to deliver safe/quality psychiatric care;	11/07/2011

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A 263	Continued from page 143C	A 263	(2) the ED Director and the Manager of Supplemental Staffing are to ensure that all ED personnel receive initial and annual re-certification of NCI to be demonstrated by the collaboration of Training and Development documentation with Staff position control sheets; (3) the Vice President of Post Acute Care, the Director of Security, and the Director of Risk Management will evaluate as to whether the health system wants law enforcement techniques used on patients and present any recommendations back to the HEAT Team; (4) the Vice President of Post Acute Care, Vice President of Patient Safety and Quality and the Vice President of Nursing will develop a plan for a Code White team to be instituted and utilized in all facilities in the health system. This will be demonstrated by the formation of a clear plan and resources dedicated to the plan; and (5) re-examination of this RCA will be completed by the HEAT team once the patient's autopsy report is received and examined regarding cause of death, and provide further recommendations as warranted. The results of this re-examination and any recommendations made from said re-examination will be reflected in the HEAT team meeting minutes. Since the RCA Team issued its recommendations, the health system has made substantial progress towards 4 of its 5 recommendations during the months of June, July, August, September, and October 2011. Specifically, (1) The Director of the ED, Service line Director of Psychiatry, and the Director of Security reviewed the staffing model in place at the time of the event. The decision was made to formalize an integrated team approach to function solely in the Red Zone-Psych ED. Specifically, the following changes were commenced based on the recommendations:	

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A 263	Continued from page 143D	A 263	a. Two licensed social workers were hired. One was employed in August 2011, but the other hire rescinded her acceptance one week prior to start. These positions have been found to be very difficult to recruit, and b. Plans for the ED psychiatric zone model will be updated in such a way that (i) the psychiatric nurse will take a holistic approach to patient care, (ii) the ED staff nurse will not be scheduled to provide direct patient care in the psychiatric zone in the ED but will always be available as a resource when help is needed, and (iii) the security officers and/or company police officers, sitters, physicians (including the psychiatrist) will continue to be a part of the team along with the psychiatric nurse; (2) The ED Director and the Manager of Supplemental Staffing have taken steps to ensure that ED staff receive and maintain appropriate NCI training. Currently, there are only 5 registered nurses in the ED (out of 92 total) that have not received NCI training. Of these 5, 3 nurses were hired within the last year, 1 nurse transferred from another nursing unit within the last year, and 1 failed to attend class. All 5 registered nurses have been scheduled for training. We are moving forward with the non-nursing staff to be trained as well. 3 non-nurses in the ED have attended the NCI training. Due to the large number of non-nurse staff in the ED (approximately 50 total), the decision was made to not mandate the training for the entire non-nursing staff. The health system will require that Allied Barton ensure that all of its staff assigned to the ED have current NCI training on file;	

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A 263	Continued from page 143E	A 263	(3) The Vice President of Post Acute Care, the Director of Security, and the Director of Risk Management evaluated law enforcement techniques and patient care. The "restraints, seclusion, and safety devices" policy does address therapeutic holds as well as Forensic restraints. Employees as well as contract employees are to follow the hospital policy. The ED nursing staff, the psychiatric staff that work in the psychiatric zone and the Allied Barton security and company police officers will all be re-educated on this policy. The necessary documentation required for any type of hold or restraint is to be re-educated to the staff as well; and (4) Currently, there is already a code white used as a call code for the health system that defines staff assistance needed. It is provided to all employees of the health system upon hire as a badge attachment. The intent is to provide staff assistance immediately where needed. A specific code white team has been discussed, but the decision was made that the current "code white" call code met the health system's needs. As to the fifth recommendation, the autopsy report was received on September 7, 2011. Please note that at no time during the RCA review was it thought there was any intentional harm inflicted by the health system on any patient. The RCA Team was updated regarding receipt of the autopsy, and the HEAT Team is scheduled to be updated on November 7, 2011. Based on the limited time since receipt of the autopsy, local law enforcement inquiry, litigation, and now agency inquiry, the health system administration is taking the lead in finalizing the RCA Team's recommendations. All essential RCA recommendations have been or will be implemented prior to November 7, 2011, and all essential follow-up for purposes of the Conditions of Participation identified during the recent survey have been or will be completed by that date as detailed throughout our response. (see "attachment 11")	

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A 263	Continued from page 143F	A 263	Monitoring: The Harm Events Analysis Team (HEAT) has oversight of RCA's. The PI Department maintains a score card of the RCA's. The recommended implementation dates will be discussed in detail at the HEAT meetings in order to hold the executive sponsor accountable for RCA completion. Responsibility: Chief Medical Officer	11/07/2011
A267	482.21(a)(2) QAPI QUALITY INDICATORS The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations. This STANDARD is not met as evidenced by: Based on policy review, restraint log review, and staff interview, the hospital failed to have a system in place to evaluate and analyze the use of physical restraints in the Emergency Department. The findings include:	A267	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: With the appropriate order entry in the computer for restraints, a daily restraint log is available. The therapeutic hold restraint will be entered in the computer and will appear on the restraint log. The ED staff has been trained to enter the therapeutic hold as any other type of restraint to ensure the quality assessment is being completed. The restraint log is provided on a daily basis to the Nursing Supervisors, Nurse Managers, members of Nursing Performance Improvement and ED leadership. This assists the resource nurse/supervisor in the ED to be knowledgeable at all times as to which patients are in restraints. The ED nursing staff have been instructed to notify the resource nurse/supervisor in the ED upon a physician order for any type of restraint. The resource nurse/supervisor is to respond to the patient with the order for restraints immediately or as soon as possible in case of other patient type emergencies. The resource nurse/supervisor in the ED is to review the patient to ensure the patient is receiving safe care as well as ensuring the least alternative means of restraint are being used first; physician orders, nursing documentation, and safety attendants (sitters) are assigned per policy. The concurrent quality assessment and performance	

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A 267	Continued From page 144 Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "...DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device,...that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely:...PROCEDURES:....21. PERFORMANCE IMPROVEMENT: A Central Log of all patients in restraints is kept by Nursing Performance Improvement. (Name of Hospital) collects data on the use of seclusion and restraint in order to monitor and improve it's performance and process and to understand the root cause of seclusion or restraint, identify trends, evaluate and create alternatives to seclusion or restraint...." Review on 10/17/2011 of hospital Restraint Logs from April 2011 to October 2011 revealed no documentation of patients that were physically restrained by staff in the Emergency Department (ED). Interview on 10/19/2011 at 1050 with a Nursing PI (Performance Improvement) Coordinator revealed the Coordinator performs monitoring of the restraint process. Interview revealed when restraint orders are entered into the computer a copy of the order prints on the Coordinator's printer to alert PI staff to the restraint. Interview revealed, "We get a report every 12 hours of all of the restraints that have been ordered. It goes to all resource nurses on each unit, so they can monitor their restraints (concurrent review process)." Interview revealed in addition to the concurrent review, PI does a retrospective review of 5 restraint episodes per unit per month.	A 267	improvement program consists of an audit check list for restraint monitoring that is completed by the resource nurse/supervisor for each shift to ensure policies and procedures are followed. They are submitted to the Director of the ED for review. Currently the Nursing Performance Improvement nurses have been assigned to check the restraints on a daily basis to assist with compliance. The house Nursing Supervisors also have the restraint log and they have been asked to check patients with restraints as well. There will be a monthly restraint report available for review as well including the compliance with monitoring and documentation completed by the nursing performance personnel that includes the ED restraints as well as Inpatient. The monthly report on restraint utilization and performance improvement monitoring is presented at the monthly nursing quality meeting known as the "Nursing Oversight Committee". This information is reported at least quarterly to the Patient Safety Committee. **Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on	11/07/2011

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A 267	Continued From page 145 Interview revealed data from that review is aggregated in a spread sheet and sent to managers and service line directors, who review the information each month. Interview revealed, "We review documentation and utilization (of restraints), the number and area of restraints. We trend to look for an increase or decrease." Interview revealed PI uses the information obtained to look for opportunities for improvement and develops performance improvement plans as necessary. Further interview revealed if an order was not entered into the computer the restraint episode would not show up on the Restraint Log and PI would not review it. Interview revealed, "BHC (Behavioral Health Care) is where I see most of the therapeutic hold (physical restraint) orders. I don't see orders for therapeutic holds in the ED. None of the therapeutic holds are reported to me as restraints, so they are not reviewed as restraints. I do not review therapeutic holds in the ED. If an order was put in then I would review it."	A 267	restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. Responsibility: Vice President of Nursing	
A287	482.21(c)(2) QAPI IMPROVEMENT ACTIVITIES [Performance improvement activities must track medical errors and adverse patient events,] and analyze their causes, and ... This STANDARD is not met as evidenced by: Based on policy review, adverse event report review, hospital investigative document review, and staff interview, the hospital failed to analyze reported incidents of patient restraint by Company Police Officers (CPO) to ensure safe and appropriate patient restraints for 2 of 3 sampled reported incidents of patient restraint by CPO (Patients #2 and #7).	A287	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: Performance Improvement (PI) implemented a new process for review of all Quality Care Control Reports (QCCs), Security Reports and Company Police Reports. This process is outlined in the policy entitled "PI Review of Event Reports" (see "attachment 5"). All Quality Care Control Reports (QCCs), Security Reports and Company Police Reports will be reviewed by a Performance Improvement/Patient Safety Coordinator daily. Friday, Saturday and Sunday reports will be reviewed on Monday. A Patient Safety Response Team (PSRT) (see "attachment 6") is activated prior to Monday if the event warrants. For all other	

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A 287	Continued From page 146 The findings include: Review of hospital policy entitled "Quality Care Control Report (QCC)" dated 04/25/2011 revealed, "...10. Follow-up process for online reporting: a. A report is generated daily in Corporate Risk Management. b. A member of the Corporate Risk Management support staff then sends individual reports via e-mail to the Manager of the location listed. The e-mail indicates if a written response is due based. on the incident type reported....c. If requested, the Manager responds to the Corporate Risk Manager with the follow-up via e-mail....d. Corporate Risk Management support staff enters the response...and closes the report. e. Additional inquiry or investigation of the patient event may be taken by or at the direction of (Hospital) Director of Corporate Risk Management or designee...in accordance with the Director's responsibility to the Patient Safety Performance Improvement Team..." 1. Review on 10/17/2011 of a hospital's adverse event report (QCC), dated 04/24/2011, involving Patient #2 revealed on 04/24/2011 at 0500 Nurse #5 sustained a "minor injury" as a result of a "fall-hallway". Report revealed the incident occurred during a "Therapeutic Hold". Report further revealed, "...Nurse acquired minor injuries while trying therapeutic holds on aggressive patient which quickly escalated. Multiple reports to physician for early intervention produced no orders for chemical or physical restraints. Provider reporting completed through medical review. ED nursing administration currently working with provider staff to create new policy and procedure concerning agitated and	A 287	occurrences PI will perform an initial screening/analysis considering severity and frequency of the occurrence. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) algorithm (see "attachment 7") will be the tool used to assign a severity score to all occurrences. PI will identify whether immediate investigation, Event Response Team (ERT) activation, or further review and analysis is warranted. Please see Sentinel Events and Root Cause Analysis policy (see "attachment 8") for composition of the ERT. The ERT will determine whether the occurrence is a sentinel event or serious near miss/close call and whether an RCA should be conducted. If further review and analysis by the involved department is warranted the staff conducting the analysis may be requested to document on a PSRT Form (see "attachment 9"). PI and Risk Management (RM) will also track these reports and identify trends. Individual PSRTs, ERT activations, Root Cause Analyses (RCA), Failure Mode Effects Analyses (FMEA) and system issues, as well as trending of incidents over time are reported to the Harm Events Analysis Team (HEAT). Individual events that are resolved during an ERT are documented on the ERT form, are attached to the QCC and saved for future potential trending. HEAT provides periodic reports to the Quality Council, Patient Safety Committee, the Medical Executive Committee and the Board Quality and Patient Safety Committee. Identified trends will be considered for further statistical analysis or FMEA.	

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A 287	Continued From page 147 destructive patients to prevent further incidents." Review on 10/21/2011 of a second QCC report, dated 04/24/2011 and reported by Security Officer #3, revealed "Type: Patient Assistance Provided by Security...Comments: At about 0450 (Patient #2) started yelling and coming out of his room the nurse (Nurse #5) and myself attempted to put him back in his room he hit the door, and CPOs (Company Police Officers) and (CPO #2) responded and handcuffed the patient....Attending Physician (#3) stated to put the pt., in leather restraints at 0515 verbally, he requested that the medication be given to the pt., while he was on the floor before he was put in restraints, pt was assessed by staff, and at 0517 taken to bluezone 29 still in restraints." Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "...(Nurse #5) HEAD STRUCK WALL DURING PHYSICAL ALTERCATION (with Patient #2)..." Report review revealed a narrative stating "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient....(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with Security Officer #3, Nurse #5, and Security Officer #4 used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was restrained and under control I placed my handcuffs onto the patient so that	A 287	Monitoring: The monitoring system will involve a second review by another PI/Patient Safety coordinator. A weekly random sample review of 2 of each type of report will be conducted. The initial assignment of error will be blinded to the second reviewer in order to establish inter-rater reliability. Results of this review will be discussed in PI department meetings and reported to the HEAT. Responsibility: Chief Medical Officer	11/07/2011

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A 287	Continued From page 148 (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us. Medical staff arrived and administered medication...by giving him an injection in his left arm and left buttocks that would help calm him down...walked the patient back to room 66 until a stretcher arrived so that four point's restraints could be placed on the patient by medical staff... (Patient #2)'s vitals and heart rate were monitored after the incident by medical staff...(Patient #2) had an elevated heart rate and was moved out of the Psych area into treatment room 29 so that he could be monitored more closely. (Nurse #5) fell against the wall striking his head during the physical altercation." Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2. Interview on 10/19/2011 at 1200 with Nursing Administration revealed "(Physician #4) stated there is too much variation with psych patients to have any standard protocols or orders for these patients." Interview revealed as of survey date there were no new policies and procedures concerning agitated and destructive patients implemented in the ED. Interview on 10/21/2011 at 1330 with Performance Improvement (PI) staff revealed the QCC report and Security Investigation reports regarding the incident of Patient #2 being handcuffed by CPO staff were sent to Risk Management. Interview revealed Risk Management did not send either report to Performance Improvement, and thus a quality/PI	A 287		

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A 287	Continued From page 149 review was not completed. 2. Review of hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #4 and dated 06/30/2011 revealed "...Patient (#7) was combative, resistant and attempted to grab equipment on officers duty belt...." Review of document revealed a narrative by CPO #4 stating, "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone room #31 in reference to an involuntarily committed white male (patient #7)...attempting to leave by fighting with Security Personnel and Medical staff. When I arrived on scene Security Officer's and Medical staff were laying on (Patient #7) in an attempt to gain control. I was informed by (Nurse #8) that (Patient #7) was involuntarily committed and may still be intoxicated. I told (Patient #7) he needed to allow medical staff to help him and that he could not leave. (Patient #7) became verbally uncooperative but got up off the floor and went into his room and sat down on his bed. (Security Officer #5) and I were standing outside the room obtaining information...when (Patient #7) jumped off his bed throwing his body and arms into the glass door of his room and sat back down on the bed. Approximately three or four minutes later (Patient #7) came out of his room and said 'arrest me I want you to (expletive) arrest me.' I informed (Patient #7) he was not under arrest but could not leave due to being involuntarily committed and attempted to walk him back to his room. I asked (Patient #7) to sit down and relax on his bed. (Patient #7) put his finger in my face and stated '(expletive) you get out of my face and my (expletive) room'. Once again I told (Patient #7) to relax. (Patient #7)	A 287		

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A 287	Continued From page 150 pushed my chest and said '(expletive) you make me lay the (expletive) down' and pushed me again. I attempted to gain control of (Patient #7)'s hands to keep from being pushed again when he became combative and resistant to my commands. Security Officer #5 entered the room along with Nurse #8 to assist me in gaining control of (Patient #7). (Patient #7) started thrashing and attempted to grab my handcuffs to prevent being handcuffed to the bed putting nicks and cuts on my fingers. Approximately ten to twelve minutes later I told (Patient #7) I would take him out of handcuffs if he agreed to cooperate with medical staff. (Patient #7) agreed. I took (Patient #7) out of handcuffs without further incident." Interview on 10/21/2011 at 1330 with Performance Improvement (PI) staff revealed the Security Investigation report regarding the incident of Patient #7 being handcuffed by CPO staff was sent to Risk Management. Interview revealed Risk Management did not send the report to Performance Improvement, and thus a quality/PI review was not completed.	A 287		
A288	482.21(c)(2) QAPI FEEDBACK AND LEARNING [Performance improvement activities must track medical errors and adverse patient events, analyze their causes and] implement preventive actions and mechanisms that include feedback and learning throughout the hospital. This STANDARD is not met as evidenced by: Based on policy review, adverse event report review, hospital investigative document review, and staff interview, the hospital failed to implement actions to improve the safety of	A288	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: Performance Improvement (PI) implemented a new process for review of all Quality Care Control Reports (QCCs), Security Reports and Company Police Reports. This process is outlined in the policy entitled "PI Review of Event Reports" (see "attachment 5"). All Quality Care Control Reports (QCCs), Security Reports and Company Police Reports will be reviewed by a Performance Improvement/Patient Safety Coordinator daily. Friday, Saturday and Sunday reports will be reviewed on Monday. A Patient Safety Response Team (PSRT) (see "attachment 6") is activated prior to Monday if the event warrants. For all other	

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A 288	Continued From page 151 patients placed in physical restraints after the hospital's analysis of an incident of patient harm during physical restraint identified areas of needed improvement for 1 of 1 sampled incidents of patient harm during physical restraint (Patient #5). The findings include: Review of hospital policy entitled "Sentinel Events and Root Cause Analysis" dated 08/22/2011 revealed, "...PURPOSE: To improve care, maintain a safe environment, and focus attention on the underlying causes to promote risk reduction...DEFINITIONS:... Sentinel Event: A Sentinel Event is an unexpected occurrence involving death, serious physical...injury,....Root Cause Analysis (RCA): A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a Sentinel Event....A goal of the analysis is to identify and prioritize opportunities to improve the process and reduce the risk of the Sentinel Event or near miss reoccurring....Action Plan: The product of a RCA....The action plan addresses system and process deficiencies for which improvement strategies are developed and implemented....The goal of the action plan is to find ways to prevent a repeat of Sentinel Events, occurrences, or near misses....GUIDELINES:...Root Cause Analysis (RCA):....2. The RCA Team looks at the systems/processes involved in the occurrence and identifies and documents the root causes thought to be contributing to the event....The RCA Team develops an action plan that includes measures to monitor plan effectiveness....Recommendations targeted at the	A 288	occurrences PI will perform an initial screening/analysis considering severity and frequency of the occurrence. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) algorithm (see "attachment 7") will be the tool used to assign a severity score to all occurrences. PI will identify whether immediate investigation, Event Response Team (ERT) activation, or further review and analysis is warranted. Please see Sentinel Events and Root Cause Analysis policy (see "attachment 8") for composition of the ERT. The ERT will determine whether the occurrence is a sentinel event or serious near miss/close call and whether an RCA should be conducted. If further review and analysis by the involved department is warranted the staff conducting the analysis may be requested to document on a PSRT Form (see "attachment 9"). PI and Risk Management (RM) will also track these reports and identify trends. Individual PSRTs, ERT activations, Root Cause Analyses (RCA), Failure Mode Effects Analyses (FMEA) and system issues, as well as trending of incidents over time are reported to the Harm Events Analysis Team (HEAT). Individual events that are resolved during an ERT are documented on the ERT form, are attached to the QCC and saved for future potential trending. HEAT provides periodic reports to the Quality Council, Patient Safety Committee, the Medical Executive Committee and the Board Quality and Patient Safety Committee. Identified trends will be considered for further statistical analysis or FMEA.	

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A 288	Continued From page 152 root causes are developed to significantly reduce the likelihood of recurrence of the event....5. Action plans are forwarded to the HEAT (Harm and Events Analysis Team) or Quality Council for evaluation and approval for implementation by (Hospital) departments identified in the action plan. The HEAT establishes deadlines for completion of the action plans...." Review of an adverse event report dated 04/17/2011 revealed, "...Comments: (Patient #5) brought in by EMS at 4:40pm and put in red zone room 65 (in locked psychiatric area of ED). The whole time the patient was in room 65 he was agitated, and confused. The psychiatrist saw patient and involuntarily committed him. The patient was medicated by day shift but continued to be agitated. After shift change the on coming ED (nurse tried to get) patient in a hospital gown. The nurse medicated patient by shot, Company police officers (CPO #1) and (CPO #2), and Security officer (SO #2) were standing by. Patient continued to be agitated so I called for CPO's assistance. The CPO's went into patients room to try and calm him, patient then became combative, and was taken down by CPO's and security. (SO #1) called for more assistance and medical and psych staff arrived, everyone assisted in getting patient into bed so he could be restrained. After patient was in the bed a nurse said that something was wrong with the patient he wasn't breathing. Patient was then rushed to the resuscitation room....Entered by: (SO #1)...." Review of hospital investigative documentation revealed a RCA was conducted and concluded on 06/20/2011. Review of the RCA report revealed, "...Root Cause Analysis/Failure	A 288	**Monitoring:** The monitoring system will involve a second review by another PI/Patient Safety-coordinator. A weekly random sample review of 2 of each type of report will be conducted. The initial assignment of error will be blinded to the second reviewer in order to establish inter-rater reliability. Results of this review will be discussed in PI department meetings and reported to the HEAT. **Responsibility:** Chief Medical Officer **The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** A Root Cause Analysis (RCA) Team was pulled together immediately after the incident. In reviewing the incident, the RCA team issued five (5) key recommendations in June 2011: (1) the Director of the ED, Service Line Director of Psychiatry, and the Director of Security will form an integrated team to function solely in the Red Zone-Psych ED. This team will consist of physicians, nursing, mental health specialists, security and a Licensed Clinical Social Worker who have clearly defined roles and responsibilities to deliver safe/quality psychiatric care; (2) the ED Director and the Manager of Supplemental Staffing are to ensure that all ED personnel receive initial and annual re-certification of NCI to be demonstrated by the collaboration of Training and Development documentation with Staff position control sheets; (3) the Vice President of Post Acute Care, the Director of Security, and the Director of Risk Management will evaluate as to whether the health system wants law enforcement techniques used on patients and present any recommendations back to the HEAT Team;	11/07/2011

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A 288	Continued From page 153 Scenario: The root cause was identified as no clinical person in charge of the patient's care and well being. The contributing factors were:...2. Clinical staff relinquished responsibility for the patient's care to Security and CPOs. 3. Law enforcement techniques were utilized versus therapeutic interventions as outlined in non-violent crisis intervention (NCI) training. 4. The patient's assigned nurse was not trained in NCI...." Further review of the RCA report revealed the following recommendations: 1. formation of an integrated team (including physicians, nurses, mental health specialist, security, and a licensed clinical social worker) to function solely in the Psychiatric ED - to be completed within 3 months; 2. ensure all ED staff receive NCI training - to be completed within 3 months; 3. administrative and risk management staff to evaluate whether the hospital wants law enforcement techniques used on patients - to present recommendations to HEAT team within 1 month; 4. develop a Code White (behavioral emergency response) team - within 3 months; and 5. Re-examination of the RCA to be completed by the HEAT team after the patient's autopsy report is received and examined regarding cause of death and proved further recommendations as warranted. Interview on 10/21/2011 at 1455 with the Vice President of Nursing, with the Director of Performance Improvement present, revealed the hospital had attempted to implement the integrated team model, but because of difficulty recruiting appropriate staff (psychiatric nurses and licensed clinical social workers [LCSW]) the implementation was not completed. Interview revealed two LCSW staff were hired in August,	A 288	(4) the Vice President of Post Acute Care, Vice President of Patient Safety and Quality and the Vice President of Nursing will develop a plan for a Code White team to be instituted and utilized in all facilities in the health system. This will be demonstrated by the formation of a clear plan and resources dedicated to the plan; and (5) re-examination of this RCA will be completed by the HEAT team once the patient's autopsy report is received and examined regarding cause of death, and provide further recommendations as warranted. The results of this re-examination and any recommendations made from said re-examination will be reflected in the HEAT team meeting minutes. Since the RCA Team issued its recommendations, the health system has made substantial progress towards 4 of its 5 recommendations during the months of June, July, August, September, and October 2011. Specifically, (1) The Director of the ED, Service line Director of Psychiatry, and the Director of Security reviewed the staffing model in place at the time of the event. The decision was made to formalize an integrated team approach to function solely in the Red Zone-Psych ED. Specifically, the following changes were commenced based on the recommendations: a. 2 licensed social workers were hired. One was employed in August 2011, but the other hire rescinded her acceptance one week prior to start. These positions have been found to be very difficult to recruit, and	

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A 288	Continued From page 154 but one resigned before starting employment and the other one worked briefly and was terminated from employment due to performance. Interview revealed currently the hospital was working towards changing the nursing model in the psychiatric ED so that the psychiatric nurse would assume the role of primary nurse, rather than consultant nurse. Interview revealed the goal for completion was 03/30/2012. Interview revealed on 04/30/2011, the hospital began to have additional NCI classes, which are ongoing in an attempt to ensure all ED staff were trained. Interview revealed a few staff members were currently not trained. Regarding recommendation #3 ("administrative and risk management staff to evaluate whether the hospital wants law enforcement techniques used on patients"), interview revealed, "This was not started initially, but I put it in my updated plan this week. It was assigned to the Vice President of Post Acute Care and the Director of Risk Management...I addressed it more futuristically." Interview revealed there had been no change in the process of which staff (including CPO staff) were allowed to put physical restraints on patients prior to the survey. Interview revealed, after HEAT team further evaluated the implementation of a Code White team, it was decided that it was not feasible to implement and the hospital's current Code White process was sufficient and would thus continue. Interview revealed no further actions were implemented after the patient's autopsy report was received on 09/07/2011.	A 288	b. Plans for the ED psychiatric zone model will be updated in such a way that (i) the psychiatric nurse will take a holistic approach to patient care, (ii) the ED staff nurse will not be scheduled to provide direct patient care in the psychiatric zone in the ED but will always be available as a resource when help is needed, and (iii) the security officers and/or company police officers, sitters, physicians (including the psychiatrist) will continue to be a part of the team along with the psychiatric nurse; (2) The ED Director and the Manager of Supplemental Staffing have taken steps to ensure that ED staff receive and maintain appropriate NCI training. Currently, there are only 5 registered nurses in the ED (out of 92 total) that have not received NCI training. Of these 5, 3 nurses were hired within the last year, 1 nurse transferred from another nursing unit within the last year, and 1 failed to attend class. All 5 registered nurses have been scheduled for training. We are moving forward with the non-nursing staff to be trained as well. 3 non-nurses in the ED have attended the NCI training. Due to the large number of non-nurse staff in the ED (approximately 50 total), the decision was made to not mandate the training for the entire non-nursing staff. The health system will require that Allied Barton ensure that all of its staff assigned to the ED have current NCI training on file;	

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A 288	Continued From page 154A	A 288	(3) The Vice President of Post Acute Care, the Director of Security, and the Director of Risk Management evaluated law enforcement techniques and patient care. The "restraints, seclusion, and safety devices" policy does address therapeutic holds as well as Forensic restraints. Employees as well as contract employees are to follow the hospital policy. The ED nursing staff, the psychiatric staff that work in the psychiatric zone and the Allied Barton security and company policy officers will all be re-educated on this policy. The necessary documentation required for any type of hold or restraint is to be re-educated to the staff as well; and (4) Currently, there is already a code white used as a call code for the health system that defines staff assistance needed. It is provided to all employees of the health system upon hire as a badge attachment. The intent is to provide staff assistance immediately where needed. A specific code white team has been discussed, but the decision was made that the current "code white" call code met the health system's needs. As to the fifth recommendation, the autopsy report was received on September 7, 2011. Please note that at no time during the RCA review was it thought there was any intentional harm inflicted by the health system on any patient. The RCA Team was updated regarding receipt of the autopsy, and the HEAT Team is scheduled to be updated on November 7, 2011. Based on the limited time since receipt of the autopsy, local law enforcement inquiry, litigation, and now agency inquiry, the health system administration is taking the lead in finalizing the RCA Team's recommendations. All essential RCA recommendations have been or will be implemented prior to November 7, 2011, and all essential follow-up for purposes of the Conditions of Participation identified during the recent survey	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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A 288	Continued from page 154B	A 288	have been or will be completed by that date as detailed throughout our response. (see "attachment 11") Monitoring: The Harm Events Analysis Team (HEAT) has oversight of RCA's. The PI Department maintains a score card of the RCA's. The recommended implementation dates will be discussed in detail at the HEAT meetings in order to hold the executive sponsor accountable for RCA completion. Responsibility: Chief Medical Officer	11/07/2011

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A385	Continued from page 154C 482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, and hospital investigation document review, the hospital failed to have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care and ensure nursing staff were trained and competent to ensure the safe and appropriate physical restraint of patients. The findings include: 1. The hospital's nursing staff failed to supervise and evaluate patient care during patient restraint. ~cross refer to 482.23 (b)(3) Nursing Services Standard: Tag A0395 2. The hospital failed to ensure nursing staff were trained and competent to ensure the safe and appropriate physical restraint of patients. ~cross refer to 482.23 (b)(5) Nursing Services Standard: Tag A0397	A385	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** There is a resource nurse/supervisor assigned each shift in the ED. The resource/nursing supervisor is to be called to the patient area as soon as the restraint is ordered by the physician. The clinical nurse is not to leave the patient during any type of escalation of the behavioral health/psychiatric patient until the patient's condition stabilizes or the clinical nurse is relieved by another nurse. The resource nurse/supervisor in the ED is to ensure there is enough nursing staff available to gather items needed for the behavioral health/psychiatric patient such as medication, restraints etc. This was part of the training and education provided to the nursing staff ongoing at shift change. There is a team leader in most zones of the ED to assist with patient care and oversight. There is also a Director of the ED that is responsible for the overall patient care provided to the ED patients (see "attachment 10"). Also there is a house Nursing Supervisor on duty 24 hours per day, 7 days per week that is also responsible for overseeing the ED as part of the supervisor responsibility. The Director of the ED reports directly to the Vice President of Nursing. **Monitoring:** The ED leadership maintains a roster of education for the ED nursing staff to show evidence of class attendance for the restraint education and the NCI training. Copies of this education are to be in the education file of the nursing staff. The security officers and company police officers will also have evidence of the attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the	11/07/2011

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A 385	Continued From page 155	A 385	health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. If an audit shows that staff are not appropriately trained, not performing in accordance with their training, or identifies opportunities for improvement, the employee will not be assigned to any location where behavioral health/psychiatric patient care is provided and the health system will determine if further education/training is needed for staff. The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see "attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. Responsibility: Vice President of Nursing	11/07/2011

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A395	Continued From page 155A 482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, and hospital investigation document review, the This STANDARD is not met as evidenced by: Based on policy review, medical record review, video taped footage review, staff interview, and hospital investigation document review, the hospital's nursing staff failed to supervise and evaluate patient care during restraint for 3 of 11 sampled patients that were restrained by staff (Patients #5, #7, and #2). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm....DEFINITIONS: 1. RESTRAINT - A manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely....7. INITIATION & ASSESSMENT: A qualified licensed staff member with established competencies may initiate seclusion or apply restraint. Assessment of the patient who has new onset or worsening of confusion/agitation is done by an RN (registered nurse) prior to or within 30 minutes of application	A395	The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan: There is a resource nurse/supervisor assigned each shift in the ED. The resource/nursing supervisor is to be called to the patient area as soon as the restraint is ordered by the physician. The clinical nurse is not to leave the patient during any type of escalation of the behavioral health/psychiatric patient until the patient's condition stabilizes or the clinical nurse is relieved by another clinical nurse. The resource nurse/supervisor in the ED is to ensure there is enough nursing staff available to gather items needed for the behavioral health/psychiatric patient such as medication, restraints etc. This was part of the training and education provided to the nursing staff ongoing at shift change. There is a team leader in most zones of the ED to assist with patient care and oversight. There is also a Director of the ED that is responsible for the overall patient care provided to the ED patients (see "attachment 10"). Also there is a house Nursing Supervisor on duty 24 hours per day, 7 days per week that is also responsible for overseeing the ED as part of the supervisor responsibility. The Director of the ED reports directly to the Vice President of Nursing. There is a call made to the resource nurse/supervisor of the ED for any restraint order from the physician. It is the resource nurse/supervisor responsibility to arrive to the patient and ensure safety and security of the patient as well as the least restrictive means for the behavioral health/psychiatric patient that is combative, hostile or out of control. The	

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A 395	Continued From page 156 of a restraint....11. RESTRAINT/SECLUSION MONITORING:...Behavioral Seclusion/Restraint: Staff provides continuous face-to-face observation of the patient in rigid limb restraint(s) and maintains documentation on the Restraint Flowsheet (excluding therapeutic holds less than 15 minutes) and on the Special Observation Flowsheet....At the initiation of seclusion or restraint, and every 15 minutes, a staff member monitors the patient with the intent to prevent harm and maintain well-being....15. DOCUMENTATION:...Each episode of restraint/seclusion use is recorded in the medical record. Documentation includes: a. The circumstances that led to their use; b. Consideration or failure of non-physical less restrictive interventions; c. Medical conditions or physical disability that would place the patient at greater risk....d. The rationale for the type of physical intervention selected; e. The type of restraint used,...vital signs, circulation to extremities,...patient response to treatment, patient rights, dignity and privacy maintained, and time released...h. Behavior criteria for release...; i. Informing the patient of behavior criteria for release from restraint...; l. Injuries that are sustained and treatment received for these injuries; and m. Deaths..." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638 with complaints of not taking his medicine. Record review revealed upon arrival the patient was placed in Room 65 (within the locked psychiatric area of the ED). Record review revealed the psychiatrist evaluated the patient and he was then involuntarily committed (IVC). Review of RN #1's note at 1929 revealed, "Assumed patient care. Patient awake and alert, breathing even and unlabored. Patient stares at RN, nonverbal. No response to questions or requests. Patient is INVOL(untary)." Review of	A 395	documentation is to be checked as well for the physician order as well as the appropriate monitoring of the patient. This is the concurrent monitoring process that has been put in place. The restraint log is to be reviewed by the ED leadership as well as nursing performance improvement staff and a monthly report will be submitted to Nursing Oversight committee and up to the Patient Safety Committee and reviewed by the Vice President of Nursing. **Monitoring:** The concurrent monitoring by the ED leadership for compliance with restraints is ongoing. The restraint log is reviewed on an ongoing basis by the ED resource nurse/supervisor during the shift. This provides the name of the patient that has restraints at the time the restraint log report is printed. There is ongoing rounding throughout the ED by the ED resource nurse/supervisor to observe nursing care on ED patients. Currently the nursing PI staff are rounding on a daily basis until further directed by the Vice President of Nursing to check restraint patients based on the restraint log to ensure appropriate nursing care is being provided to the patient in restraints (see attachment 4 and 4A"). Currently there is baseline data for compliance on restraints for the end of October and retrospective data is to be collected weekly and compiled into a weekly report until further directed by the Vice President of Nursing. This data is based on a chart review and is submitted to Vice President of Nursing for review. Any deficiencies noted are to be reviewed with the appropriate nursing leadership and corrective action taken. At the end of the month there is a monthly report generated to identify trends. Corrective action is taken based on the trends. This data is presented to Nursing Oversight Committee and forwarded up to Patient Safety Committee, Quality Council, Board Quality & Patient Safety Committee, and BOT. **Responsibility:** Vice President of Nursing	11/07/2011

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A 395	Continued From page 157 RN #1's note at 1951 revealed, "Patient more verbal at this time, answering questions. Patient requested water; provided. patient continues to refuse to change into gown." Review of RN #1's note at 2017 revealed, "Patient continued to refuse gown, now stating ' I want my momma. I'm not putting on no mother (expletive) gown'. Patient more active in room, pacing. Patient multiple trips back and forth to bathroom; not following directions of security or nurse. CPO (Company Police Officer) and security to bedside; patient medicated." Review of RN #1's note at 2110 revealed, "Patient pacing in hallway, appears to becoming more agitated. Refusing to stay in room, becoming aggressive with staff. (RN #2) from Psych ED aware of patients increasing agitation; will inform (Physician #2)." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/06/2011 and signed by a physician from the Medical Examiner's office	A 395		

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A 395	Continued From page 158 revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....He was being involuntarily committed and was at the local hospital when his death occurred. He was agitated and attempting to leave his room when he was physically restrained by multiple individuals. Video of the events show one person placing an arm around his neck prior to him being taken to the ground. The neck restraint appears to be maintained as several other individuals restrain his body. His respiratory function would have been further compromised if overlay occurred on the chest and/or abdomen. The decedent appears unresponsive immediately following the restraint. Significant findings at autopsy include small, multifocal and thin subarachnoid hemorrhages, hemorrhages in the tongue and laryngeal mucosa and chronic active hepatitis of unknown etiology. Toxicology studies are positive for therapeutic concentrations of Risperidone (Risperdal) in aorta blood. Benzodiazepines, cocaine, ethanol, opiates, organic bases, ziprasidone and haloperidol are not detected. Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the camera angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing	A 395		

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A 395	Continued From page 160 and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed the following events at the noted times: 21:13:00 - Patient #5 in room with lights off. CPO #1 and CPO #2 go into patient's room and turn light on. One Security Officer (SO) in room and another SO at the patient's doorway looking into room (SO #1 and SO #2). RN #1 and RN #2 outside of and looking into room. (No nurse in room). 21:13:14 - RN #1 goes into room. SO #1 and SO #2 in room and CPO #1 and CPO #2 standing in doorway of room. Patient not in view. 21:13:26 - Patient walks into view in front of bed (which is against the back wall). All staff looking at patient. Patient sits on bed. 21:13:53 - Patient stands up off of bed with a cup in his hand. 21:14:16 - Patient throws water from cup onto a Security Officer (unable to determine which one). CPO reaches for cup. 21:14:22 - RN #1 goes out of room and out of view. RN #2 in doorway looking into room. Patient not in view, but can see 2 Security Officers and 1 CPO in room (other CPO is in room out of view). No nurse in room. 21:15:21 - Patient moves towards door and CPO #1 moves in front of him (between patient and door). SO #1 and SO #2 outside of and looking into room. RN #1 walks towards room while wiping her shirt with a towel. 21:15:22 - CPO #2 walks towards patient (from right side of room) with arms reached out towards patient. 21:15:23 - SO #1 and SO #2 move into the patient's doorway. Patient is facing doorway with CPO #1 on his right side and CPO #2 on his left	A 395		

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A 395	Continued From page 161 side (both CPOs positioned towards the front of the patient). 21:15:25 - RN #1 turns away from the patient's room and walks down the hall. The 2 CPOs are holding the patient's arms, one on each side. (No nurse in room as physical restraint is initiated by CPOs). 21:15:26 - Patient lifts up slightly and sits on bed (CPOs still beside of and with hands on the patient). 21:15:28 - RN #1 looks over shoulder then turns around and faces the patient's room. SO #1 and SO #2 head into room. CPO #1 leans down towards bed. CPO #2 not in view. 21:15:29 - RN #1 turns back away from and continues to walk away from room. Patient is visible standing and facing towards the right side of the room. CPO #1 goes behind the patient. CPO #1 lifts his right arm out with elbow bent and moves it towards the patient. 21:15:30 - CPO #1's arm not visible. CPO #1 is leaning forward or bending down. Patient not visible. SO #1 and SO #2 in doorway looking in. CPO #1 and patient go backwards (towards left side of room) together. CPO #2 comes into view with in front of patient with his arms extended, but hands not visible. RN #1 looks back towards room again, then turns and continues to walk away from room. 21:15:31 - Patient's right hand is in the doorway, holding onto the door jam. The 2 Security Officers are still in the doorway. Both CPOs face the doorway as they and the patient are going down. 21:15:32 - Patient down and out of view. CPO #1 (who was behind patient) is not visible. CPO #2 in front of patient and leaning towards floor. SO #1 and SO #2 enter room and are on the right	A 395		

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A 395	Continued From page 162 side of the patient, with their backs towards the camera. The Security Officer closest to the patient's legs is leaning down. (No nurse in room) 21:15:35 - CPO #2 leaning down towards patient and out of view. Both Security Officers leaning towards patient, the one near the top of the patient is standing and the one near the patient's legs is leaning towards patient with his (officers) legs extended to the side. 21:15:38 - CPO #1 and patient remain out of view. CPO #2 and both Security Officers are leaning towards the left, over the patient. 21:15:44 - The Two Security Officers stand, but still lean over the patient. 21:15:46 - One of the Security Officers goes around to the patient's other (left) side. 21:15:49 - CPO #1 and patient remain out of view. CPO #2 appears to be on the patient's legs. 21:15:52 - CPO #2 is up on his toes with his legs extended behind him. The top of his body is positioned towards the patient, but the view is blocked by the back of the Security Officer that is positioned on the patient's right side. (No nurse in room) 21:15:53 - Patient's right leg goes up, then down. Security Officer on right side of patient appears to hold it. 21:16:03 to 21:16:12 - The footage jumps and there is no footage available during this period of time. 21:16:12 - The Security Officer on the right side of the patient and CPO #2, now located near the patient's legs on the right side, are both leaning over the patient with their backs to the door. No one else in the room is visible. 21:16:27 - Security Officers and CPOs visible on	A 395		

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A 395	Continued From page 163 floor, no apparent struggling at this point. (No nurse in room) 21:16:30 - RN #2 and RN #3 (a male psychiatric ED nurse) go to the doorway of the patient's room and look in. 21:16:35 - RN #2 goes into room (first time a nurse has been in room since CPOs put hands on patient at 21:15:25). 21:16:38 - RN #3 goes into room 21:16:42 - RN #3 leans toward patient's feet. CPO #1 now visible and near the top of and to the right of the patient. A Security Officer is visible on each side of the patient. 21:16:48 - RN #1 walks to door, drops restraints on the floor in the hall near the door, and turns and walks away from room. RN #2 goes into room and goes to the left side of the room. 21:16:54 - Both Security Officers now standing and leaning over patient. CPO #1 is near the top of the patient and is leaning over patient, either on his knees or with his legs extended. 21:16:55 - RN #2 leaning over the patient, near his head and to the left of CPO #1, then standing up. 21:17:04 - RN #2 comes out of room. 21:17:22 - Licensed Practical Nurse (LPN) #1 (an ED nurse) enters room, followed by 1 EMS staff and ED Tech #1. RN #1 is standing in the doorway with restraints in her hand. 21:17:48 - Security Officers and other staff are standing looking towards the patient on the floor. 21:17:50 - Several staff (unable to determine who or how many) lift the patient from the floor to the bed. 21:17:52 - Patient is on bed. Staff, including SO #1, SO #2, and CPO #2, surround the patient. CPO #1 is standing in the doorway. 21:17:54 - RN #1 goes into room with restraints in	A 395		

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A 395	Continued From page 164 hand. 21:17:58 - CPO #1 goes out of room and rubs his head. 21:18:30 - Physician #2 (psychiatrist) walks towards room and stops and talks to CPO #1 in the hall on the way. 21:18:37 - Physician #2 stands in patient's doorway, leans on doorway, and looks into room. (Does not go into room). 21:18:42 - RN #4 (psychiatric nurse) walks towards room and talks to CPO #1 in hall. 21:18:49 - RN #3 is standing in room and looking down. 21:18:55 - Physician #2 walks away from room. RN #3 mops floor with towel. 21:19:02 - Patient is seen laying on bed. Patient is not moving and his clothes are off (can see naked right side). 21:19:08 - RN #2 exits room and talks to Physician #2 in hall. 21:19:34 - RN #3 exits room and talks to Physician #2 in hall. RN #2 goes back into room. 21:19:49 - RN #3 and CPO #1 go into room. 21:19:56 - RN #3 exits room. RN #1, RN #2, and LPN #1 are in room near the patient's head. Patient is not moving. 21:20:15 - RN #3 goes into room with BP (blood pressure) machine. 21:23:26 - Someone takes BP cuff off of patient's arm. 21:23:33 - Staff roll patient out of room on bed. He is naked with a sheet laying over his groin. Restraints are visible on his ankles (cannot see his clearly see his wrists). Patient is not moving. Interview on 10/19/2011 at 1100 with Security Officer (SO) #1 revealed the officer was posted in the psychiatric area of the ED on 04/17/2011 from	A 395		

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A 395	Continued From page 165 4 PM to Midnight and was involved in the physical restraint of Patient #5. Interview revealed, "(When the patient was on the ground) I grabbed his legs and then moved to his arm, I think on the right side. I think the Company Police Officers were on his arms and upper body. As far as I could tell they were leaning on his chest....They had their back to us, so I don't remember if I could see his (the patient's) face or neck." Further interview revealed the officer thought he had to call, by waving his arm so as to be seen on video monitor at the ED desk, to get a nurse in the room. Interview revealed the officer thought someone had pushed the panic button (initiated an emergency response) because "so many" staff showed up. Further interview revealed, "We moved him to the bed. He was still struggling and urinating on himself (when on the floor and the bed). He was moving his arms and legs, trying to get up. He was muttering some stuff....They gave him some shots and tried to put restraints on because he was fighting pretty hard. Before putting restraints on him, they tried to get his clothes off and put a gown on him. I think they got a gown on him, but I'm not sure. Restraints were placed on his arms and legs by medical staff, I'm not sure who...a couple of females and a male. Sometime during that point he quit moving a lot, because they had given him the shots, it usually works pretty quick. That's when the nurse noticed there seems to be something wrong, seems like he's not breathing. She told (RN #2) to go get the bag (BVM). A male nurse checked the pulse and said it was weak. They got him out of there and to the resuscitation room." Interview was requested with RN #1.	A 395		

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A 395	Continued From page 166 Administrative staff informed surveyor RN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of a "Witness Statement" for RN #1 dated 04/17/2011. Review of the statement revealed the following: The patient was IVC and began making attempts to leave the facility. He began pacing, cursing, and became physically violent with staff. CPO and security staff were at bedside and intervened when the patient made attempt to leave department and began assaulting staff. While CPO and security were attempting to calm patient, he threw water on staff members and the floor. He then lunged at the CPO and had to be restrained. RN #1 left the area at that time to inform the psychiatrist of the patient's status and events. Upon returning to the area, the patient had stopped resisting CPO and security and was placed on the stretcher. Patient then began to have ineffective breathing and was taken to the resuscitation room. Interview on 10/18/2011 at 1515 with RN #2 revealed, "The patient made a move towards (CPO #2) so they called the other CPO (#1). I went to his room and he threw water towards staff....I'm not sure if his nurse was in the room. He backed up and said he was sorry and sat on his bed. I went to tell (Physician#2), but he was with another patient. I came back after I told (RN #3) what had happened. I went to the room and he was on the floor on his back...with a CPO towards the upper part of his body on his right side. Somebody had his feet....I don't know who, it was more than one person....He was struggling....I tried to tell him to calm down. I told him we'd let him up if he'd calm down and stop	A 395		

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A 395	Continued From page 167 struggling. He was breathing and sweaty, but he was sweaty when he got there. I stepped out and was at the doorway and he stopped struggling. They were in the process of getting him up on the bed. He was a heavy boy....He was making raspy sounds on the bed....They determined he wasn't breathing. The ED nurse told me to go get the bag/mask....When I got back with the bag/mask they called a code and rushed him to the resuscitation room." Further interview revealed the psychiatric nurse works in the ED and also on the behavioral health unit. Interview revealed during a hold a patient should be monitored for breathing and safety. Interview revealed, "If we do a hold on behavioral health (unit) we document on the restraint form. They document differently in the ED." Interview on 10/19/2011 at 0915 with RN #3 revealed the male nurse was a psychiatric nurse that worked in the ED. Interview revealed when the nurse arrived to the patient's room on 04/17/2011 the patient was on the floor with at least 4 security officers (including security officers and CPOs). Interview revealed, "(CPO #1) was up at the head on the patient's right side helping hold him down. He was holding his chest or head....was in a position to hold the top part of the body. Another person (unsure who) was on the patient's right side holding his right leg. (CPO #2) was on the left side holding his leg or thigh. A security officer...was semi-squatting over (CPO #2)....I held his left foot. A police or security officer was at the top of the left shoulder area. I couldn't see what he was holding. I was just seeing (other staffs') backsides....I think his primary nurse was in the room...but that might have been when I went back and we got him on	A 395		

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A 395	Continued From page 168 the stretcher." Interview revealed the nurse wasn't sure what staff monitored the patient's condition during the physical restraint. Interview revealed, "I couldn't see him at all really. He was kicking and fussing and trying to be violent and all of that. I couldn't see his face....All I am seeing is back and arms. They would basically have to be holding him on the chest. He was a big fellow and was doing some pretty good struggling to start with...I could only see him from the knees down because they pretty much had him covered up with their bodies....I stopped holding his foot when he stopped fighting and I went out of the room to get the vital signs machine....I came back in with the vital signs machine and they (staff) were standing up and he didn't look like he was breathing. He had quit fighting. I think (LPN #1) said, 'Let's get him to the stretcher.'...After he was on the stretcher his breathing was very, very shallow....I don't remember his clothes coming off....One (restraint) got put on his leg....There's no point in doing that because he's not breathing right....Everybody's trying to look ahead and get him tied down in case that's what's needed. I got out of the way and they rolled him to the resuscitation room." Interview on 10/20/2011 at 1245 with ED Technician #1 revealed during April 2011 the staff member worked as an ED Tech(nician), but starting in May 2011 he joined EMS as an Emergency Medical Technician (EMT). Interview revealed on 04/17/2011 the ED Tech went to the patient's room after he heard a radio call for security assistance. Interview revealed, "I went to see what was going on...The patient was standing and there were 2 Company Police Officers telling him to calm down. The patient	A 395		

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A 395	Continued From page 169 was cursing and was trying to get out of his room. I left...and later went back over to see if the situation had calmed down. He (the patient) was on the floor. He was kicking and combative. I went to the right, to his feet....I couldn't see his face. They were around him so I couldn't see him....I never heard him say get off me or you're hurting me. He didn't say anything....The only parts (of him) I saw was the legs. I think 3 officers were at the top, I couldn't tell what position or what they were trying to hold....After he calmed down, he was still breathing. I helped lift him to the bed. He was calm and peaceful on the bed. They brought the vital signs machine in and took his vital signs. Then he started going down. Respirations didn't seem right...slow and thready respirations....I left to clear the hallway to move him and to get the resuscitation room ready....I don't remember taking his clothes off or putting restraints on him. He never struggled or fought when he was on the bed. (LPN #1) was at the head of the bed and was directing people.... (RN #1) was in the doorway." Interview was requested with LPN #1. Administrative staff informed surveyor LPN #1 had moved and was no longer employed at the hospital. Review of hospital investigation documents revealed documentation of an interview on 05/18/2011 of LPN #1 by Root Cause Analysis team members. Review of the interview revealed the interviewer documented the nurse's response as, "(RN #1) asked for help with restraints. When I got to the patient's room, he was still on the floor being restrained, but not longer resisting. We got him up on the stretcher, we were getting him straight and trying to get the restraints on and I didn't like his breathing. So, I	A 395		

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A 395	Continued From page 170 repositioned his head, still didn't like his breathing. So I asked for a nasal airway. That didn't help, his respirations were decreased, agonal-like. The psych nurse brought the ambu (BVM) bag, but I was concerned about his poor respirations and I said 'We need to go' and we took him to the resuscitation room." Review revealed, when asked was there anything that caused the nurse concern about the case, the interviewer documented the nurse's response as, "I thought they were a little forceful while restraining him and I didn't Like them holding him near his head and neck." Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed physical restraints in the ED are usually rapid and temporary, not lasting more than a few minutes, until a patient either calms down or is placed in-mechanical restraints. Interview revealed, "The nurse is with the patient the entire time that is happening. A tech can assist, at time security can assist, but we try not to use them. They follow the direction of nursing staff. The nurse should be clinically directing and overseeing that (the physical restraint). (The physically restrained patient) is monitored more often. A behavioral health emergency is the same as a medical emergency. Interview on 10/20/2011 at 1130 with the Vice President of Nursing during video taped footage review of the physical restraint of Patient #5 on 04/17/2011 confirmed nursing staff was not continuously present and did not continuously supervise the restraint. Further interview confirmed nursing staff did not continuously monitor the patient to ensure safety during the	A 395		

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A 395	Continued From page 171 physical restraint. 2. Closed medical record review for patient #7 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via private transportation on 06/29/2011 at 2011 with complaints of neck and back pain. Record review revealed the patient was discharged on 06/30/2011 at 1451 with diagnoses UTI (Urinary Tract Infection) and alcohol intoxication. Record review of Nurse #7's notes dated 06/30/2011 at 0848 revealed "...Pt (patient #7) found to have attempted to leave the ED. Pt escorted back to room 31...Pt stated he wanted to leave and smoke. Pt began swinging and acting out in the lobby, pt had to be taken to the floor by room 31 by security and panic alarm sounded by staff. Pt then proceeded to head butt the glass door of room 31..." Record review of physician #4 note dated 06/30/2011 at 0851 revealed "Pt got up, angry, verbally abusive and started to walk out of ED. I explained he could not leave due to ETOH (Alcohol) level. I told him not to leave or I would have to involuntarily commit him until legally sober. Pt came back in with staff escort, then tried to leave again and became combative. Pt now will be involuntarily committed until MBA (Alcohol Level) comes down." Review of hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #4 and dated 06/30/2011 revealed "On Thursday June 30, 2011 at approximately 0830 hours I responded to blue zone room #31 in reference to an involuntarily committed white male (patient #7)...attempting to leave by fighting with Security Personnel and Medical staff....(Patient #7) became verbally uncooperative but got up off the	A 395		

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A 395	Continued From page 172 floor and went into his room and sat down on his bed. (Security Officer #5) and I were standing outside the room obtaining information...when (Patient #7) jumped off his bed throwing his body and arms into the glass door of his room and sat back down on the bed. Approximately three or four minutes later (Patient #7) came out of his room and said 'arrest me I want you to (expletive) arrest me.' I informed (Patient #7) he was not under arrest but could not leave due to being involuntarily committed and attempted to walk him back to his room. I asked (Patient #7) to sit down and relax on his bed. (Patient #7) out his finger in my face and stated '(expletive) you get out of my face and my (expletive) room'. Once again I told (Patient #7) to relax. (Patient #7) pushed my chest and said '(expletive) you make me lay the (expletive) down and pushed me again. I attempted to gain control of (Patient #7)'s hands to keep from being pushed again when he became combative and resistant to my commands. (Security Officer #5) entered the room along with (Nurse #8) to assist me in gaining control of (Patient #7). (Patient #7) started thrashing and attempted to grab my handcuffs to prevent being handcuffed to the bed putting nicks and cuts on my fingers. Approximately ten to twelve minutes later I told (Patient #7) I would take him out of handcuffs if he agreed to cooperate with medical staff. (Patient #7) agreed. I took (Patient #7) out of handcuffs without further incident." Interview on 10/21/2011 at 1200 with nurse #8 revealed, "The patient was trying to leave, (Physician #4) said 'you can't leave I'm going to IVC you'...we did have to do a therapeutic hold...I think I was at the waist, he was taken to the floor	A 395		

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A 395	Continued From page 173 and he started to fight...there were 3 or 4 people, maybe, I don't remember...he was down about 20 seconds...I'm not 100% sure if the CPO put hand cuffs on him...we helped him to stand and walked him back to his room...(Physician #4) was there and saw the patient before and after (the hold)..I don't remember (patient #7) head butting the glass..." Interview revealed "...Hand cuffs are restraints when used by duly swore officers, but it is the ultimate responsibility of the nurse to monitor the patient...there are ways to walk a patient back without cuffs...I don't remember him being cuffed to the bed...there was a nurse in the room when I left..." Further medical record review for Patient #7 revealed no documentation of how long the patient was on the floor, the patient's condition while on the floor, how the patient was held on the floor, what security staff where involved in the hold, or of the use of handcuffs by CPO staff to restrain the patient. Record review revealed patient #7's vital signs were not reassessed until 0952 on 06/30/2011 (1 hour and 4 mins after held to floor and subsequently handcuffed to the bed). Record review revealed no documentation of an assessment of the patient's wrists. Interview on 10/21/2011 at 1445 with administrative nursing staff confirmed nursing did not reassess the patient's vital signs per policy after a physical restraint/hold or after the patient was handcuffed. 3. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at	A 395		

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A 395	Continued From page 174 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review of Nurse # 5's notes dated 04/24/2011 at 0458 revealed. "...PT continues to be very agitated and begin(n)ing to self infilct. slapping slef (self) over body and arms...No orders given..." Record review revealed ED physician #3 ordered "Restraints-Mechanical...Leather 4 point" on 04/24/2011 at 0501 and "Ziprasidone (medication for short term control of severe agitation) 10 mg Inj.(injection)" and "Lorazepam (medication used to calm and treat anxiety) 2 mg IM (intramuscular injection) " on 04/24/2011 at 0502. Record review of " Restraint/Seclusion Orders, " dated 04/24/2011 at 0511, revealed the following types of restraints were ordered by the physician: "Side Rails intended to restrict bed exit...Chemical...RUE (Right Upper Extremity) (rigid), LUE (Left Upper Extremity) (rigid), LLE (Left Lower Extremity) (rigid), RLE (Right Lower Extremity) (rigid)..." Record review of Unit Secretary's note dated 04/24/2011 at 0524 revealed the patient was moved to bed "Blue 26 South" (outside locked Psych Unit). Record review revealed Ziprasidone and Lorazepam, chemical restraints, were administered at 0528 and 0529, respectively, by nurse #6. Record review revealed the 4 point (bilateral wrists and ankles) leather (rigid) restraints were initiated at 0529. Record review of Unit Secretary's note dated 04/24/2011 at 0539 revealed Patient #2 was moved to "RED 63 South" (outside locked Psych Unit). Record review of Nurse #6's notes dated 04/24/2011 at 0551 revealed "Pt moved to room 63 from 29 on stretcher, in 4 point restraints. Pt on cardiac monitor, nibp (blood pressure) cuff and spo2 (Oxygen) monitor. Pt still rocking back in forth in bed from side to side and	A 395		

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A 395	Continued From page 175 shaking his legs. Pt sinus tach (tachycardia -elevated heart rate) in 140's - 150's on monitor. (Physician #3) aware." Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing (throwing) his body against the doors tot he (of the) unit. With assistance of Security Guard # 3 and CPO (Company Police Officer) # 2 PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "...(Nurse #5) HEAD STRUCK WALL DURING PHYSICAL ALTERCATION (with Patient #2)..." Report review revealed a narrative stating "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical force had to be used to retain the patient." Further review of report revealed narrative continued stating "...(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with (Security Officer #3), (Nurse #5), and (Security Officer #4) used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. After the patient was	A 395		

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A 395	Continued From page 176 restrained and under control I placed my handcuffs onto the patient so that (Patient #2) wouldn't injury himself or any others. At no time did I, security or medical staff strike Mr (Patient #2) and Mr (Patient #2) did not strike any of us. Medical staff arrived and administered medication...by giving him an injection in his left arm and left buttocks that would help calm him down...walked the patient back to room 66 until a stretcher arrived so that four point's restraints could be placed on the patient by medical staff... (Patient #2)'s vitals and heart rate were monitored after the incident by medical staff...(Patient #2) had an elevated heart rate and was moved out of the Psych area into treatment room 29 so that he could be monitored more closely. (Nurse #5) fell against the wall striking his head during the physical altercation." Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Report review revealed CPO #2 placed handcuffs on Patient #2. Interview with Security Officer #4 on 10/21/2011 at 0930 revealed "When I responded the patient (#2) was wrestling (staff). I went in and observed (Patient #2) was trying to assault staff. (I) grab him around the waist to calm him down." Interview revealed the staff involved in the restraint of Patient #2 were Nurse #5, Security Officers #3, #4 and CPO #2. Interview revealed "(Patient #2) went to the floor as I arrived, CPO and Security had his arms, I grabbed his waist so he wouldn't get hurt. (Nurse #5) was on the floor in the mist of everything, he went down first...he was off to the side rolling holding his head...The psych nurse was checking on (Nurse #5). I (Security #4) was down on the ground with the	A 395		

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A 395	Continued From page 177 patient. (Security #3) and (CPO #2) were standing over talking to the patient while he was down. We picked him up, he walked on his own, we escorted him back to the room. The psych nurse was checking on (Nurse #5)...I don't know who put restraints on the patient, he ended up being transported to another room, I don't know why he was transported out of psych..." Interview revealed there was no nursing staff directing security or monitoring the patient during the therapeutic hold or handcuffing of the patient. Interview with Nurse #5 on 10/19/2011 at 0950 revealed "The patient (#2) was throwing himself against the doors...to prevent harm I, security, and a CPO tried to get him to the floor. I ended up under all 3 and the patient...the BCH (psych) nurse pulled on my leg to get me." Interview further revealed "I don't have any current training in deescalation, CPI (Crisis Prevention Institute) or NCI (Nonviolent Crisis Intervention), it was many years ago. I've never had any CPI, NCI at this hospital, they offer training but I've never had training at this hospital." Interview revealed nursing staff were distracted from directing security staff and monitoring the patient during the therapeutic hold and handcuffing of the patient.	A 395		
A397	482.23(b)(5) PATIENT CARE ASSIGMENTS A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. This STANDARD is not met as evidenced by: A 397 Based on policy review, medical record review,	A397	**The plan of correcting the specific deficiency cited/procedure for implementing the acceptable plan:** It is the responsibility of the resource nurse/supervisor of the ED to make the staffing assignments for each shift. There is to be direct oversight by the Director of the ED to ensure that only current NCI certified nurses and nurses with restraint training are assigned to these behavioral health/psychiatric patients. A list of any non certified NCI nurse and any nurse without restraint training is to be provided to each resource nurse/supervisor in the ED. It is mandatory for ED nurses to obtain and maintain a current NCI certification as well as receive the annual education on restraints.	

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A397	Continued From page 178 video taped footage review, personnel file review, staff interview, and hospital investigation documentation, the hospital failed to ensure nursing staff were trained and competent to ensure the safe and appropriate physical restraint of patients for 2 of 3 sampled patients that were physically restrained by staff (Patients #5 and #2). The findings include: Review of hospital policy entitled "Restraints, Seclusion, and Safety Devices" dated 06/28/2010 revealed, "POLICY:...5. THERAPEUTIC HOLD - The brief physical holding of a patient in a manner that restricts his/her movement for the purpose of calming or providing physical safety to the patient, other patients, staff members or others. A therapeutic hold is used only by individuals trained in therapeutic hold techniques, and only when less restrictive measures have been attempted and have been determined to be ineffective....PROCEDURES:....2. TRAINING: Hospital staff involved in meeting the patient's needs are educated upon hire before they participate in the use of seclusion/restraint and annually thereafter. Training can be completed via didactic class or online self-study with successful completion of a post-test and competency. Hospital staff includes personnel from the following areas: Nursing,...Training Requirements Include: a. The underlying causes of threatening behavior. b. Less restrictive alternative. c. Proper and safe application/removal...of restraints. d. Monitoring patient's physical/psychological status...." 1. Closed record review for Patient #5 revealed a 27 year-old male with a history of schizophrenia	A 397	The Vice President of Post Acute Care has issued a mandate for Allied Barton (contract agency for security) to obtain and maintain a current NCI certification as well as receive annual education on restraints. This is required for the security officers and the company police officers. In the event of any non certified NCI security officer or company police officer (i) they are not to be assigned to the ED or (ii) respond to any area within the hospital whereby care of the behavioral health/psychiatric patient resides unless there are criminal and/or emergent situations and no other alternative is available. The same procedure applies for the officers without restraint training. Security officers and company police officers will be aware that in addition to doing what is in the best interest of the patient they also have responsibility for the protection of other patients and staff. It is the responsibility of the Vice President of Post Acute Care to ensure the contract company (Allied Barton) follows the policies and procedures of the Health System as well as rules established by regulatory agencies. **Monitoring:** The Director of the ED oversees the staffing and scheduling of the ED to ensure there is a resource nurse/supervisor in the ED 24 hours per day, 7 days per week. The resource nurse/supervisor is responsible for assigning NCI certified and restraint trained nurses to care for the behavioral health/psychiatric patient. There is also a house nursing supervisor scheduled 24 hours per day, 7 days per week that has oversight responsibility for the entire hospital.	11/07/2011

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A397	Continued From page 179 presented to the Emergency Department (ED) via Emergency Medical Services (EMS) on 04/17/2011 at 1638 with a complaint of not taking his medication. Record review revealed the patient was involuntarily committed by the physician. Review of RN #1's note at 1929 revealed, "Assumed patient care. Patient awake and alert, breathing even and unlabored. Patient stares at RN, nonverbal. No response to questions or requests. Patient is INVOL(untary)." Review of RN #1's note at 1951 revealed, "Patient more verbal at this time, answering questions. Patient requested water; provided. patient continues to refuse to change into gown." Review of RN #1's note at 2017 revealed, "Patient continued to refuse gown, now stating 'I want my momma. I'm not putting on no mother (expletive) gown'. Patient more active in room, pacing. Patient multiple trips back and forth to bathroom; not following directions of security or nurse. CPO (Company Police Officer) and security to bedside; patient medicated." Review of RN #1's note at 2110 revealed, "Patient pacing in hallway, appears to becoming more agitated. Refusing to stay in room, becoming aggressive with staff. (RN #2) from Psych ED aware of patients increasing agitation; will inform (Physician #2)." Review of RN #1's note at 2120 revealed, "Patient now states he is leaving, attempting to walk to double doors. When patient informed that he must stay in room he became very angry. States 'I need some water'. Patient then picks up water and proceeds to pour water on all staff member. Patient instructed to stop by CPO and water taken from patient. Patient then attempts to leave room and begins to push and punch staff. Patient instructed to stop, refused. At this time patient was restrained by CPO and	A 397	The security officers and company police officers will have evidence of attendance at restraint training and NCI. Copies of this education are to be in the education file of the security officers and company police officers which will be maintained by the health system onsite. An ongoing review of education files will be conducted to ensure current certification and education is maintained for security officers and company police officers. The Director of Security is responsible for the staffing and scheduling of security officers and company police officers to ensure that only NCI certified and restraint trained officers are assigned to the ED or any other location where behavioral health/psychiatric patient care is provided. An ongoing review of education files will be conducted to ensure current certification and education is maintained for ED nurses, security officers and company police officers. **Responsibility:** Vice President of Nursing, Vice President of Post-Acute Care	11/07/2011 11/07/2011

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A397	Continued From page 180 security. This RN then left area to inform Psychiatrist of situation. Upon returning to Psych area security states that patient has stopped resisting. When patient was moved to stretcher he was noted to have agonal respirations. Patient moved to resus(citation) room at this time." Review of RN #1's note at 2125 revealed, "Patient was being bagged with BVM (bag-valve mask). Upon arrival to resus room patient was pulseless, asystole on monitor; CPR (cardiopulmonary resuscitation) started." Review of RN #1's note at 2217 revealed, "Resuscitation attempts unsuccessful; efforts stopped. TOD (time of death) 2211." Record review revealed patient's body was sent to the Office of the Chief Medical Examiner for autopsy. Review of the "Report of Autopsy Examination" dated 09/06/2011 and signed by a physician from the Medical Examiner's office revealed, "Date of Exam 04/18/2011....SUMMARY AND INTERPRETATION....Based on the history and investigative findings, it is my opinion that the cause of death in this case is asphyxia due to restraint." Review on 10/18/2011 at 1130 and on 10/20/2011 at 1130 of video taped footage of the Psychiatric Area of the ED dated 04/17/2011 and beginning at 2113 revealed two different views were recorded. Review on 10/18/2011 with a staff member from the ED (to identify staff in footage) and legal department staff revealed the camera angle from down the hall that showed Room 65 on the right side of the hall. Review on 10/20/2011 with the Vice President of Nursing and legal department staff revealed the camera angle was from down the hall and looking directly into Room 65. Review of the footage revealed	A 397		

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A397	Continued From page 181 the patient was physically restrained from 21:15:26 (when CPOs begin to hold the patient by his arms and then go to the floor with the patient at 21:15:30) until 21:17:50 (when staff lift the patient off of the floor and place him on a stretcher). Further review of footage revealed the following events at the following times: 21:15:25 - RN #1 turns away from the patient's room and walks down the hall. The 2 CPOs are holding the patient's arms, one on each side. (No nurse in room as physical restraint is initiated by CPOs). 21:15:26 - Patient lifts up slightly and sits on bed. (CPOs still beside of and with hands on the patient). 21:15:28 - RN #1 looks over shoulder then turns around and faces the patient's room. SO #1 and SO #2 head into room. CPO #1 leans down towards bed. CPO #2 not in view. 21:15:29 - RN #1 turns back away from and continues to walk away from room. Patient is visible standing and facing towards the right side of the room. CPO #1 goes behind the patient. CPO #1 lifts his right arm out with elbow bent and moves it towards the patient. 21:15:30 - CPO #1's arm not visible. CPO #1 is leaning forward or bending down. Patient not visible. SO #1 and SO #2 in doorway looking in. CPO #1 and patient go backwards (towards left side of room) together. CPO #2 comes into view with in front of patient with his arms extended, but hands not visible. RN #1 looks back towards room again, then turns and continues to walk away from room. 21:15:31 - Patient's right hand is in the doorway, holding onto the door jam. The 2 Security Officers are still in the doorway. Both CPOs face the doorway as they and the patient are going	A 397		

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A397	Continued From page 182 down. Video footage review revealed the CPO and Security staff continued to physically restrain the patient on the floor with no nurse present to monitor the patient until 21:16:35, when RN #2 entered the room. Personnel file review for RN #1 revealed the staff member was hired on 12/04/2000 and became a registered nurse during 2005 and remained employed at the hospital. File review revealed the nurse worked in the ED until 05/21/2011, at which time she moved and terminated employment. File review revealed no documentation the nurse received NCI (Nonviolent Crisis Intervention) training during her employment at the hospital. Interview on 10/19/2011 at 1215 with the Service Line Director of Emergency Services revealed NCI (Nonviolent Crisis Intervention training) is required for all permanent ED staff within a year of hire. Interview revealed nurse should be present throughout a physical restraint. Interview revealed, "A tech can assist, at time security can assist, but we try not to use them. They follow the direction of nursing staff. The nurse should be clinically directing and overseeing that (the physical restraint). (The physically restrained patient) is monitored more often. A behavioral health emergency is the same as a medical emergency. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #1 received NCI training during her employment at the hospital. Further interview with the Vice President on 10/20/2011	A 397		

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A397	Continued From page 183 at 1130 with the Vice President of Nursing during video taped footage review of the physical restraint of Patient #5 on 04/17/2011 confirmed nursing staff was not continuously present and did not continuously supervise the restraint. Further interview confirmed nursing staff did not continuously monitor the patient to ensure safety during the physical restraint. 2. Closed medical record review for patient #2 revealed a 42 year old male presenting to the hospital's Emergency Department (ED) via Emergency Medical Services on 04/24/2011 at 0203 involuntarily committed (IVC) for a psychiatric evaluation. Record review of Nurse # 5's notes dated 04/24/2011 at 0650 revealed "Late entry (not timed) PT became extreamly (extremely) agitated unable to verbally deescalate. PT pacing and shouting in room. Unable to obtain additional orders. Pt charged from room and begain (began) thoughing (throwing) his body against the doors tot he (of the) unit. With assistance of Security Guard # 3 and CPO (Campus Police Officer) # 2 PT was placed in a threaputic (therapeutic) hold and assited (assisted) to the floor. As to prevent harm to self." Record review revealed Security Guard #3 and CPO #2 assisted Nurse #5 in the therapeutic hold of patient #2. Review of Hospital's Security Company's document titled "INCIDENT/INVESTIGATION REPORT" prepared by CPO #2 and dated 04/24/2011 revealed "On Sunday April 24th, 2011 at approximately 0500 hrs while in the psychiatric department patient in room 66 came combative to where he attempted to escape the psychiatric department through the double doors. Physical	A 397		

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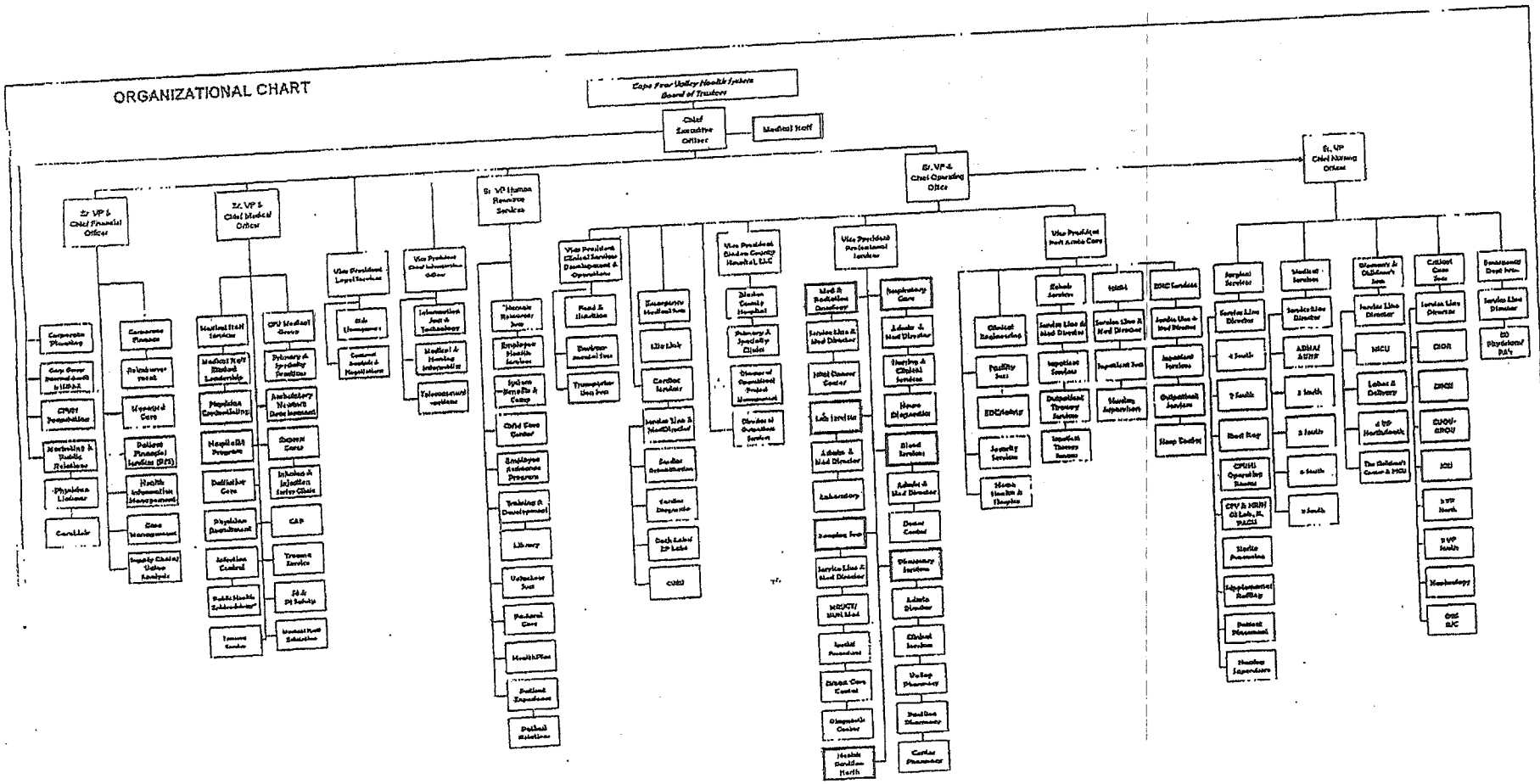
A397	Continued From page 184 force had to be used to retain the patient. Further review of report revealed narrative continued stating "...(Patient #2) tried to leave through double doors...by hitting and kicking the doors... (CPO #2) along with (Security Officer #3), (Nurse #5), and (Security Officer #4) used soft hands on Mr.(Patient #2) so that lay him on to the floor so that we could better restrain the patient. Report review revealed Patient #2 was restrained on the floor by Nurse #5, Security Officers #3 and #4, and CPO #2. Personnel file review for RN #5 revealed the staff was a contracted agency nurse that began work as a psychiatric nurse in the ED on 02/07/2011. File review revealed the nurse's contract expires on 11/26/2011. File review revealed no documentation the nurse received NCI training or other nonphysical intervention skill training during his employment at the hospital. Interview on 10/19/2011 at 0950 with RN #5 revealed the nurse had not received NCI training or other nonphysical intervention skill training in many years. Interview revealed the nurse was aware NCI training was offered at the hospital, but he had not been required to take it. Interview on 10/19/2011 at 1510 with the Vice President of Nursing confirmed there was no documentation that RN #5 received NCI training during his employment at the hospital. NC00076070	A 397		



Attachment 1

Staff Education for Behavioral Health/Psychiatric Patients and EMTALA

At the beginning of each shift there will be a huddle to discuss the process for ensuring the safety of our Behavioral Health patients. It is important to remember the Registered Nurse is ultimately responsible for the clinical care and safety of the patient. The following information is to be reviewed every shift:

- Read and review the "Restraints, Seclusion and Safety Devices" policy.
  - Define restraint, seclusion (do not use in the ED), therapeutic hold and forensic restraint.
  - Forms:
    - Restraint/seclusion orders
    - Restraint, seclusion assessment and monitoring flow sheet
    - Special observation record-used for 1:1 observation of the patient. Example: suicide precautions and/or four point restraints.

- **Therapeutic hold** is considered a restraint. The restraint order form is required and has to be signed by a physician within 30 minutes. The therapeutic hold has to be ordered in the computer. The physician has to document a face to face assessment within an hour.

- Only a non-violent crisis intervention (NCI) trained registered nurse is assigned in the red zone Psychiatric ED. The RN is never to leave a patient during escalation, combativeness, agitation, etc. The least restrictive measures for de-escalation are to be utilized by the Registered Nurse prior to any type of restraint. The behavior of the patient is to be documented. Only NCI trained personnel are allowed to utilize a therapeutic hold.

Monitoring Process:

- The Supervisor/Resource Nurse in the ED is to ensure staff is placing all restraint orders to include the therapeutic hold order in the computer. The Supervisor/Resource Nurse is to be called by the staff member for every restraint and therapeutic hold initiation. There is a concurrent restraint audit tool to be completed by the Supervisor/Resource Nurse in the ED. The Supervisor/Resource Nurse is responsible at the time of the restraint and or therapeutic hold to ensure compliance.

- A retrospective review of restraints/therapeutic holds is completed by the PI nurse from nursing administration.

EMTALA:

- The Interhospital Transfer (EMTALA) form is to be completed on patients who are being transferred to another facility for reasons such as a higher level of care, services not provided at CFV, etc.

- This form is to be completed by a physician in its entirety. The risks or benefits of transfer are to be individualized according to the patient's illness.

- The original copy of the form stays on the chart and a copy of the form goes with the patient. If formfast is used a copy has to be made to go with the patient. If the duplicate form is used, the original stays in the chart and a copy goes with the patient.

- The EMTALA form cannot be signed by the physician prior to date of transfer. In other words, the EMTALA form is signed within a reasonable time prior to patient departure.

Attachment 2A

Questions for staff interviews

Have you been educated regarding restraints and therapeutic holds?

Is a therapeutic hold a restraint?
Yes

What are the deference between a Therapeutic Hold (Restraint) and a Medical Hold?

A therapeutic hold (restraint) if for Behavioral Health Patients to control behavior that is a danger to the patient or others, a medical hold is used when a confused medical patients is restrained to prevent tubes, IVs being pulled out or climbing out of bed.

If you are placing a NGT in a confused medical patient and have to hold the patients arms while placing the NGT in is that medical or therapeutic hold?

Medical

Describe a therapeutic hold.

A therapeutic hold is for control of the Behavioral Health patient that is physically doing something that can be harmful to the patient or others. Anytime hands are placed on a behavioral health patient to control this type of behavior it is a therapeutic hold.

Who can perform a therapeutic hold?
Only NCI trained employees

Who is in charge of the overall nursing care and safety of the psychiatric patient when multiple members of the health care team are in assistance with the patient?
Nurse, the nurse is in charge of the patients safety at all times am must be the one directing the care of a patient in a descalation or restraint situation. Nursing documentation must show this and that the least restrictive was use first before the most restrictive.

Should the nurse ever leave the patient during a de-escalation or agitated patient?
No

Do all nurses and security officers who work in the psychiatric ED have to be NCI trained?
Yes

Cumberland County Hospital System, Inc.

Administrative Policy - Procedure

TITLE:	POLICY NUMBER	APPROVED BY	EFFECTIVE DATE	Page 1 of 18
RESTRAINTS, SECLUSION, AND SAFETY DEVICES		MN	7/94	

Restraints, Seclusion, and Safety Devices
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Revised Effective	Reviewed/No Change	Originating Department:	Did this Policy Replace Another Policy?	If Yes, Old Policy Title:
1/3/97, 4/23/97, 7/27/98, 6/7/99, 8/9/99, 6/19/00, 04/02, 05/02, 02/03, 02/04, 11/04 8/24/05, 7/27/07, 8/14/07, 9/4/07, 5/20/08, 8/18/08, 10/31/08, 3/23/09, 4/27/09, 5/15/09, 8/31/09, 6/28/10, 6/27/11,11/1/11		Restraint Team	Yes No X	

Cumberland County Hospital System, Inc.

Administrative Policy - Procedure

TITLE:	POLICY NUMBER	APPROVED BY	EFFECTIVE DATE	Page 2 of 18
RESTRAINTS, SECLUSION, AND SAFETY DEVICES		MN	7/94	

POLICY: It is the policy of Cape Fear Valley Health System(CFVHS) to use restraints, seclusion, or safety devices only when justified to prevent a patient from injuring himself/herself, a staff member or others, and when less restrictive measures have been considered (see page 7). The type or technique of restraint or seclusion is the least restrictive intervention that is effective to protect the patient, a staff member or others from harm. Restraints, seclusion, and safety devices are used in a manner that attempts to prevent harm, physical discomfort, embarrassment, or pain to the patient. The patient's basic human rights, dignity, and well-being are maintained and respected. Restraints, seclusion and safety devices are not to be used for punishment or for the convenience of the staff. Restraints are discontinued at the earliest possible time.

NOTE: The Department of Psychiatry and other selected departments have specific policies on restraint and/or seclusion, which are considered Departmental Policies for the purposes of this Policy.

PURPOSE: To provide an organizational approach to restraint, seclusion and safety devices when such means are necessary, utilizing the least restrictive therapeutic interventions and to protect the patient's and/or other's health and safety while preserving the patient's dignity, human rights, and well-being.

DEFINITIONS:

1. RESTRAINT-The term 'restraint' includes either physical restraint or a drug that is being used as a restraint.
    a. A restraint is any manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely.
    b. A drug or medication is being used as a restraint when the INTENT of drug or medication is to control the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's medical or psychiatric condition.
    c. A restraint doesn't include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve physical holding of a patient for the purpose of conducting routine physical exams or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm.

2. RESTRAINT SITUATIONS

There are two categories of restraints:

a. Restraints used to ensure the physical safety of the non-violent, non-self-destructive patient (MED-SURG RESTRAINTS): INTENT of the restraint is for acute medical and surgical care that directly supports medical healing. INTENT of the restraint is to ensure the immediate physical safety of patient, staff member or others. Use of the restraint is to limit mobility or temporarily immobilize a patient related to a medical condition or post-surgical procedure (for example, to ensure that an IV or feeding tube is not removed or that the patient who is incapacitated with a broken hip will not attempt to walk before it is medically appropriate.

b. Restraints used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff member, or others (BEHAVIORAL RESTRAINTS): Used to protect the patient from injuries to self or others in emergency situations where the patient becomes extremely aggressive or violent and where the behavior presents an immediate and serious danger to the safety of the patient, other patients, staff, or others.

c. Vests, soft or rigid limb devices, bed enclosures, immobilizers and mitten that are tied are defined as restraints at CFVHS. The restraint device chosen is determined by the behavior demonstrated by the patient.

3. SAFETY/PROTECTIVE (NOT RESTRAINTS) INTERVENTIONS

NOTE: Safety devices do not require a physician's order for use; however, documentation is to reflect justification for use of device.

a. MEDICAL IMMOBILIZATION – Devices customarily employed during medical, diagnostic or surgical procedures that are considered a regular part of such procedures or tests. EXAMPLES: application of leg restraints during childbirth, body restraint during surgery, arm board during intravenous (IV) administration, restraints during electroconvulsive therapy (ECT), or post-anesthesia care.

b. ADAPTIVE SUPPORT – Mechanisms intended to help a patient achieve maximum bodily function, including braces, orthopedic appliances, wheelchairs, or postural support. Seatbelts used to maintain proper body alignment, balance, and position are examples of adaptive support.

4. AGE OR DEVELOPMENTALLY APPROPRIATE PROTECTIVE/SAFETY INTERVENTIONS – such as stroller safety belts, high chair safety belts, swing safety belts,

high chair lap belts, raised crib rails and crib covers that a safety conscious child care provider outside the health care setting would use to protect an infant, toddler or pre-school child would not be considered a restraint. A staff member picking up, redirecting, or holding an infant, toddler, or preschool; age child would not be considered a restraint.

a. Side Rails on the Versa Care Bed, which do not extent the full length of the bed and allows the patient to easily exit the bed if he/she wishes,, even of all four side rails are raised, are not considered restraints.

b. Side Rails that are in Sections, if not all sections are raised and if the patients is able to easily get out of the bed, if he/she wishes, are not acting as restraints.

c. Raised side rails are not considered restraints in the following circumstances/situations:
   - During transport of patient
   - Specialty beds requiring side rails raised for therapy
   - Stretchers
   - Patient is sedated for medical purposes
   - Patient request
   - Adjunct to mobility or movement

d. Physical Escort: Would include a "light grasp" to escort the patient to a desired location. If the patient can easily remove or escape the grasp, this would not be considered a physical restraint. However, if the patient cannot easily remove or escape the grasp, this would be considered physical restraint and all the requirements would apply.

e. Physical Holding for Medications: In certain circumstances, a patient may consent to an injection or procedure, but may not be able to hold still for an injection, or cooperate with a procedure. In such circumstances, and at the patient's request, staff may hold the patient in order to safely administer an injection (or obtain a blood sample or insert an IV line) or to conduct a procedure.

f. Seizure Precautions: The use of padded side rails in this situation should protect the patient from harm; including falling out of bed should the patient have a seizure.

NOTE: Devices that serve multiple purposes such as tabletop chairs, when they have the effect of restricting a patient's movement and **cannot be easily removed** by the patient constitute a restraint, Use of these devices are not typically used to address violence or aggression, therefore if used to restrict patient movement, their use would be governed by the Med-Surg Restraint guidelines.

5. SECLUSION - The involuntary confinement of a patient alone in a room or area where the patient is physically prevented from leaving for a period of time and is separated from others. Seclusion does not include involuntary confinement of prisoners in the custody of the police or other legal authorities. Seclusion is a method utilized in the Behavioral Health Center.

   NOTE: Contraindications of seclusion include: 1) the patient requires physical or mechanical restraint because of significant risk of self-injury; 2) the patient is claustrophobic

or otherwise extremely fearful of being alone in a room; 3) the patient has a history of abuse in which he/she was locked alone in a room; or 4) the use increases the patient's agitation.

6. THERAPEUTIC HOLD - The brief physical holding of a patient in a manner that restricts his/her movement for the purpose of calming or providing physical safety to the patient, other patients, staff members or others. A therapeutic hold is used only by individuals trained in therapeutic hold techniques, and only when less restrictive measures have been attempted and have been determined to be ineffective.

7. FORENSIC RESTRAINTS - A locking restraint required by legal authorities when a person needs to be restrained to provide for safety or detention by legal authorities for legal reasons when that person is in custody of legal authorities or is under arrest/police hold in accordance with Federal and State laws and regulations (see the Administrative Policy "Forensic Patients and Attendant Law Enforcement/Correctional Officers). The legal authority is responsible for monitoring and maintaining the custody of the prisoner (our patient) and may do so with legal restraint devices so long as the devices do not hamper on-going medical care. Forensic restraint mechanisms (body wraps, handcuffs, manacles, shackles, and other chain-type restraint devices) are not health care restraint interventions and are not applied by the staff of CFVHS.

8. TIME-OUT - Refers to a procedure used to help an individual regain emotional control by removing them from the immediate environment and restricting them to a quiet area or unlocked quiet room in which he/she is not physically prevented from leaving when its use is consistent with the individual's treatment plan. Time-out is a method utilized in Behavioral Health Center.

9. RIGID LIMB DEVICES - May be used when other types of restraints are insufficient to protect the patients or others from harm. Rigid limb devices may be utilized at Behavioral Health Center or in the Emergency Department. The use of rigid limb devices requires direct visualization of the patient as with any 4-point application of restraints. The intent of application (medical-surgical or behavioral) dictates the frequency of flow sheet monitoring/documentation (every 2 hours versus every 15 minutes). Rigid limb devices are sent to Central Sterile Supply for cleaning after each patient use.

   NOTE: For the protection of patient and staff, appropriate discontinuation of rigid limb devices is systematic such that one upper or lower device is removed followed by the opposite upper or lower device. Example: If the right arm is released then the left leg is next. Do not remove rigid limb devices solely on one half of the body, left/right, or top/bottom. Once two limbs are released, the patient is assessed for the need to reapply the devices, or to remove the remaining two restraints.

10. PHYSICIAN – For the purpose of this policy, a physician is a licensed independent practitioner (LIP) defined as Doctor of Medicine, Doctor of Osteopathy or Podiatrist.

PROCEDURES:

1. STAFFING:

An interdisciplinary approach is utilized to provide patient care in a safe, therapeutic environment. Care Team members take an active role in collecting data pertinent to their discipline. Staffing interventions include:

a. Considering assessed patient needs and behavior as well as patient/staff safety when making assignments
b. Flexibility to allow for assignment changes as patient needs/behavior change
c. Consistency in staffing i.e. assigning staff familiar to patient as often as possible
d. Placing patient in room close to Nurse's Station
e. Close frequent observation
f. One to one direct observation for both 4-point leather restraints and 4-point soft restraints on all units

2. TRAINING:

Hospital staff involved in meeting the patient's needs are educated upon hire before they participate in the use of seclusion/restraint and annually thereafter. Training is completed via didactic class or online self-study with successful completion of a post-test and competency. Hospital staff includes personnel from the following areas: Nursing, Transporters, Radiology, Security, Occupational Therapy, Physical Therapy, Speech, Surgical Technicians, Respiratory Therapy, Mental Health Specialists, and Recreational Therapy.

Training Requirements Include:

a. The underlying causes of threatening behavior
b. Less restrictive alternatives
c. Proper and safe application, removal, disposal, and disinfection (rigid, safety enclosure beds) of restraints
d. Monitoring patient's physical/psychological status

3. ADMISSION ASSESSMENT:

Medical/Surgical	Behavioral Seclusion/Restraint
The initial assessment of each individual at the time of admission or intake assists in obtaining information about the individual that could help minimize the use of restraint or seclusion	The initial assessment of a patient identifies: -Pre-existing medical conditions or physical disabilities and limitations that would place the patient at greater risk during the seclusion/restrain. - History of sexual or physical abuse that would place the patient at greater psychological risk during a seclusion/restraint
Patients are reassessed by an RN a minimum of every 24 hours, or more frequently, based on clinical status	

For patients who are at risk, being proactive rather than reacting to the patient's behavior protects that patients health safety and allows the implementation of less restrictive alternative measures.

4. LESS RESTRICTIVE ALTERNATIVES:

Attempts are made to evaluate and/or consider interventions/alternatives such as:

a. Monitoring:
   i. Companionship; friend, guardian or family stay with the patient
   ii. Room near or visible from nurse's station
   iii. Close, frequent observation

b. Environmental Measures:
   i. Decrease stimulation; quiet surroundings, appropriate lighting, relaxing music
   ii. A light/call bell accessible at all times
   iii. Orientation of patient to surroundings
   iv. Occupied bed in low position with brakes locked
   v. Room/halls clear of obstacles such as excess equipment
   vi. Use of bed check alarm device
   vii. Availability of bedside commode/urinal
   viii. Familiar possessions such as photographs, cards, etc.

c. Comfort Measures:
   i. Address pain management or other sources of physical discomfort
   ii. Comfortable positioning and clothing, keeping patient clean and dry
   iii. Reduce noise and avoid waking patient during periods of sleep, if possible

iv. Gentle touch, soothing voice

d. Medication/Nutrition:
   i. Implement interventions necessary to assist in adjustment of treatment to stabilize physiological changes by notifying physician
   ii. Discontinue all lines that may no longer be medically necessary and initiate oral as opposed to IV or Gastric Intestinal tube feedings
   iii. Provide snack/nutritional supplement and assess hydration needs
   iv. Assess for PRN medication

e. Regular Toileting:
   i. Establish consistent toileting schedule; offer every 2 hours
   ii. Encourage patient to ask for assistance at first feeling of toileting need; respond to patient's needs promptly and positively

f. Diversional Activities:
   i. Distract patient with videos, TV, photographs, radio, reading materials, engage in conversation
   ii. Purposeful activity i.e. puzzles or sorting
   iii. Provide alternative activity for hands, i.e. rubber ball, squeezing devices, etc.
   iv. Sensory Aides/Activity Boxes (mobiles, stuffed animals, etc.)
   v. Be sure patient has and is using eyeglasses, hearing aides as appropriate
   vi. Provide alternative system for sensory deficiencies, if needed

g. Education:
   i. Educate patient/family/significant other to patient deficits and have consistent plan of approach; reeducate/remind them of goals/potentials on an ongoing basis
   ii. Specifics of educational content provided is documented on the Interdisciplinary Patient/Family Education Record
   iii. Solicit patient/family/significant other ideas for alternative measures
   iv. Provide patient/family/significant other with opportunities for control; offer choices

h. Interpersonal Skills:
   i. Pleasant, consistent interaction with patient and family/significant other
   ii. Actively listen to patient, calm reassurance
   iii. Family assistance/staff to stay with patient

i. Communication/Interpersonal Relationships
   i. Encourage verbalization of feelings, especially anger
   ii. Acknowledge the patient's tension
   iii. Be physically available to patient during period of increasing tension
   iv. Respect a patient's need for personal space
   v. Set consistent limits on type and degree of aggression tolerated
   vi. Do not ignore threats of physical aggression
   vii. Recognize the need for clear cut staff/patient boundaries
   viii. Avoid sudden movement around a potentially violent patient
   ix. Convey acceptance of the person, but not of the physical behavior
   x. Provide a consistent set of expectations for a patient to develop self control
   xi. Allow the patient to participate actively in his or her care to decrease frustration
   xii. Keep the patient well informed of his/her treatment to reduce fear
   xiii. Validate the patient's feelings of anger

5. APPLICABILITY STATEMENT:

A reassessment of the patient's behavior by the qualified Registered Nurse (RN) at least every calendar day, with input from other disciplines, as appropriate, is critical in determining whether the intervention decision was effective. If the current measure is determined to be effective, consideration is given to a less restrictive measure. Restraints are released as specified in policy and circulatory motor sensory is reassessed. Continuation of restraint use requires a physician order at least every calendar day. The specific nature of the device used to restrain a patient does not in itself determine whether these standards are applied. Rather, it is the device's intended use and/or the identified patient need that determines whether the device triggers the application of these standards. Therefore, these standards do not apply to Medical Immobilization, Adaptive Support or Protective Devices.

6. CLINICAL JUSTIFICATION:

Medical/Surgical	Behavioral Seclusion/Restraint
In Medical/Surgical care, the use of a restraint may be indicated to facilitate medically necessary treatment based on procedure and/or cognitive criteria.	The use of seclusion or restraints (physical or chemical) to manage behavior is an emergency measure that is reserved for those occasions when an unanticipated, severely aggressive or destructive behavior places the patient or others in imminent danger.
Clinical justification includes: • Threatens placement and/or patency of necessary therapeutic lines/tubes and appropriate alternative measures have been attempted. • Examples include self-removal of IV lines, NG tubes, ET tubes or Foley catheter • Interferes with necessary medical treatment and appropriate alternative measures have been attempted • Examples include: picking at open wounds or removing complex dressings • Unable to follow directions to avoid self-injury, and appropriate protective, alternative measures have been attempted. • Example includes: confused patient with unsteady gait repeatedly attempting to get out of bed or chair without assistance	Clinical justification includes: • Harmful to self or others, as evidenced by hitting, hair pulling, striking at or biting staff or family, and/or self-mutilation or serious destruction to unit property, and appropriate alternative measures have been attempted

7. INITIATION & ASSESSMENT:

A qualified licensed staff member with established competencies may initiate seclusion or restraint. Assessment of the patient who has new onset or worsening of confusion/agitation is done by an RN prior to or within 30 minutes of application of a restraint. Assessment includes vital signs/pulse oximetry and blood sugar. See algorithm for Least Restrictive Measure/Assessment of Patient with Confusion/Agitation on Page 19. Staff with established restraint competencies may assist with the application of restraints and the monitoring of the patient's safety while in restraints.

8. TIME LIMITED ORDERS:

A verbal or telephone order is obtained from the physician within 30 minutes of the placement of the restraints.

Medical/Surgical	Behavioral Seclusion/Restraint
The physician's order is to specify: • The seclusion and/or restraint type • The justification for seclusion and/or restraint • Date and time orders	Same as Acute Medical/Surgical
Duration (amount of time restraint/seclusion can last- maximum of one calendar day)	Duration (initial and/or renewal) are time limited to: • 4 hours for adult 18 years of age and older • 2 hours for ages 9 to 17 • 1 hour for under 9 years of age
** Orders are Not to be written as standing orders or PRN, as needed basis	Same as Medical/Surgical
After the patient is released from restraint, a new order for restraint is obtained for each additional encounter.	Same as Medical/Surgical
Renewal orders are required every calendar day when the patient still requires restraint. Renewal of restraints is as follows: Examples: • Restraint orders are renewed by the physician on routine rounds regardless of the initiation time • Example: Restraints initiated at 0400 per telephone order from physician are renewed during routine rounds the same day. The physician provides signature of initial telephone order for restraint and completes a renewal order for restraints if still indicated.	Renewal orders are required: • 4 hours for adult • 2 hours for ages 9 to 17 • 1 hour for under 9 years of age

If restraints or seclusion are discontinued prior to the expiration of the original order, a new order is obtained prior to reinitiating seclusion or reapplying the restraints and the requirements restart. Trial releases are not permitted since this would be considered a PRN. However, a temporary release that occurs for the purpose of caring for a patient's needs- for example, toileting, feeding, therapy, range of motion or perform a procedure—is not considered a discontinuation of the intervention. As long as the patient remains under direct staff supervision, the restraint is not considered discontinued because the staff member is present and is serving the same purpose as the restraint or seclusion.

9. FACE-TO-FACE ASSESSMENT/EXAM:

Acute Medical/Surgical	Behavioral/Seclusion Restraint
The physician is to conduct a face-to-face exam within one calendar day of placement of the restraints and each calendar day thereafter. The physician's signature on the Restraint/Seclusion Orders is evidence the face-to-face assessment/exam has been completed.	The physician, or specialty trained RN, is to perform a face-to-face assessment/exam of the patient upon initiation, if present, or within one hour after initiation of restraints.
This exam is followed by consultation with the patient's treating physician, as soon as possible if the patient's treating physician does not order the restraint.	If a patient remains in restraint or seclusion for the management of violent or self-destructive behavior (behavioral restraint) 24 hours after the original order, the physician must see the patient and conduct a face-to-face re-evaluation before writing a new order for the continued use of restraint or seclusion.
If the patient recovers before the physician's assessment, the physician still assesses the patient within one calendar day.	

10. RESTRAINT/SECLUSION MONITORING:

Medical/Surgical	Behavioral/Chemical/Seclusion Restraint
• Observe the patient and maintain adequate documentation on the Restraint Flowsheet. • Each patient is individually monitored with the intent to prevent harm, maintain well-being, to insure that the physical and emotional needs are met during use, and to address exercise, nourishment, and personal care. • At the initiation of seclusion or restraint, and every 2 hours, a staff member monitors the patient with the intent to: prevent harm and maintain well-being. • Documentation of the physical and emotional needs include but are not limited to: ◆ Signs of injury associated with application of seclusion or restraint ◆ Nutrition hydration ◆ Circulation and range of motion in each extremity ◆ Vital signs ◆ Hygiene and elimination ◆ Physical and psychological status and comfort ◆ Readiness for discontinuation of seclusion or restraint ◆ Trial releases are not permitted	• Staff provides continuous face-to-face observation of the patient in rigid limb restraint(s) and maintains documentation on the Restraint Flowsheet (excluding therapeutic holds less than 15 minutes) and the Special Observation Flowsheet. • If the patient is restrained for behavioral reasons, monitoring is every 15 minutes. At the initiation of seclusion or restraint, and every 15 minutes, a staff member monitors the patient with the intent to prevent harm and maintain well-being. • Documentation of the physical and emotional needs include but are not limited to: ◆ Signs of injury associated with application of seclusion or restraint ◆ Nutrition hydration ◆ Circulation and range of motion in each extremity every 2 hours ◆ Vital signs ◆ Hygiene and elimination ◆ Physical and psychological status and comfort ◆ Readiness for discontinuation of seclusion or restraint ◆ Trial releases are not permitted
• <u>Every 2 hours</u>: ◆ Provide range of motion and monitor circulation and skin integrity in restrained extremities ◆ Offer the patient fluids/nourishment while awake if not contraindicated ◆ Provide hygiene care, as required and PRN ◆ Monitor and document the patient's response to restraints, if negative, reassess patient for other interventions	• Release each extremity, at least every 2 hours, for range of motion exercises, when limb restraints are being used. • <u>Every 2 hours</u>: ◆ Provide range of motion and monitor circulation and skin integrity in restrained extremities ◆ Offer the patient fluids/nourishment while awake if not contraindicated ◆ Provide hygiene care, as required and PRN ◆ Monitor and document the patient's response to restraints, if negative, reassess patient for other interventions

11. CRITERIA FOR DISCONTINUATION:

A patient who requires seclusion and/or restraint is continuously monitored and evaluated for appropriateness of an early release. Evaluation of the patient by an RN, with established competencies, may be based on:

a. Improved mental status
b. Patient's agreement and compliance with instructions for safety
c. Improved ability to transfer or ambulate without risk of injury
d. Less restrictive measures are effective
e. Patient's lines are discontinued or no longer required for medical treatment
f. Patient meets identified behavior criteria

SAFE TRANSPORT PROVISION OF PATIENT BETWEEN ANCILLARY/DIAGNOSTIC/ PROCEDURE AREAS:

g. The physician or RN assess whether the patient needs to remain in restraints, and may be safely transported and adequately monitored in or out of restraints. See Nursing Policy: Assessment and Reassessment, Attachment 1: "Assessment of Patients Clinical Status and Safety Needs Prior to Transport".
h. The RN or therapist contacts the staff in the ancillary/diagnostic/procedure area(s) and individual(s) responsible for transport to coordinate arrangements for care and monitoring if the patient requires maintaining restraint(s) and/or constant supervision.
i. The assigned safety attendant/sitter accompanies a patient in 4 point restraints.
j. Upon arrival in the ancillary/diagnostic/procedure department, the transporter notifies the department staff of the patient's arrival and reminds them of the need for restraint(s) and/or monitoring and remains with the patient until the receiving department staff can arrange to monitor the patient.
k. Staff in the ancillary/diagnostic/procedure department provides care and monitoring as per policy.

12. DOCUMENTATION:

Documentation within the patient's record is to indicate a clear progression in how techniques were implemented with less intrusive restrictive intervention attempted or considered prior to the introduction of more restrictive measures.

Only hospital personnel, who have received training and demonstrated competency, may document information related to the use of restraints within the scope of their license. Each episode of restraint/seclusion use is recorded in the medical record. Documentation includes:

l. The circumstances that led to the use of restraints or seclusion;
m. Consideration or failure of non-physical less restrictive interventions;
n. Medical conditions or physical disability that would place the patient at greater risk. (History of physical/sexual abuse)
o. The rationale for the type of physical intervention selected;
p. The type of restraint used, medications administered, nourishment offered, vital signs, circulation to extremities, range of motion performed, patient response to treatment, patient rights, dignity and privacy maintained, and time released.
q. Written orders for use;
r. Behavior criteria for release from restraint or seclusion;
s. Informing the patient of behavior criteria for release from restraint or seclusion;
t. Each verbal order received from a physician;
u. Injuries that are sustained and treatment received for the injuries; and
v. Death

13. MODIFICATION TO THE PATIENT'S PLAN OF CARE:

The plan of care is to clearly reflect a loop of assessment, intervention, evaluation and re-intervention. Restraint use is in accordance with a written modification to the patient's plan of care, which may occur:

w. At the time of initiating interventions and alternatives to restraint use;
x. After an interdisciplinary team meeting;
y. After determining the least restrictive restraint method;
z. As a result of patient/family education related to restraints;
aa. During the care of the restrained patient
bb. After the restraint has been discontinued.

14. NURSING LEADERSHIP:

Medical/Surgical	Behavioral Seclusion/Restraint
	The Patient Care Manager or designee or Nursing Supervisor is notified whenever a patient remains in seclusion or restraint: • More than 12 hours • Two (2) or more episodes of duration within 12 hours Psychiatric Liaison in Emergency Department may be notified for consultation.

15. RETURN OF RESTRAINTS/SAFETY DEVICES:

Bed enclosures and rigid restraints are cleaned according to department/area policies. Soft limb restraint(s) are cut into three pieces and discarded in the nurses' station trash. Arm immobilizers are cut between metal bars and discarded in the nurses' station trash. Mitt netting is cut out and the device is discarded in the nurses' station trash. Vests and straps are destroyed by cutting into several pieces and discarding in nurses' station trash. Restraints are not to be sent home with a patient or with the patient to another facility.

16. NOTIFICATION OF INJURY:

If a patient receives an injury while in a restraint, staff present completes a Quality Care Control Report (QCC). In addition, if there is a serious injury or death related to the use of restraints, Corporate Risk Management is notified by phone or in person.

17. NOTIFICATION OF DEATH:

a. The hospital reports to the Centers for Medicare and Medicaid Services (CMS) death that occurs (1) while a patient is restrained or in seclusion; (2) within 24 hours of patient being restrained/secluded, or (3) within seven days of restraint/seclusion when it is reasonable to believe the death is directly related to the patient being restrained. A Nursing Supervisor reviews each death to determine if it meets reporting criteria. If so, a Restraint/Death Notification form is completed. The completed form is delivered to Corporate Risk Management promptly to allow time for reporting to CMS the next business day following the patient's death.
b. The completed form, as reported to CMS, is forwarded from Corporate Risk

Management to Health Information Management (HIM) with an annotation on the form of the date and time the death was reported to CMS. This form is filed in the deceased patient's medical record.

18. PERFORMANCE IMPROVEMENT:

A Central Log of all patients in restraints is kept by Nursing Performance Improvement. Cape Fear Valley Health System collects data on the use of seclusion and restraint in order to monitor and improve its performance and process and to understand the root cause of seclusion or restraint, identify trends, evaluate and create alternatives to seclusion or restraint. Data is reviewed by the Nursing Oversight Committee.

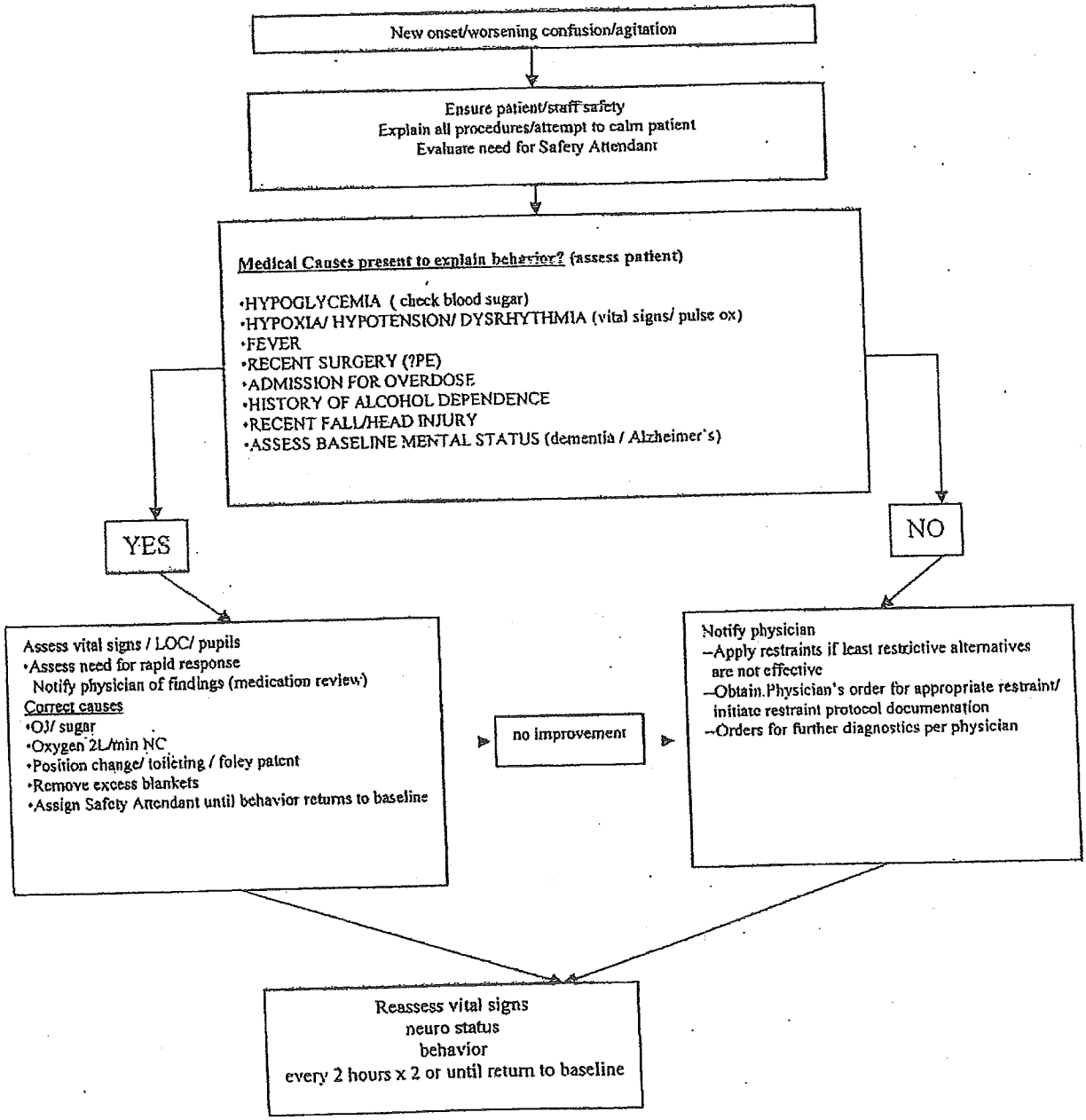
The data is to include:

a. Date initiated
b. Shift initiated
c. Day of week
d. Patient name
e. Patient age
f. Account Number
g. Type of Restraint
h. Number of episodes per department

Cumberland County Hospital System, Inc.
Administrative Policy - Procedure

TITLE: RESTRAINTS, SECLUSION, AND SAFETY DEVICES	POLICY NUMBER	APPROVED BY MN	EFFECTIVE DATE 7/94	Page 18 of 18

Least Restrictive Measures/Assessment of Patient with Confusion/Agitation



FORM IS NOT A PART OF THE MEDICAL RECORD

Mar 20 2009

Order Date_____ Order Time_____ **RESTRAINT/SECLUSION ASSESSMENT & MONITORING FLOW SHEET**
SMS Order #_____ ☐ Acute Medical/ Surgical ☐ Behavioral ☐ Seclusion

Type of Restraint:
☐ Side Rails intended to restrict bed exit ☐ Geri/Tabletop Chair ☐ Vest ☐ Enclosure Bed ☐ Chemical ☐ RUE (soft) ☐ LUE (soft)
☐ LLE (soft) ☐ RLE (soft) ☐ RUE (rigid) ☐ LUE (rigid) ☐ LLE (rigid) ☐ RLE (rigid) ☐ Seclusion ☐ Therapeutic Hold ☐ Immobilizers
☐ Mitts with ties

CATEGORY 1: Acute Med/Surg Justification: (check all that apply)
☐ Pulls at necessary lines/tubes
☐ Interferes with necessary treatment
☐ Is unable to follow directions to avoid self-injury

CATEGORY 2: Behavioral/ Seclusion: (check all that apply)
☐ Is harmful to self as evidenced by hitting, pulling hair or self mutilating
☐ Is harmful to others as evidenced by hitting, pulling hair, striking at or biting others
☐ Has caused serious destruction to unit property

Least Restrictive Measures that have been tried or considered: (check all that apply)
☐ Verbal Intervention ☐ Direct Observation ☐ Family/friend attends/sits with ☐ Structure/limit setting, activities, noise control, etc.
☐ Environmental Modification (placed near nurse's station, etc.) ☐ Other (specify): _____

☐ Restraint Care Plan Updated
☐ Explanation of restraint use ☐ Criteria for discontinuation of restraint to: ☐ Patient ☐ Family ☐ No Family Available

Vital Signs prior to initiation: BP: _____ T:____ P:____ R:____ Pulse Ox: _____ Blood Sugar (Accuchek) prior to initiation: _____

Document Monitoring/Activity Every 2 hours for Acute Medical/Surgical or every 15 min for Behavioral Restraint (use legend below)

Skin	ROM	Restraint	Position	Fluid/ Nourishment	Toileting	Behavior (use all that apply)	
I = Intact	Y = Yes	I = Initiate	O = Out of bed	PO = By Mouth	Y= Yes	1.Calm (Consider D/C of restraint)	6. Pulling at necessary tubes/lines (ET tube, IV, Chest tube, etc...)
*R = Reddened	N = No	C = Continue	R/L = Rt/Left	TF = Tube Feed	* N = No	2. Cooperative (Consider D/C of restraint)	7. Repeatedly attempts to get out of bed/chair unassisted with potential for self-injury
* B= Broken	S = Sleeping	D=Discontinue	S = Supine	*N = No	I = Incontinent	3. Sleeping	8.Threatening
*M = Mottled	AM = Ambulate		B = Back	NPO = Nothing by mouth	F = Foley	4. Agitated	9. Combative
						5. Confused when awake	10. Yelling

Circle and describe variations in nurse's notes.

Time (00-23hrs) (Start new flowsheet for each new order)																											
Skin																											
ROM																											
Restraint or Seclusion																											
Position																											
Fluid/Nourishment																											
Toilet Offered																											
Behavior																											
15 Minute Checks																											
Staff Initials																											

Staff Signature	Printed Name	Initials	Staff Signature	Printed Name	Initials

Cape Fear Valley Health System
P.O. Box 2000 / Fayetteville, NC 28302
RESTRAINT/SECLUSION ASSESSMENT & MONITORING FLOW SHEET

NN0330

0440; Lawson #007922; 8/7/07, 8/15/11

CAPE FEAR VALLEY HEALTH SYSTEM

Fayetteville, North Carolina

DATE	HOUR	RESTRAINT/SECLUSION ORDERS
		Orders preceded by a ☐ require a √ to activate. Fill in blanks if applicable. Initial each page of the order set. Initial any change, addition or deletion.
		Reason/Justification for Restraint:
		Category 1: Acute Med/Surg:
		☐Threatens placement and/or patency of necessary lines/tubes
		☐ Interferes with necessary treatment
		☐ Is unable to follow directions to avoid self-injury
		Duration Acute Med/Surg:
		Utilize for one calendar day **OR** ☐ Next _____ hours.
		Category 2: Behavioral/ Seclusion:
		☐ Is harmful to self as evidenced by hitting, pulling hair, self mutilating
		☐ Is harmful to others as evidenced by hitting, pulling hair, striking at or biting others
		☐ Has caused serious destruction to unit property
		Duration Behavioral/Seclusion (limited to the following):
		☐ 4 hours for ages 18 years or older
		☐ 2 hours for ages 9 to 17
		☐ 1 hours for under 9 years of age
		Type(s) of Restraint(s):
		☐ Side Rails intended to restrict bed exit ☐ Geri/Tabletop Chair ☐ Vest ☐ Enclosure Bed ☐ Immobilizers
		☐ Mitts with ties ☐ RUE (soft) ☐ LUE (soft) ☐ LLE (soft) ☐ RLE (soft) ☐ Chemical ☐ Seclusion
		☐ Therapeutic Hold ☐ RUE (rigid) ☐ LUE (rigid) ☐ LLE (rigid) ☐ RLE (rigid)
		Least Restrictive Measures that have been tried or considered: (check all that apply)
		☐ Verbal Intervention ☐ Direct Observation ☐ Family/friend attends/sits with
		☐ Structure/limit setting, activities, noise control, etc.
		☐ Environmental Modification (placed near nurse's station, etc.)
		☐ Other _____
		Physiological Assessment (prior to initiation of restraint):
		Vital Signs: (TPR, BP, Pulse ox)
		☐ Accu-Chek if indicated (change in physical or mental status)
		Physician Assessment:
		I have performed the face-to-face physical and psychological evaluation of this patient.
		This evaluation does not indicate physical or psychological contraindications to the ordered restraint.
		Physician Signature: Date: Time:
		Print/Stamp Name:

Admitting Diagnosis:

Patient ID Label

PHYSICIAN'S ORDERS TAB 3

PO0005

Attachment 4

Cape Fear Valley Health System
ValleyLink Clinicals
CFVHS Restraint Orders
10/31/2011 6:10:42PM

CFVMC

PatientName EnteredDateTime	StopDateTime	BirthDate	MRN RequestedBy	ACCT#	OrderDescAsWritten ReasonForRequest	Svc	Bed
KAITLYNNE CORBETT 10/31/2011 5:45:00PM	10/31/2011 5:48:00PM	10/09/1995	935513 SAMUEL REINER, MD	1001668263	BEHAVIORAL RESTRAINT Stat Q2H Until 10/31/2011 5:48:00 PM Has caused serious destruction to unit property	CED	
KAITLYNNE CORBETT 10/31/2011 5:49:00PM	10/31/2011 5:51:00PM	10/09/1995	935513 SAMUEL REINER, MD	1001668263	BEHAVIORAL RESTRAINT Stat Q2H Until 10/31/2011 5:51:00 PM Is harmful to others by hitting,pulling hair,striking or biting	CED	
CYNTHIA MCDONALD 10/30/2011 11:34:00PM		01/25/1978	339256 BLAKE ILLSTON, DO	1001672759	BEHAVIORAL RESTRAINT Stat Restraint Harmful to self by hitting, pulling hair, self mutilation	EBS	
CYNTHIA MCDONALD 10/30/2011 11:45:00PM	10/31/2011 10:46:00PM	01/25/1978	339256 BLAKE ILLSTON, DO	1001672759	ACUTE MED/SURGICAL RESTRAINT Q24H Until 10/31/2011 10:46:00 PM Threatens placement and/or patency of necessary lines/tubes	EBS	

Number of restraint orders for CFVMC - 2

3SOU ROBERT JOHNSON 10/31/2011 4:38:00AM		01/19/1929	304767 BABATUNDE A. OJO, MD	1001672509	ACUTE MED/SURGICAL RESTRAINT Q24H Is unable to follow directions to avoid self-injury	MED	6335ST

Number of restraint orders for CFVMC - 1

3VPS JOHNNY BERRY 10/31/2011 12:09:00PM	11/1/2011 11:00:00AM	11/05/1941	777250 ROUNDER11 VMA	1001672066	ACUTE MED/SURGICAL RESTRAINT Q24H Until 11/1/2011 11:00:00 AM Threatens placement and/or patency of necessary lines/tubes	MED	8329VP

Attachment: 4A

Restraint Audit Tool

Unit	Acct Number	Computer Order #	Episode Date	Is there a signed order present for this episode?	Reason/Justification Documented on order sheet?	Is Order Time limited on order sheet?	Order Renewed in 4 hours (Behavioral)	Order renewed within one calendar day (Medical)	Type of Restraint Marked on Order sheet?	Least restrictive measures documented on order sheet?	Restraint Monitoring Flow sheet completed?	Time restraint discontinued documented on flowsheet?			Comments:

Revised October 20, 2011

Attachment 5

Cumberland County Hospital System, Inc.
Performance Improvement/Patient Safety
Policy-Procedure

TITLE: PI Review of Event Reports	POLICY NUMBER:	APPROVED BY: ESG	EFFECTIVE DATE: October 31, 2011	Page 1 of 3

POLICY: Performance Improvement (PI) / Patient Safety (PS) conducts a review of Quality Care Control Reports (QCCs), Medication Occurrences (MOs), Security and Company Police (CPO) Reports

PURPOSE: The purpose of this policy is to provide guidelines for PI / PS review of quality and safety concerns reported by staff.

PROCEDURE:

1. Review All Reported Events:
   a. Access Midas report titled "PI_Risk". Enter the date preceding the current day (on Mondays, review Friday, Saturday and Sunday reports). This report includes MOs and QCCs entered by staff.
   b. Review any PSRT (Patient Safety Response Team) activations after hours and on the weekends.
   c. Review Security Reports and CPO (Company Police Officer) Reports for quality and/or safety issues.
   d. Respond to verbal/email reports or notifications of quality or safety occurrences.

2. Analysis:
   a. Assess the location/ date/ time of the occurrence, the parties involved and the comments/description of the event.
   b. Determine if more information is needed to analyze error
   c. If more information is needed, perform a preliminary investigation by requesting information from the involved department manager, reviewing the chart and/or interviewing staff.
   d. Utilize the NCC MERP Index (National Coordinating Council for Medication Error Reporting and Prevention) to determine the severity of the occurrence.

3. Determine Disposition:
   a. Events are then categorized as:

      1. Track and Trend
         Occurrences that are usually categorized as A-D. These are tracked over time to identify trends and are reported to HEAT (Harm Events Analysis Team) on a quarterly basis.

      2. Event Response Team (ERT) activations
         The ERT is activated as outlined in the Administrative Policy--Sentinel Event and Root Cause Analysis (RCA).

      3. Requests for Follow-up Action Plan
         These events usually are categorized A-D. In the event that the occurrence does not require an ERT activation or RCA, the Department Manager or Service Line Director may be requested to provide follow-up to the PI Department. The event remains open until sufficient follow-up is obtained. Open events are

reviewed weekly until closed. These are tracked/trended over time and reported to HEAT.

4. Forwarded to Manager/Department for information and education.

5. Referred to a Medical Staff Peer Review Committee (Clinical/Department Performance Improvement Committee).

Medication Occurrences: Additionally, Medication Occurrences are received, reviewed, and followed-up by Pharmacy. Medication occurrences involving nursing are received, reviewed and follow-up by Nursing PI. Medication occurrences involving the medical staff are referred for Peer Review (CPIC/DPIC). Any trends will be reported to PI, HEAT, and appropriate committees.

Security/CPO Reports: Additionally, Security and Company Police Reports are received and reviewed by Director of Security and Vice President of Post-Acute Care Services. These reports are provided to PI and Risk Management. Events involving therapeutic holds or restraint assistance will be identified and will be referred to Nursing PI to verify appropriate use of restraint.

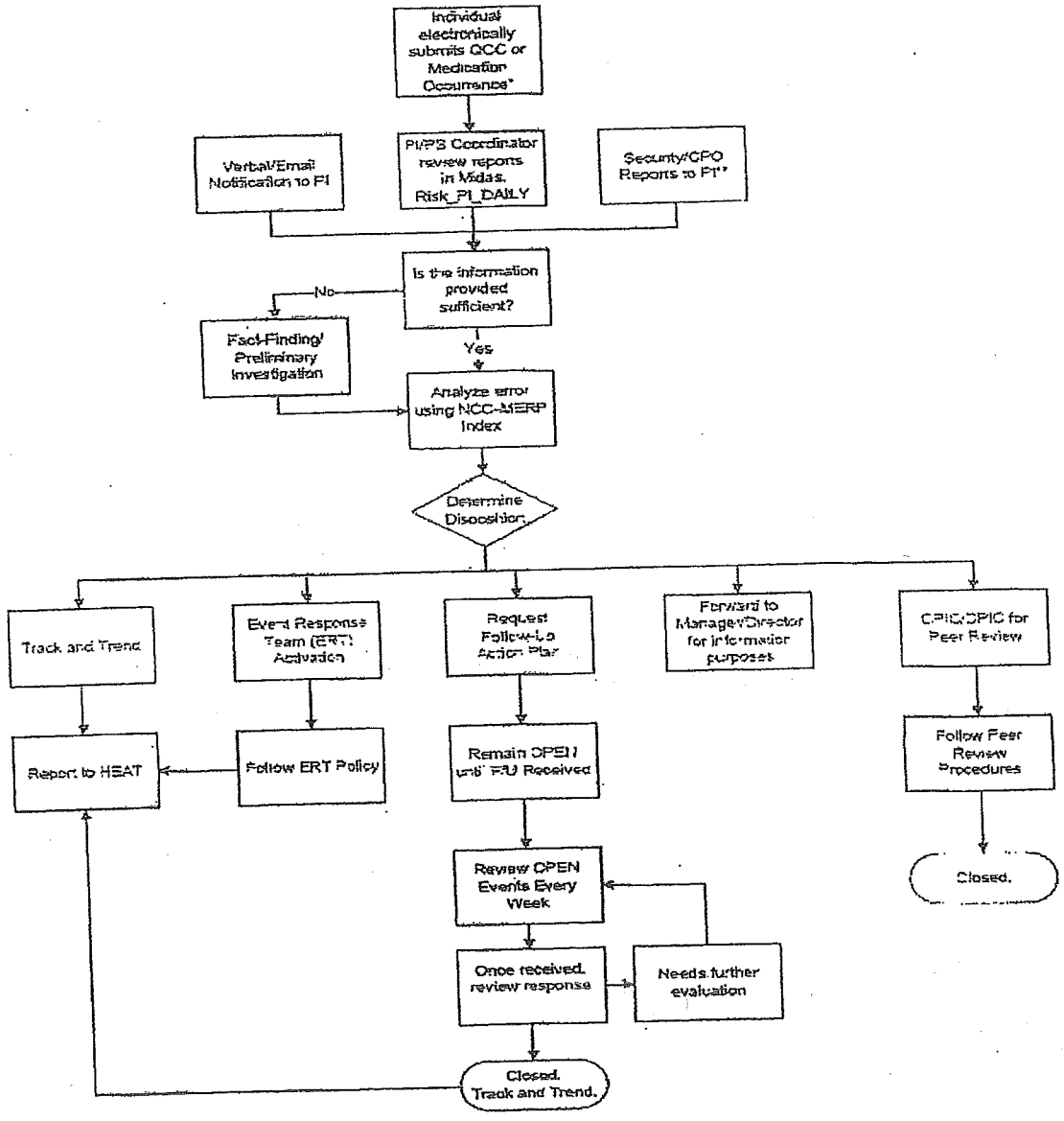
Patient Safety Response Team Activations: Once a PSRT has been convened, an ERT may be activated per policy (See Administrative Policy- Patient Safety Response Team).

Attachments:

- *Performance Improvement Review of Event Reports Process Flowchart*
- *National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Medication Errors and Algorithm.*

Cumberland County Hospital System, Inc.
Performance Improvement/Patient Safety
Policy-Procedure

TITLE: PI Review of Event Reports	POLICY NUMBER:	APPROVED BY: ESG	EFFECTIVE DATE: October 31, 2011	Page 3 of 3



*See Policy "PI Review of Event Reports" for specific procedures regarding Medication Occurrences
** See Policy "PI Review of Event Reports" for specific procedures regarding Security/CPO Occurrences.

Reviewed/Revised:	Reviewed/No Change	Department PI/Pt Safety	Did this Policy Replace Another Policy? No	If Yes, Old Policy Title and Number:

Cumberland County Hospital System, Inc.

Attachment 6

Administrative Policy - Procedure

TITLE:	POLICY NUMBER	APPROVED BY	EFFECTIVE DATE	Page 1 of 3
Patient Safety Response Team (PSRT)		MN	10/28/08	

POLICY: The Patient Safety Response Team (PSRT) is activated when there is an actual or potential serious threat that might cause harm to patients, staff, family members or visitors within Cape Fear Valley Health System (CFVHS).

These safety events include but are not limited to an event that may be classified as a Sentinel Event, defined as an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. Serious risks could include a serious/significant "near miss/close call" event, used to describe any process variation that did not affect an outcome but for which recurrence carries a significant chance of a serious adverse outcome (see Sentinel Events and Root Cause Analysis (RCA) Policy.)

PURPOSE: To provide a rapid response system to prevent/mitigate harm or further injury to patients, staff, and/or visitors when an actual or potential serious threat is identified that might cause harm or injury.

GUIDELINES:

1. Any staff member, patient or family member may activate the system.
2. When a staff member identifies an actual or serious potential threat or is made aware of a serious potential threat by a patient, family member or visitor, the staff members takes immediate action to mitigate risk or prevent further injury (see algorithm).
3. The House Supervisor/Department Manager is notified and an on-site assessment is conducted.
4. Regardless of hour, the House Supervisor/Department Manager activates the PSRT if the potential for serious adverse outcome exists or the potential for further harm exists.
5. The PSRT consists of the Associate Chief Medical Officer for Quality and Safety and/or the Chief Medical Officer or designee, the VP, Service Line Director and/or the manager with responsibility for the area in which the potential threat exists and the Administrator on Call (AOC). In the event that either one or both VPs are not available, the AOC assists or assumes leadership.
6. Within 3 hours of notification, the PSRT completes an on-site assessment (assessment form link http://infoweb3.capefearvalley.com/doc_ref/Patient_Safety_Response_Team.pdf), eliminates/mitigates any immediate threat to safety of patients, staff, and/or visitors, conducts an initial assessment of any further risk of similar incidents or events at Cape Fear Valley Health System or Highsmith-Rainey Specialty Hospital (HRSH.)
7. The PSRT remains on-site until the immediate harm/threat is investigated and action is taken to prevent further occurrences.

Revised Effective	Reviewed/No Change	Originating Department:	Did this Policy Replace Another Policy? Yes No X	If Yes, Old Policy Title:
1/26/09; 10/27/09, 2/28/11, 10/31/11	8/24/09, 4/26/10	Patient Safety & Quality		

8. If the event is the performance of wrong procedure on correct patient, performance of procedure on patient not scheduled for procedure, or performance of correct procedure on wrong site or body part, the AOC contacts the Health Information Management Coding Manager to ensure account is not inappropriately billed.
9. If the event involves the use of equipment, medical supplies, or any other device, the item(s) is removed from use or services until it has been inspected by engineering or Clinical Engineering. Risk Management is contacted about the occurrence.

10. Based upon this risk assessment, the PSRT develops a written action plan outlining further steps to take, utilizing the PSRT form (attachment.) The PSRT notifies the Chief Executive Officer (CEO) and Chief Operating Officer (COO) of the condition that prompted PSRT activation and the current situation/status.

11. The PSRT has access to the full resources of CFVHS to resolve the immediate threat to safety. When the immediate threat to safety situation is resolved and the action plan initiated, a handoff of responsibility to other staff members occurs and any further investigation or corrective actions proceeds. The Event Response Team (ERT), as defined in the Sentinel Event and Root Cause Analysis Policy, makes a determination of the type of action needed (i.e. RCA, Failure Mode and Effects Analysis (FMEA) or departmental action. The ERT also determines the Vice President assigned to the project.

12. Ongoing accountability and monitoring to verify that immediate steps and follow-up is taken is the responsibility of the Department Manager, Service Line Director and respective Vice President.

13. FMEA and RCA findings and action plans are reported to the Harm Events Analysis Team (HEAT), the Quality Council, the Board Quality Committee (BQC) and the Medical Executive Committee (MEC.)

14. All PSRT findings and action plans are reported to the HEAT, who updates the Quality Council, Board Quality Committee (BQC), and Medical Executive Committee (MEC).

Overview diagram of the processes related to the Patient Safety Response Team (PSRT), the Event Response Team (ERT), the Root Cause Analysis (RCA) Team and a Failure Mode and Effects Analysis (FMEA) Team

EVENT

A perceived potential or actual serious threat that might cause harm to patients, staff, or visitors.

INITIAL ON-SITE ASSESSMENT

House Supervisor/Department Manager is notified and conducts an on-site assessment. Immediate action is taken to mitigate risk or prevent further injury.

Regardless of hour, the House Supervisor/Department Manager activates the PSRT if the potential for serious adverse outcome exists or the potential for further harm exists.

ON-SITE ASSESSMENT AND ACTIONS BY PSRT

- Completes an on-site assessment.
- Assessment form:http://infoweb3.capefearvalley.com/doc_ref/Patient_Safety_Response_Team.pdf
- Eliminates/mitigates any immediate threat to safety of patients, staff, and/or visitors.
- Conducts an initial assessment of any further risk of similar incidents or events within the organization.
- Develops a written action plan. Makes recommendations of action to take.
- Notifies the Chief Operating Officer (COO) and the Chief Executive Officer (CEO).
- Confers with Event Response Team (ERT), Risk Management, PI, and Administration.

EVENT RESPONSE TEAM MAKES DETERMINATION OF TYPE OF ACTION(S) NEEDED AND VICE PRESIDENT (VP) ASSIGNED TO PROJECT

Determination that a FMEA is warranted.

Communication of FMEA from team to Department Manager and VP.

Handoff to VP Sponsor of FMEA Team from PSRT within 7 days.

FMEA completed by FMEA Team within 60 days. Reported through the Harm Events Analysis Team (HEAT) to Board Quality Committee and MEC.

Determination that a RCA is warranted.

Department Manager and respective VP monitors situation to verify that immediate steps and follow-up is taken.

Handoff to VP Sponsor of RCA Team from PSRT within 72 hours.

RCA completed by RCA Team within 45 days. Reported through HEAT to the Quality Council to the Board Quality Council

OTHER ACTION warranted (i.e. Departmental process improvement).

Hand-off of information to Department Manager, Service Line Director (SLD) and VP. The VP, SLD and Manager are responsible for implementation of actions

Reported to committees as indicated.

NCC MERP Index for Categorizing Medication Errors Algorithm

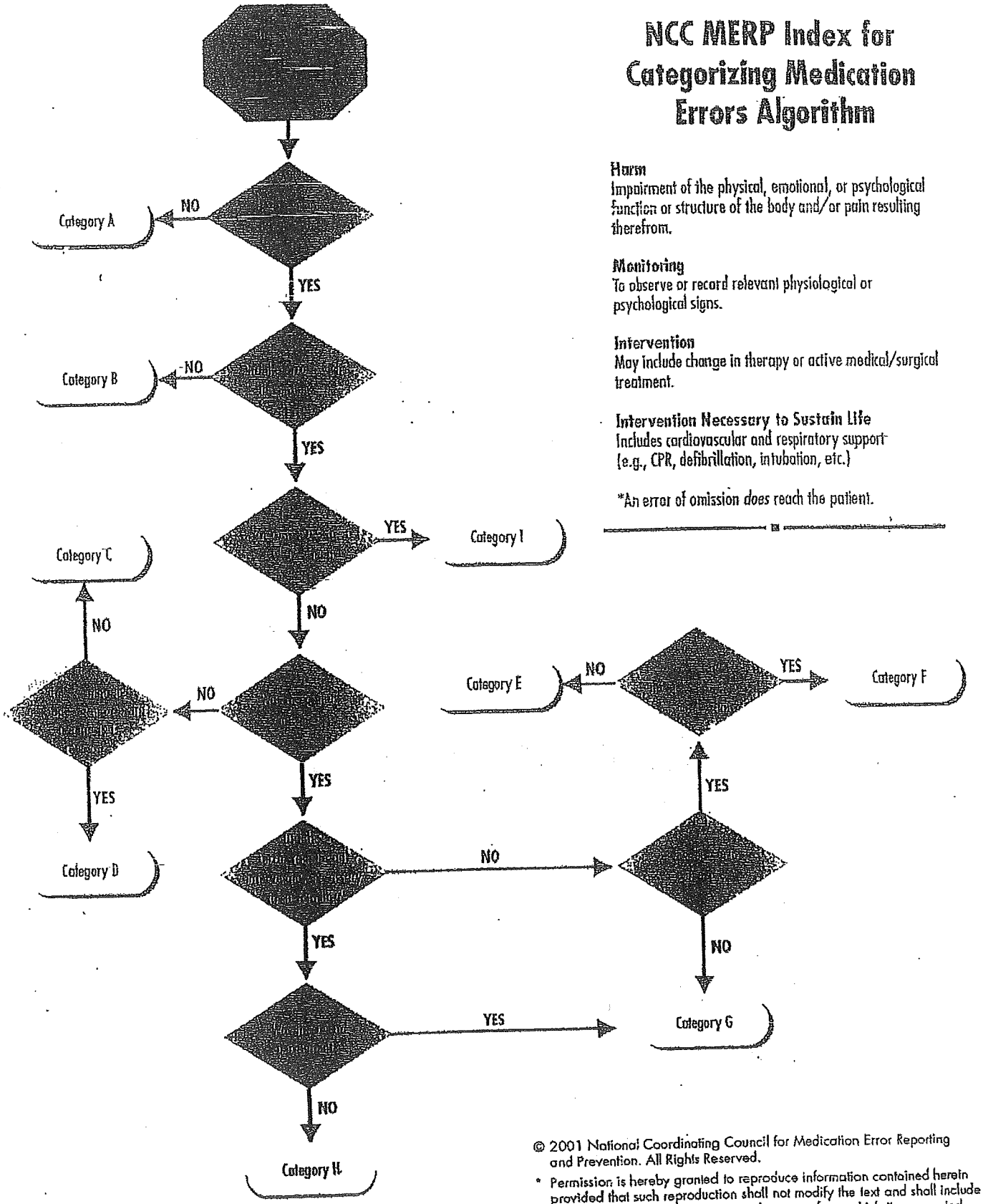
Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

*An error of omission *does* reach the patient.



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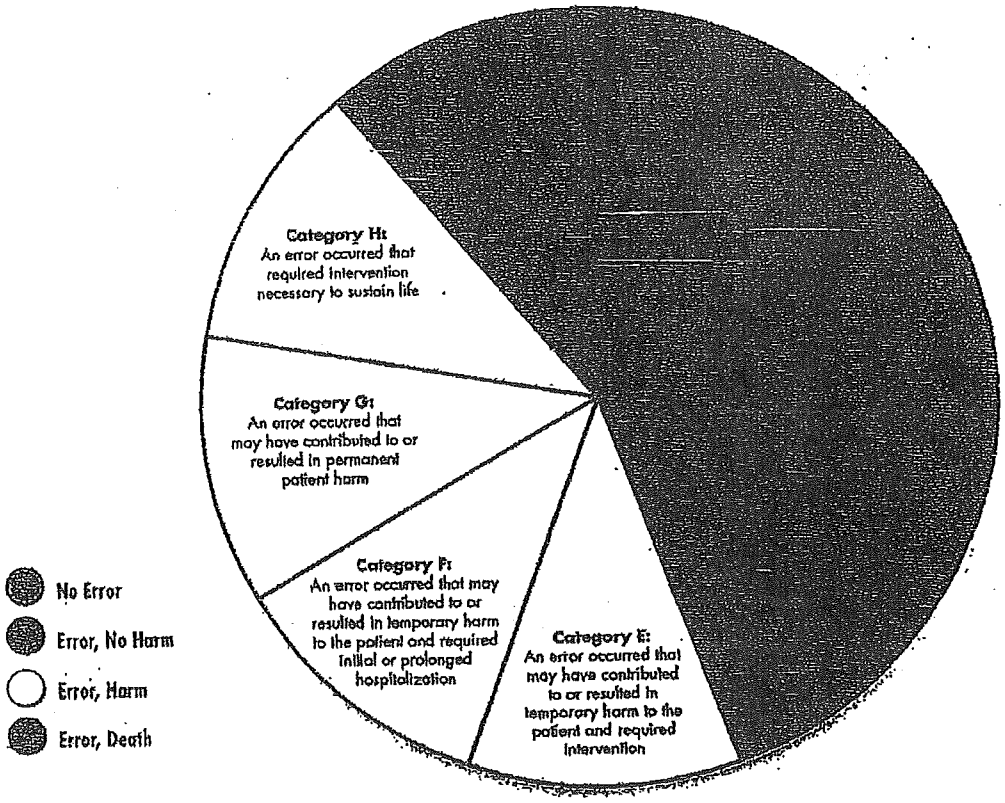
NCC MERP Index for Categorizing Medication Errors



Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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Cumberland County Hospital System, Inc.

Attachment 8

Administrative Policy - Procedure

TITLE:	POLICY NUMBER	APPROVED BY	EFFECTIVE DATE	Page 1 of 5
Sentinel Events and Root Cause Analysis		MN	7/22/98	

POLICY: An interdisciplinary team evaluates Sentinel Events and performs Root Cause Analyses (RCA) and related processes.

PURPOSE: To improve care, maintain a safe environment, and focus attention on the underlying causes to promote risk reduction.

DEFINITIONS:

Sentinel Event: A Sentinel Event is an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Sentinel Events may include but are not limited to:

- Suicide of any individual receiving care, treatment, or services in a staffed around-the-clock setting or within 72 hours of discharge.
- Unanticipated death of a full-term infant.
- Abduction of any individual receiving care, treatment or services.
- Discharge of an infant to the wrong family.
- Sexual abuse/assault (including rape)
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities. (ABO, Rh, other blood groups)
- Invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure.
- Unintended retention of a foreign object in an individual after surgery or other invasive procedures.
- Severe neonatal hyperbilirubinemia (bilirubin greater than 30 milligrams/deciliter).
- Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or greater than 25% above the planned radiotherapy dose.

Event Response Team (ERT): Composed of the CMO, the Associate CMO for Quality and Patient Safety, the Director of Corporate Risk Management or General Counsel/VP of Legal Services, the Director of Performance Improvement/Patient Safety (PI/PS), and the Chief Operating Officer (COO) or respective designees.

Revised Effective: 5/00, 8/01, 12/02, 03/03, 05/03, 07/03, 05/05, 09/28/05, 01/25/06, 03/22/06, 12/06, 5/20/08, 4/27/09, 8/31/09, 10/27/09, 8/22/11, 10/24/11, 10/31/11	Reviewed/No Change 8/23/10	Originating Department: Performance Improvement/ Patient Safety	Did this Policy Replace Another Policy? Yes No X	If Yes, Old Policy Title:

Root Cause Analysis (RCA) Team: Composed primarily of facilitators trained in Failure Mode and Effects Analysis/RCA techniques. Members of the RCA team are selected by the PI/PS Department. Members may change, according to the type of event that occurred. A member of the PI/PS Department provides oversight for the RCA process.

Quality Council: The Quality Council (QC) evaluates performance improvement related to improving the care provided at Cape Fear Valley Health System and makes recommendations directly to the MEC on a monthly basis and to the Board Quality and Patient Safety Committee on a regular basis. The QC standing members are the Chief Executive Officer and the Chief of Staff who serve as co-chairs, the Chief Medical Officer, the Chief Operating Officer, the Associate CMO for Quality and Patient Safety, the Chief Nursing Officer; the Director of Performance Improvement and members of the Medical Staff.

Clinical Performance Improvement Committee (CPIC): Responsible for the oversight of performance improvement as it relates to physician practice and performance. The medical staff departments perform ongoing monitoring of physician practice through the use of aggregate data, peer review of individual cases, and education of medical staff regarding practice guidelines.

The CPIC, Quality Council, and the interdisciplinary review committees involved in Sentinel Event and RCA activities are considered Medical Review Committees as defined by N.C. General Statute 131E-76. The proceedings of these committees, the records and materials they produce, and the materials they consider are confidential pursuant to N.C. General Statute 131E-95.

Near Miss or Close Call: Used to describe any process variation that did not affect an outcome but for which recurrence carries a significant chance of a serious adverse outcome. Such events fall within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by The Joint Commission under its Sentinel Event Policy

Root Cause Analysis (RCA): A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a Sentinel Event or near miss. The RCA focuses on the comprehensive review of applicable systems and processes and does not focus on corrective action of individuals. A goal of the analysis is to identify and prioritize opportunities to improve the process and reduce the risk of the Sentinel Event or near miss reoccurring.

Failure Mode and Effects Analysis (FMEA): A systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors occur in some situations and may even be likely to occur. See Patient Safety Plan located on the InfoWeb under CFVHS Plans.

Action Plan: The product of a RCA or Failure Mode and Effects Analysis. The action plan addresses system and process deficiencies for which improvement strategies are developed and implemented. The plan includes outcome measures to indicate that system and process deficiencies are effectively eliminated, controlled, or accepted. The goal of the action plan is to find ways to prevent a repeat of Sentinel Events, occurrences, or near misses.

GUIDELINES:

Sentinel Events:

1. Sentinel Events may be identified by various means throughout CFVHS, including but not limited to:
   a. Quality Care Control Reports.
   b. Medical Staff or CFVHS staff notification to Corporate Risk Management, PI/PS, senior leaders, or the Administrator on Call.
   c. Performance Improvement retrospective review of established indicators.
   d. Confidential Report of Medication/IV Occurrence.
   e. Outside correspondence and reports from patients/families or external agencies.
   f. Physician Action Line (PAL).
   g. Safety/Regulatory Hotline.

2. When an employee or medical staff member learns of or suspects an event may be considered a Sentinel Event or a near miss, that individual contacts the Department Manager, Administration or the Administrator on Call who then notifies the Director of PI/PS, or Director of Corporate Risk Management or the Chief Medical Officer (CMO) or their respective designees. If the medical staff member uses the PAL during after-hours or on weekends, they also notify the Nursing Supervisor [see Administrative Policy, Patient Safety Response Team (PSRT)].

3. If the event is the performance of wrong procedure on correct patient, performance of procedure on patient not scheduled for procedure, or performance of correct procedure on wrong site or body part, the Director / Administrator on Call contacts the Health Information Management Coding Manager to ensure the account is not inappropriately billed.

4. The PI/PS Department initiates a meeting of the ERT to determine if the event is a Sentinel Event.

When it is determined a Sentinel Event occurred, the RCA Team is initiated by the ERT. RCA investigations are presented to and tracked through the Harm and Events Analysis Team (HEAT). The HEAT provides Sentinel Event Summaries to the Quality Council. Sentinel Event summaries are forwarded to the Medical Executive Committee (MEC) through the Quality Council.

Root Cause Analysis (RCA):

1. The PI/Patient Safety Coordinator appoints a RCA team to meet when the need for a RCA has been determined by the ERT. RCA Team membership includes individuals trained as facilitators in RCA techniques. One of these individuals serves as leader. A sponsor for the team is selected from Senior Leadership. Others involved may include but are not limited to:
    a. Department manager(s) from the relevant area(s).
    b. Physician representative from the relevant area(s).
    c. One or more front-line employees/supervisors (optional).
    d. Direct caregivers/staff involved as needed.

2. The RCA Team looks at the systems/processes involved in the occurrence and identifies and documents the root causes thought to be contributing to the event. The RCA Team conducts the RCA investigation, conducts interviews, organizes meetings, documents the investigative results and failure scenario, and makes recommendations. The recommendations include measures to monitor effectiveness. A representative of the PI/PS Department maintains oversight of the RCA process. Recommendations targeted at the root causes are developed to significantly reduce the likelihood of recurrence of the event.
3. The goal of the RCA Team is to perform a RCA to identify system and/or process issues and events that negatively impact care and/or services of a specific patient or could potentially impact the care and/or services of other patients.
4. The team meets for a period of usually no more than 30 days to identify root causes and develop an action plan to address identified opportunities for improvement or formulate the rationale for not undertaking such changes. The final plan is usually completed within 45 days of the determination that a RCA was warranted.
5. The RCA team presents the investigation and recommendations to the Harm Events Analysis Team (HEAT.) The HEAT approves or requests amendment of the recommendations, and assigns owners.
6. Vice President sponsors report updates of recommendations to the HEAT monthly until completion. The RCA is then transitioned to Measures of Success. The Vice President sponsor reports data at three months, six months and 12 months following completion of all recommendations.

Reporting: The ERT discusses the need to self-report to The Joint Commission, the Division of Health Service Regulation or any other agency and makes recommendations to Administration. Administration makes the determination to self-report. Events that are voluntarily reported to The Joint Commission are reported within five (5) business days of the occurrence, or the discovery thereof, by the PI/PS Department. A RCA and risk reduction plan is completed within 45 days by the PI/PS Department. Administration determines of which review option is selected under The Joint Commission Sentinel Event Policy.

Support of Staff Involved in an Occurrence with an Unanticipated Outcome and/or Sentinel Event:

CFVHS supports its staff and provides them with the tools and training to fulfill the responsibilities of their role in caring for our patients. If staff has been involved in a Sentinel Event or near miss, CFVHS provides the resources to address concerns and provide emotional support.

If staff members feel they need to discuss the occurrence and the circumstances involved with a member of the Leadership Team or Employee Assistance Program (EAP), CFVHS provides every opportunity to do so and takes measures to see that the staff member's needs are addressed.

Attachment 9

Patient Safety Response Team

Activation Date/Time _____
Response Date/Time _____
Actions Date/Time _____
Closed Date/Time _____

Team Members Responding
_____
_____
_____
_____

Situation

Who called: _____

Why called: _____

What happened: _____

Where happened: _____

When happened: _____

Background

Details leading up to the "What happened":

Assessment

Actions needed to address/mitigate the "What happened":

Recommendation

Actions taken to address the Situation:
Actions addressing the "Who called":

Actions addressing the "What happened":

Forwarding to: & Why forwarding:

Sustainment F/Us assigned to:

12hr _____

24hr _____

72hr _____

96hr _____

Readback

Sustainment Follow ups

12hrs Date/Time/Reviewer: _____

- ☐ Actions in place and functioning appropriately
- ☐ Actions not in place or not functioning appropriately

New actions taken: _____

_____

24hrs Date/Time/Reviewer: _____

- ☐ Actions in place and functioning appropriately
- ☐ Actions not in place or not functioning appropriately

New actions taken: _____

_____

72hrs Date/Time/Reviewer: _____

- ☐ Actions in place and functioning appropriately
- ☐ Actions not in place or not functioning appropriately

New actions taken: _____

_____

96hrs Date/Time/Reviewer: _____

- ☐ Actions in place and functioning appropriately
- ☐ Actions not in place or not functioning appropriately

New actions taken: _____

_____

Forwarding Tracking: Who and Actions Taken

_____

_____

_____

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Closure Summary

Date/Time/Name: _____

_____

_____

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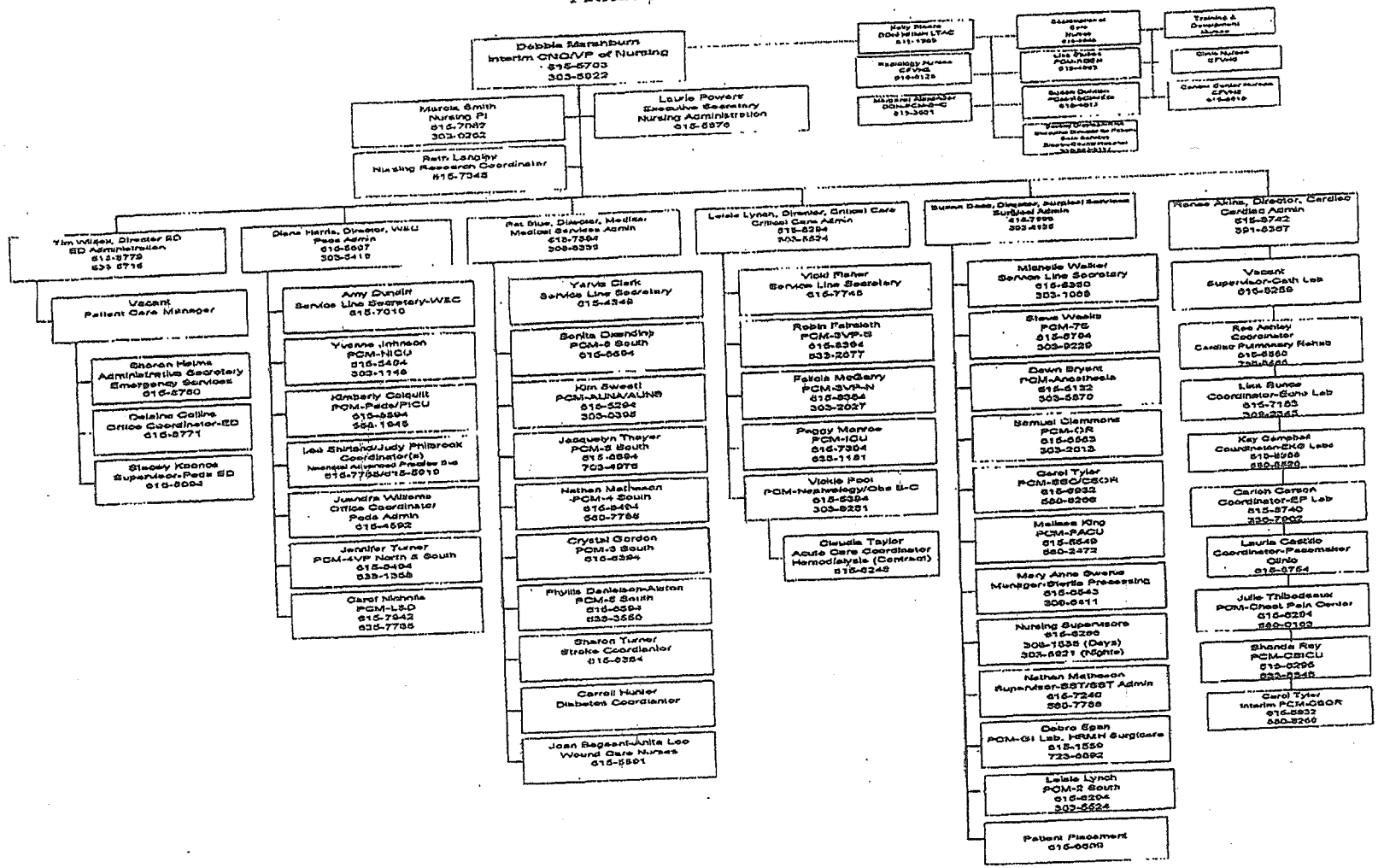
Attachment 10

Patient Care Services



Revised: 11/1/2011

Unexpected Death of Psychiatric Patient (April 17, 2011)
Root Cause Analysis
Progress Report

RCA INITIAL RECOMMENDATIONS	CFVHS Actions	Current Status	Completion Date
#1 The Director of the ED, Service Line Director of Psychiatry, and the Director of Security will form an integrated team to function solely in the Red Zone- Psych ED. This team will consist of physicians, nursing, mental health specialists, security and a Licensed Clinical Social Worker who have clearly defined roles and responsibilities to deliver safe/quality psychiatric care. This will be completed within 3 months as evidenced by the identification and selection of team members.	The Director of the ED, Service line Director of Psychiatry, and the Director of Security reviewed the staffing model in place at the time of the event. The decision was made to formalize an integrated team approach to function solely in the Red Zone-Psych ED. Specifically, the following changes were commenced based on the recommendations: 1. 2 licensed social workers were hired. One was employed in August 2011, but the other hire rescinded her acceptance one week prior to start. These positions have been found to be very difficult to recruit. 2. The ED psychiatric zone model was updated in such a way that (i) the psychiatric nurse will take a holistic approach to patient care, (ii) the ED staff nurse will not be scheduled to provide direct patient care in the psychiatric zone in the ED but will always be available as a resource when help is needed, and (iii) the security officers and/or company police officers, sitters, physicians (including the psychiatrist) will continue to be a part of the team along with the psychiatric nurse.	Parts of the team approach are in place. Psychiatric nurse recruitment continues. Psychiatric nurses will to be trained and provided skills and knowledge in ED nursing competencies that are applicable.	Ongoing; To be finalized by March 30, 2012

Attachment 11

#2 Within 3 months, the ED Director and the Manager of Supplemental Staffing are to ensure that all ED personnel receive initial and annual re-certification of NCI to be demonstrated by the collaboration of Training and Development documentation with Staff position control sheets.	The ED Director and the Manager of Supplemental Staffing have taken steps to ensure that ED staff receive and maintain appropriate NCI training. Currently, there are only 5 registered nurses in the ED (out of 92 total) that have not received NCI training. Of these 5, 3 nurses were hired within the last year, 1 nurse transferred from another nursing unit within the last year, and 1 failed to attend class. All 5 registered nurses have been scheduled for the November 18, 2011 class. We are moving forward with the non-nursing staff to be trained as well. 3 non-nurses in the ED have attended the NCI training. Due to the large number of non-nurse staff in the ED (approximately 50 total), the decision was made to not mandate the training for the entire non-nursing staff. CFVHS will require that Allied Barton ensure that its entire security staff assigned to the ED has current NCI training on file. The Vice President of Post Acute	The Clinical Educator is working closely with the Training and Development Department to ensure that new ED registered nurses are scheduled for NCI training as they are hired and to meet the goal of the recertification prior to the expiration date. Additionally, NCI training will be offered to non-nurse ED staff as well. CFVHS will audit HR personnel files of all ED staff annually to ensure that NCI training is current. On an annual basis, CFVHS will audit Allied Barton staff assigned to the ED to ensure that NCI training is current.	Ongoing; To be finalized by November 18, 2011

#3 The Vice President of Post Acute Care, the Director of Security, and the Director of Risk Management to evaluate as to whether Cape Fear Valley Health System wants law enforcement techniques used on patients and present any recommendations back to the HEAT Team within 1 month.	Care, the Director of Security, and the Director of Risk Management evaluated law enforcement techniques and patient care. The "restraints, seclusion, and safety devices" policy does address therapeutic holds as well as Forensic restraints. Employees as well as contract employees are to follow the hospital policy. The ED nursing staff, the psychiatric staff that works in the psychiatric zone and the Allied Barton security and company policy officers will all be re-educated on this policy. The necessary documentation required for any type of hold or restraint is to be re-educated to the staff as well.	All staff continue to be educated on the appropriate policies and necessary documentation requirements for holds and restraints.	Ongoing; To be provided on at least an annual basis
#4 The Vice President of Post Acute Care, Vice President of Patient Safety and Quality and the Vice President of Nursing to develop a plan within 3 months for a Code White team to be instituted and utilized in all facilities in the Health System. This will be demonstrated by the formation of a clear plan and resources dedicated to the plan.	Currently, there is already a code white used as a call code for the Health System that defines staff assistance needed. It is provided to all employees of the Health System upon hire as a badge attachment. The intent is to provide staff assistance immediately where needed. A specific code white team has been discussed, but the decision was made that the current "code white" call code met the Health Systems' needs. At no time during the RCA review was it thought there was	The Health System will continue to monitor whether a Code White team is necessary in the future.	December 20, 2011

#5 Re-examination of this RCA to be completed by the HEAT team once the patient's autopsy report is received and examined regarding cause of death, and provide further recommendations as warranted. The results of this re-examination and any recommendations made from said re-examination will be reflected in the HEAT team mtg minutes.	any intentional harm inflicted on the patient. The autopsy report was received on September 7, 2011, and the RCA / HEAT teams were updated regarding receipt of the autopsy. The Health System has questions regarding some of the autopsy's findings. However, based on the limited time since receipt of the autopsy, local law enforcement inquiry, litigation, and now agency inquiry, the Health System has not yet had an opportunity for any further analysis. Initially, the security officers/company police officers were placed on leave, and these individuals have since been reassigned away from the ED while Allied Barton continues its internal review.	On hold pending input from local law enforcement, legal counsel, and licensing agency.	On hold
Additional action plan: Define the role of the nurse and security in the care of the psychiatric/behavioral health patient in the Emergency Department to ensure patient rights are followed. The goal is to provide patient safety and security at all times.	In the event a psychiatric/behavioral health patient is combative, hostile, violent etc., the registered nurse is responsible for the safety and security of the patient as well as the overall clinical nursing care. Least restrictive measures are utilized first with the patient such as verbal de-escalation. If the verbal de-escalation attempt is unsuccessful, other techniques such as therapeutic hold may be required. The registered nurse provides direction to the team assisting with the therapeutic hold	Monitoring of these type patients is being completed by concurrent review of the care of the patient and the documentation in the medical record. Any deficiencies noted are reviewed with the staff to provide continuous improvement. Ongoing education is being completed at each shift change to ED nursing staff. This includes the restraint policy, the forms	Ongoing

	technique. Only non-violent crisis intervention certified staff may perform the therapeutic hold on the patient. If this technique is unsuccessful, other methods of restriction such as restraints may be utilized. The nurse is to remain with the patient during the escalation and initiation of any restrictive measures. The nurse must be able to visualize the patient in order to continue an on-going assessment of this patient. At no time does the nurse leave the patient in the care of security officers or company police during the therapeutic hold.	associated with the policy, and the role of the registered nurse. A meeting was held with the Medical Director of the Emergency Department. Information has also been provided to the ED physicians. Education is to be provided to the security officers/company policy officers to include the role of the registered nurse who is ultimately in charge of the patient and the environment. Only NCI certified nurses and security officers are scheduled to work in the red zone (psychiatric ED).	

Monitoring:

The clinical educator in the ED is to review the files of the ED registered nurse for the non-violent crisis intervention (NCI) training to ensure all registered nurses are certified and re-certified prior to the expiration date. The clinical educator is to work closely to ensure there are adequate classes to

STATE OF NORTH CAROLINA

COUNTY OF CUMBERLAND

IN THE OFFICE OF ADMINISTRATIVE HEARINGS
11 DHR 14886

CUMBERLAND COUNTY HOSPITAL SYSTEM, INC., D/B/A CAPE FEAR VALLEY MEDICAL CENTER,

Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent.

SETTLEMENT AGREEMENT

This Agreement is entered into by and between Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center ("Cape Fear Valley") and the Certificate of Need Section, Division of Health Service Regulation, North Carolina Department of Health and Human Services ("the Agency") (collectively referred to as "the Parties"), regarding the remaining matters at issue in the above-captioned contested case.

RECITALS

Cape Fear Valley's 65 Bed Application

WHEREAS, on or about June 14, 2011, in accordance with the CON review schedule as set forth in the 2011 SMFP, Cape Fear Valley filed a CON application, identified as Project I.D. No. M-8689-11, to construct a new hospital site, to be known as Cape Fear Valley North, with 65 acute care beds, 7 observation beds, two operating rooms, 24-hour emergency services, diagnostic imaging, laboratory and pharmacy services in Cumberland County (the "Cape Fear

EXHIBIT
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Valley Application"), to address the need determination in the 2011 SMFP for 65 additional acute care beds in the Cumberland-Hoke service area.

WHEREAS, by letter dated November 23, 2011 and by the Required State Agency Findings issued December 2, 2011, the CON Section notified Cape Fear Valley that the Cape Fear Valley Application had been disapproved.

WHEREAS, Cape Fear Valley filed a Petition for a Contested Case Hearing in Case No. 11 DHR 14886 on December 23, 2011, claiming that the Agency erred in disapproving the Cape Fear Valley Application and that Cape Fear Valley was substantially prejudiced by the erroneous disapproval.

FirstHealth's 65 Bed Application

WHEREAS, on or about June 15, 2011, in accordance with the CON review schedule as set forth in the 2011 SMFP, FirstHealth of the Carolinas, Inc. d/b/a FirstHealth Moore Regional Hospital ("FirstHealth") filed a CON application, identified as Project I.D. No. N-8690-11, to construct a hospital on U.S. Highway 401 in Raeford, Hoke County, with 65 acute care beds, 2 operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services, to address the need determination in the 2011 SMFP for 65 additional acute care beds in the Cumberland-Hoke service area (the "FirstHealth Application").

WHEREAS, by letter dated November 23, 2011, and by the Required State Agency Findings issued December 2, 2011, the CON Section notified FirstHealth that the FirstHealth Application had been disapproved.

WHEREAS, FirstHealth filed a Petition for a Contested Case Hearing in Case No. 11 DHR 14792 on December 21, 2011, claiming that the Agency erred in disapproving the FirstHealth Application and that FirstHealth was substantially prejudiced by the erroneous

disapproval.

WHEREAS, thereafter, Cape Fear Valley and FirstHealth moved to intervene in each other's contested cases, and all parties moved to consolidate the cases, which motions were granted (such cases hereinafter being referred to as the "Consolidated Cases");

WHEREAS, Cape Fear Valley and FirstHealth have resolved all matters between them; FirstHealth dismissed with prejudice 11 DHR 14792, its appeal of the Agency's disapproval of the FirstHealth Application; and FirstHealth has withdrawn as an intervenor in this contested case, 11 DHR 14886;

WHEREAS, the only remaining issues between the Parties hereto is Cape Fear Valley's appeal in this case, Case No. 11 DHR 14886, regarding the Agency's disapproval of Cape Fear Valley's Application;

WHEREAS, Cape Fear Valley contends that the Agency erred when it disapproved the Cape Fear Valley Application, and the Agency contends that it properly disapproved Cape Fear Valley's Application for the reasons set out in the Required State Agency Findings;

WHEREAS, the execution of this Settlement Agreement ("Agreement") does not constitute an admission of error by any party;

WHEREAS, no other parties have sought to intervene in this contested case;

WHEREAS, pursuant to N.C. Gen. Stat. §150B-22, it is the policy of the State to settle disputes between State agencies and other persons whenever possible;

WHEREAS, pursuant to this policy, the Parties have discussed settlement of this contested case;

WHEREAS, Cape Fear Valley submitted information to the Agency demonstrating that Cape Fear Valley is conforming with N.C. Gen. Stat. § 131E-183(a)(13)(b); and (20) and

administrative rules 10A NCAC 14C .2103(a) and 10A NCAC 14C .3802(c)(3)(D);

WHEREAS, during these discussions, Cape Fear Valley agreed to submit additional information to the Agency demonstrating that after a full survey by the Joint Commission conducted in 2012, Cape Fear Valley received continuous accreditation from the Joint Commission; and

WHEREAS, upon reviewing the information submitted, the Agency has concluded that upon receipt of information demonstrating that Cape Fear Valley received continuous accreditation from the Joint Commission in 2012, the Cape Fear Valley Application can be approved as proposed, subject to the conditions set out in this agreement and in Exhibit A to this Agreement;

NOW, THEREFORE, pursuant to N.C. Gen. Stat.§§150B-22 and 31(b), and subject to the approval of Drexdal Pratt, Director of the Division of Health Service Regulation (the "Director"), the Parties have decided to resolve this contested case in the manner set forth below.

TERMS OF AGREEMENT

1. Voluntary Dismissal without Prejudice. Within five business days after this Agreement is approved and adopted by the Director, Cape Fear Valley and the Agency shall file a stipulated notice of voluntary dismissal, without prejudice, in the above-referenced contested case in the Office of Administrative Hearings.

2. Submission of Additional Settlement Materials. Cape Fear Valley agrees to submit additional settlement materials ("Supplemental Materials"), confirming that as a result of the 2012 full Joint Commission survey, Cape Fear Valley received continuous accreditation status from the Joint Commission.

3. Submission of Timetable for Development. Prior to the Agency's issuance of the

Certificate of Need, Cape Fear Valley agrees to submit a timetable for development of Project I.D. No. M-8689-11. The timetable, as accepted by the Agency, will be the timetable indicated on the Certificate of Need for the project's development.

4. Refile of Petition, Voluntary Dismissal With Prejudice and Issuance of Certificate of Need to Cape Fear Valley. Unless Cape Fear Valley has already refiled its Petition ("Refiled Petition") in the Office of Administrative Hearings ("Refiled Case") prior to the Agency's acceptance of the Supplemental Materials, Cape Fear Valley shall file its Refiled Petition after the Agency's acceptance of the Supplemental Materials. Once Cape Fear Valley has received the Agency's written acceptance of the Supplemental Materials:

a) Cape Fear Valley shall file a Notice of Voluntary Dismissal, with prejudice, in that Refiled Case, in the Office of Administrative Hearings; and

b) Within five business days after it receives the Notice of Voluntary Dismissal, with prejudice, in the Refiled Case, the Agency, shall issue a Certificate of Need to Cape Fear Valley for Project I.D. No. M-8689-11, subject to the conditions contained in Exhibit A to this Agreement and the timetable submitted to the Agency as referenced in Paragraph 3 above, authorizing the development of a new hospital site at 6387 Ramsey Street in Fayetteville, Cumberland County, with 65 acute care beds, 7 observation beds, two operating rooms, 24-hour emergency services, diagnostic imaging, laboratory, and pharmacy services.

5. Effect of Approval. By executing this Agreement, the Parties acknowledge that, if this Agreement is approved by the Director, Cape Fear Valley has the right to submit the Supplemental Materials to resolve all issues involved in the contested case initiated by Cape Fear Valley. Cape Fear Valley retains the right to pursue all claims in the Refiled Case if the CON-

issuing events described above do not occur. Execution of this Agreement does not constitute an admission of error by either party and the Agreement cannot be used as evidence of admission of error by either party in any other proceeding.

6. Effect of Disapproval. In the event that this Agreement is not approved by the Director, the Parties acknowledge that this Agreement shall be null and void and Cape Fear Valley shall be entitled to proceed with the pending contested case. In such event, the Director's consideration of this Agreement for his approval as provided herein shall not prejudice his authority to render the final agency decision in this matter following the hearing in accordance with N.C.G.S. §150B. In addition, if this Agreement is not approved by the Director, the Parties agree that it shall be inadmissible for any purpose in the contested case.

7. Release. Upon issuance of the Certificate of Need, Cape Fear Valley releases the Agency, its officials, employees, and representatives, from any and all liability that has arisen or might arise out of the Agency's review of its Certificate of Need Application.

8. Expenses. The Parties agree that each shall bear its own expenses. No claim for any other costs or expenses shall be made by one party against the other.

9. Waiver of Right to Appeal Agreement. The Parties irrevocably waive any right to initiate an appeal from this Agreement, assuming that any such right exists; provided that nothing in this Agreement shall be construed to waive any claim for enforcement or breach of this Agreement.

10. Merger. The Parties further agree and acknowledge that this written agreement sets forth all of the terms and conditions between them concerning the subject matter of this Agreement, superseding all prior oral and written drafts, statements and representations, and that there are no terms or conditions between the Parties except as specifically set forth in this

Agreement.

11. Modification or Waiver. No modification or waiver of any provision of this Agreement shall be effective unless it is in writing. Any modification or waiver must be signed by authorized representatives of the Parties and must be adopted and approved by the Director.

12. No Strict Interpretation Against Draftsman. Each of the Parties has participated in the drafting of this Agreement and has had the opportunity to consult with counsel concerning its terms. This Agreement shall not be interpreted strictly against any one party on the grounds that it drafted the Agreement.

13. Recitals and Headings. All parts and provisions of this Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agreement.

14. Authority to Settle. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the Parties to this Agreement.

15. *Ex Parte* Presentation. Cape Fear Valley authorizes counsel for the Agency to present this Agreement to the Director *ex parte*.

16. Effective Date. This Agreement shall be effective as of the day and year on which it is adopted and approved by the Director.

17. Successors and Assigns. This Agreement shall be binding upon the Parties and their successors and assigns.

IN WITNESS WHEREOF, the parties have executed two originals of this Settlement Agreement, with one original copy being retained by each party.

Cumberland County Hospital System, Inc.
d/b/a Cape Fear Valley Health System and
Hoke Healthcare, LLC

Michael Nagowski

Date 4/18/12

Michael Nagowski
CEO

K&L GATES LLP
Attorneys for Petitioner Hoke Healthcare, LLC

Date 4/19/12

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N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
DIVISION OF HEALTH SERVICE REGULATION

Craig R. Smith Date 4/20/12

Craig R. Smith, Chief
CON Section

ROY COOPER
Attorney General for the State of North Carolina

Date 4/20/2012

June S. Ferrell
SPECIAL DEPUTY > ~~Assistant~~ Attorney General
N.C. State Bar No. 12945
Post Office Box 629
Raleigh, NC 27602-0629
(919) 716-6860

APPROVAL AND ADOPTION

The foregoing Settlement Agreement is hereby APPROVED AND ADOPTED approved and adopted this the 20th day of April, 2012.

Drexdal Pratt, Director
Division of Health Service Regulation
Department of Health and Human Services

Exhibit A

Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center
Project I.D. # M-8689-11
Conditions

1. Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center shall materially comply with all representations made in the certificate of need application and all supplemental information submitted to the Agency on March 28, March 29 and April 23, 2012. In those instances where the representations in the supplemental information differ from those in the application, the applicant shall materially comply with the representations in the later document.

2. Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center shall develop a satellite hospital in Cumberland County to be known as Cape Fear Valley North with no more than 65 licensed general acute care beds to be developed pursuant to the need determination in the 2011 SMFP, 7 unlicensed observation beds, two shared operating rooms to be relocated from Highsmith Rainey Specialty Hospital, 24-hour emergency services, diagnostic imaging, laboratory and pharmacy services.

3. Upon completion of this project, Project I.D. #M-8004-07 and Project I.D. #M-8499-10, Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center (including Cape Fear Valley North) shall be licensed for no more than 555 acute care beds and 20 operating rooms, including 3 dedicated C-section operating rooms, 2 dedicated open heart operating rooms and 15 shared operating rooms.

4. Upon completion of this project and Project I.D. No. M-8499-10, Highsmith Rainey Specialty Hospital shall be licensed for no more than one shared operating room.

5. Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center shall not develop any new intensive care unit beds as part of this project but shall relocate 8 existing intensive care unit beds from the Owen Drive campus to Cape Fear Valley North.

6. Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley North shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.

STATE OF NORTH CAROLINA — IN THE OFFICE OF ADMINISTRATIVE HEARINGS

COUNTY OF CABARRUS

RAI CARE CENTERS OF NORTH CAROLINA II, LLC d/b/a RAI CARE CENTERS-CONCORD,

Petitioner,

vs.

N.C. DEPT. OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent,

and

TOTAL RENAL CARE OF NORTH CAROLINA, LLC,

Respondent-Intervenor.

FILE NO. 11 DHR 3173

(CONTINUED ON NEXT PAGE.)

DEPOSITION OF CRAIG SMITH

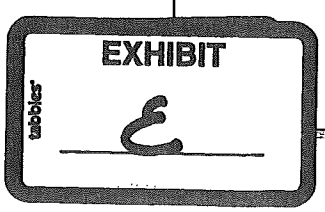
FRIDAY, AUGUST 5, 2011

9:39 A.M.

AT THE OFFICES OF
NELSON MULLINS RILEY & SCARBOROUGH, LLP
4140 PARKLAKE AVENUE, SUITE 200
RALEIGH, NORTH CAROLINA

VOLUME I

CAROLINA REPORTING SERVICE
P.O. Box 44
Sedalia, North Carolina 27342
919-661-2727 - Telephone



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Q. And how did you become aware of this incident?
A. Ms. Rupp and Ms. Mathes brought it to my attention.
Q. All right. And you mentioned earlier the expectation that you don't have something like this happen to you when you have dialysis; why is that the expectation?
A. It's a pretty -while a highly complex process, it has become a standard of care, where it has been for a number of years.
Q. ESRD?
A. Well, no.
Q. The treatment?
A. Dialysis treatment for end-stage renal disease, yes.
Q. Okay. And were you aware also that there were other issues at this facility as reflected in the survey, issues in the nature of sanitation and infection control?
A. I was aware that there were other conditions out of compliance. I'm not sure I was aware of the details.
Q. All right. And we saw a moment ago when we looked at Criterion 20 that there were four Medicare conditions of participation that were out of

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compliance here. Did you regard that as being a high number of deficiencies?
A. It's more than we typically see.
Q. Okay. What do you typically see?
A. Usually one or two conditions.
Q. Is the Agency allowed to condition an applicant under Criterion 20 the way it can condition applicants sometimes under other criteria?
A. No.
Q. Why is that?
A. It cannot condition past -past behavior.
Q. All right. And what analysis did the Agency do to determine that TRC was nonconforming with Criterion 20?
A. We reviewed the -well, with all the applications, we sent a questionnaire to the Acute and Home Care Licensure and Certification Section concerning the proposals and concerning facility history, and when we find problems with facility history, then we look into it further, usually consult with the surveyor--or with the Section Chief.
Q. And was that done in this case?
A. That -I don't know that specifically.
Q. Okay.

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A. I know the -I mean, I know the surveys were prepared. I don't know if there was consultation--
Q. Okay.
A. -with the-
Q. Does there have to be consultation with Licensure?
A. We usually do, but I -I don't know in this particular case.
Q. Okay. Would that be something that Ms. Mathes might know?
A. Yes.
Q. Since the actual incident where the patient died occurred at the Copperfield center, why were Cabarrus County Dialysis and Harrisburg also found nonconforming under Criterion 20?
A. Cabarrus County Dialysis was going to use the same Medical Director.
Q. Were there any other reasons?
A. And Harrisburg is in the same county.
Q. And are all three facilities proposed to be under common ownership?
A. Yes.
Q. Would that be a relevant factor in the Criterion 20 analysis?
A. Yes.

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Q. Does the fact that TRC elected not to appeal the Agency's decision in Copperfield have any relevance on the Agency's decision to disapprove Harrisburg and Cabarrus County Dialysis?
MR. SHENTON: Object to the form of the question.
A. Please repeat your question.
Q. Sure. You're aware that TRC elected not to appeal the Agency's decision on Copperfield, right?
A. Yes.
Q. All right. And does that fact, that they have not appealed Copperfield, have any bearing on the Agency's decision to disapprove Harrisburg and Cabarrus County Dialysis?
MR. SHENTON: Objection.
A. No.
Q. Why not?
A. Because we--the disapproval stands, and whether they appeal or not happens after the decision.
Q. And it's my understanding that subsequent to this survey finding, the applicant entered into a plan of correction with CMS, Centers for Medicaid Services. Does that have any bearing on the Agency's decision under Criterion 20?

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MR. SHENTON: Object to the form of the question.

A. No.

Q. Why not?

A. We look -we look back 18 months for the incidents.

Q. And the plan of correction would be something that is forward looking?

A. Well, the plan of correction at -if the plan of correction were not dealt with satisfactory by the provider, they would be out of business, and they wouldn't be submitting applications in the first place.

Q. Okay. And the plan of correction is to fix the problem going forward, correct?

A. Yes.

Q. And Criterion 20 is looking back; is that right?

A. Yes.

Q. I'd like to mark another exhibit, which will be number 26; is that right?

COURT REPORTER: 27.

Q. 27, excuse me.

(DEPOSITION EXHIBIT NO. 27 WAS MARKED FOR IDENTIFICATION.)

Q. Mr. Smith, the reporter has handed you what has

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been marked as Deposition Exhibit No. 27, and there are the findings that were issued in the 2008 competitive Davie County Dialysis review, which involved TRC and Wake Forest University Health Sciences. You are not listed as signing off on these particular findings, but are you nevertheless aware of this review generally?

A. Yes.

Q. All right. And how are you generally aware of this review?

A. I was aware of this review, because it was a county need review. I usually keep up with those and was aware of the decision. It was brought to my attention that we did have a Criterion 20 in this review as well.

Q. All right. And the applicant that had the Criterion 20 issue, was that Total Renal Care of North Carolina, LLC?

A. Yes.

Q. And is that the same TRC that we've been talking about with respect to Cabarrus?

A. Yes.

Q. And turn please to Criterion 20 in these findings, which is on Page 25 of Exhibit 27.

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A. Yes.

Q. And what is your understanding of what happened here with respect to Criterion 20?

A. In this case, TRC was proposing to develop a facility in Rowan County. The Medical Director of the dialysis clinic that TRC operates in Rowan County was going to be the Medical Director of the new facility in Davie County, and the -in review of the files of the Acute Home Care Licensure and Certification Section of the Division of Health Service Regulation indicate that a survey conducted of the Rowan County facility in January 2008 had identified an immediate jeopardy in failure to conform with three conditions of participation.

Q. Okay. And this Medical Director who is referenced, William K. Halstenburg, M.D., were you aware that he was also the Director or is the Director at Copperfield?

A. I am now.

Q. Okay. And in this particular situation, did—TRC-Rowan facility had three Medicare conditions of participation that it was out of compliance with?

A. That's what it says here.

Q. All right. And in the Cabarrus situation, there

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were four Medicare conditions of compliance that were out of -conditions of participation that were out of compliance?

A. That's what the findings say.

Q. And is this an example of what you had testified to earlier where you sometimes look at facilities in contiguous counties with regard to Criterion 20 issues?

A. Yes, especially if there's a linkage between the new facility and the facility in a contiguous county.

Q. Okay.

A. In this case, the link is the operator facility and the Medical Director.

Q. Okay. And would that be true in this case as well, Cabarrus, the link is the operator and the Medical Director?

A. Yes.

Q. All right. And were you aware also that Dr. Halstenburg's practice, which is called Central Carolina Nephrology, also provides physician services at TRC-Harrisburg, and would also provide them at TRC-Cabarrus County Dialysis?

A. I believe I am aware that it was the same medical

Department of Health and Human Services
Centers for Medicare & Medicaid Services

OMB NO. 0938-0390

Post-Certification Revisit Report

ublic reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and aintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information cluding suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork eduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
340028	A. Building B. Wing	11/17/2011

Name of Facility	Street Address, City, State, Zip Code
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously eported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should e fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each equirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix A0167 Reg. # 482.13(e)(4)(ii) LSC	Correction Completed 11/17/2011	ID Prefix A0168 Reg. # 482.13(e)(5) LSC	Correction Completed 11/17/2011	ID Prefix A0175 Reg. # 482.13(e)(10) LSC	Correction Completed 11/17/2011
ID Prefix A0186 Reg. # 482.13(e)(16)(iii) LSC	Correction Completed 11/17/2011	ID Prefix A0194 Reg. # 482.13(f) LSC	Correction Completed 11/17/2011	ID Prefix A0200 Reg. # 482.13(f)(2)(ii) LSC	Correction Completed 11/17/2011
ID Prefix A0287 Reg. # 482.21(c)(2) LSC	Correction Completed 11/17/2011	ID Prefix A0288 Reg. # 482.21(c)(2) LSC	Correction Completed 11/17/2011	ID Prefix A0397 Reg. # 482.23(b)(5) LSC	Correction Completed 11/17/2011
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By ✓ State Agency	Reviewed By DHC	Date: 11/22/2011	Signature of Surveyor: Tammy Holleman RN	Date: 11/22/11
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on:
10/21/2011

Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? No

EXHIBIT
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ARTMENT OF HEALTH AND HUMAN VICES — CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMI[illegible] — ID: ANPE12

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY — Facility ID: 943057

MEDICARE/MEDICAID PROVIDER NO. (L1) 340028 STATE VENDOR OR MEDICAID NO. (L2)	3. NAME AND ADDRESS OF FACILITY (L3) CAPE FEAR VALLEY MEDICAL CENTER (L4) 1638 OWEN DRIVE P O BOX 2000 (L5) FAYETTEVILLE, NC (L6) 28302	4. TYPE OF ACTION: 7 (L8) 1. Initial 2. Recertification 3. Termination 4. CHOW 5. Validation 6. Complaint 7. On-Site Visit 9. Other 8. Full Survey After Complaint
EFFECTIVE DATE CHANGE OF OWNERSHIP (L9) DATE OF SURVEY (L34) ACCREDITATION STATUS: 1 (L10) 0 NOT ACCREDITED 1 JC 3 DNV	7. PROVIDER/SUPPLIER CATEGORY 01 (L7) 01 Hospital 05 HHA 09 ESRD 13 PTIP 22 CLIA 02 SNF/NF/Dual 06 PRTF 10 NF 14 CORF 03 SNF/NF/Distinct 07 X-Ray 11 IMR 15 ASC 04 SNF 08 OPT/SP 12 RHC 16 HOSPICE	FISCAL YEAR ENDING DATE: (L35) 09/30
1. LTC PERIOD OF CERTIFICATION From (a): To (b): 2. Total Facility Beds 600 (L18) 3. Total Certified Beds 594 (L17)	10. THE FACILITY IS CERTIFIED AS: A. In Compliance With Program Requirements Compliance Based On: 1. Acceptable POC And/Or Approved Waivers Of The Following Requirements: 2. Technical Personnel 6. Scope of Services Limit 3. 24 Hour RN 7. Medical Director 4. 7-Day RN (Rural SNF). 8. Patient Room Size 5. Life Safety Code 9. Beds/Room B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: (L12)	

14. LTC CERTIFIED BED BREAKDOWN					15. FACILITY MEETS
18 SNF	18/19 SNF	19 SNF	ICF	IMR	1861 (e) (1) or 1861 (j) (1): (L15)
	597				
(L37)	(L38)	(L39)	(L42)	(L43)	

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):

See Attached Remarks follow up

17. SURVEYOR SIGNATURE	Date:	18. STATE SURVEY AGENCY APPROVAL	Date:
Tammy Holloman	11/22/2011 (L19)	[signature]	11/28/2011 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY	20. COMPLIANCE WITH CIVIL RIGHTS ACT:	21.
____ 1. Facility is Eligible to Participate ____ 2. Facility is not Eligible (L21)		1. Statement of Financial Solvency (HCFA-2572) 2. Ownership/Control Interest Disclosure Stmt (HCFA-1513) 3. Both of the Above: ____

22. ORIGINAL DATE OF PARTICIPATION (L24)	23. LTC AGREEMENT BEGINNING DATE (L41)	24. LTC AGREEMENT ENDING DATE (L25)	26. TERMINATION ACTION: (L30) VOLUNTARY 00 01-Merger, Closure 02-Dissatisfaction W/ Reimbursement 03-Risk of Involuntary Termination 04-Other Reason for Withdrawal INVOLUNTARY 05-Fail to Meet Health/Safety 06-Fail to Meet Agreement OTHER 07-Provider Status Change 00-Active
25. LTC EXTENSION DATE: (L27)	27. ALTERNATIVE SANCTIONS A. Suspension of Admissions: (L44) B. Rescind Suspension Date: (L45)		
28. TERMINATION DATE: (L28)	29. INTERMEDIARY/CARRIER NO. 00000 (L31)		30. REMARKS
31. RO RECEIPT OF CMS-1539 (L32)	32. DETERMINATION OF APPROVAL DATE (L33)		DETERMINATION APPROVAL

C&T REMARKS - CMS 1539 FORM

An unannounced onsite survey was conducted on November 9-17, 2011. The purpose of the survey was to follow up on the ongoing Immediate Jeopardy that was identified during a complaint survey on October 21, 2011 and to determine compliance with the CMS Conditions of Participation. The State Agency recommends removal of the Immediate Jeopardy as of November 10, 2011 at 1530. Based on survey findings, the State Agency recommends the hospital to be out of compliance with the following Conditions of Participation: 482.12 Governing Body, 482.13 Patients¿ Rights, 482.21 Quality Assessment and Performance Improvement, 482.23 Nursing Services, 482.41 Physical Environment, and 482.55 Emergency Services. Additionally, Standard Level deficiencies were found in the area of 482.51 Surgical Services. The State Agency recommends a 90-day termination from the Medicare/Medicaid program, effective January 19, 2012.

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr
Drexdal Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-3073

November 23, 2011

Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive P O Box 2000
Fayetteville, NC 28302

RE: Full and Follow-Up to Immediate Jeopardy Survey

Dear Mr. Nagowski,

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the Full and Follow up survey conducted November 9, 2011 through November 17, 2011. The purpose of conducting the survey was to evaluate the Hospital's compliance with the Federal Medicare Conditions of Participation for Hospitals and to follow-up on the on-going Immediate Jeopardy identified on October 21, 2011 during the complaint survey conducted October 17, 2011 through October 21, 2011.

As discussed in the exit conference, the State Agency is recommending removal of the Immediate Jeopardy as of November 10, 2011 at 1530. Based on survey findings, the State Agency recommends the hospital to be out of compliance with the following Conditions of Participation: **482.12 Governing Body, 482.13 Patients' Rights, 482.21 Quality Assessment and Performance Improvement, 482.23 Nursing Services, 482.41 Physical Environment, and 482.55 Emergency Services.** Additionally, Standard Level deficiencies were found in the area of 482.51 Surgical Services. Deficiencies affecting the Condition of Participation must be corrected within 30 days of the survey date. A follow-up visit will be conducted if a "Credible Allegation of Compliance" from the provider is received by the State Agency within 10 calendar days of receipt. The State Agency is recommending a 90-day termination from the Medicare program effective **January 19, 2012**.

Enclosed are two (2) form CMS 2567's ("Statement of Deficiencies and Plan of Correction") containing the cited deficiencies for the Conditions of Participation for Hospitals as well as the Life Safety Code survey findings. This form will be made available to the public under the disclosure of survey provisions. A plan of correction should be submitted detailing how each deficiency will be corrected and include the following:

1. A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
2. A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and
3. The date by which all corrective actions will be completed and the monitoring system will be in place (the date should be no later than 30 days from the date of the survey).

An *original* of the enclosed form CMS 2567, with the plan of correction added, **must be returned to this office, signed (with an original signature) and dated, WITHIN 10 CALENDAR DAYS OF RECEIPT.** Please submit the CMS 2567 Life Safety plan of correction to the attention of Mr. Steve Lewis. *We are unable to accept faxed reports at this time.* A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files.

The plan of correction will be reviewed and if additional information is needed we will contact you. If you have any questions, please do not hesitate to contact this office at (919)855-4620.

Sincerely,

Tammy Holleman, RN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

cc: Rosemary Robinson, RO
Azzie Conley, Section Chief
Steve Lewis, Section Chief - Life Safety

Attachments: CMS 2567 Statement of Deficiencies
CMS 2567 Life Safety Code survey findings
CMS 2567B Post-Certification Revisit Report

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERS/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	11/30/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

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A 000	INITIAL COMMENTS A complaint investigation was conducted November 29-30, 2011 to determine the hospital's compliance with the Medicare Conditions of Participation. The investigation resulted in the identification of an Immediate Jeopardy (IJ) to patients' health and safety beginning on November 22, 2011 related to the failure of hospital staff to report and respond to a patient's change in condition at the time of discharge from the hospital and the patient expired during the transport home by a contracted taxi service. The hospital's administrative staff was notified on November 30, 2011 at 1600 of the identification of the Immediate Jeopardy. Findings of the investigation revealed a 29 year-old admitted to the hospital 11/15/2011 after presenting to the hospital's emergency department on 11/14/2011 with chief complaint of right-sided chest pain. The patient was admitted with and was treated for pneumonia, as well as an electrolyte imbalance, failure to thrive, malnutrition, and had a history of non-Hodgkin's lymphoma. Findings revealed on the day of discharge (11/22/2011), nursing staff failed to reassess the patient after receiving pain medication, failed to reassess the patient at discharge and after a change in condition, and failed to initiate the hospital's rapid response team after receiving two phone calls from two different sources concerned with the patient's condition. Findings revealed a contracted taxi service transported the patient home at discharge and the patient was found to be expired when the transport service reached the patient's home approximately 45 minutes after leaving the	A 000	Cape Fear Valley Health System (CFVHS), it's Governing Body, and it's Administrative Team is committed to promoting and protecting patients' rights, ensuring a safe setting for patient care, and providing an organized and supervised nursing service that provides quality 24-hour nursing services. In furtherance of these commitments, CFVHS engaged "The Greeley Company" as an independent third party to audit procedures and operations. The Greeley Company was engaged December 2, 2011 and arrived on site December 5, 2011 to begin working with CFVHS Administration as well as Emergency Department leadership, nursing staff and physicians. The Greeley Company will continue to work with CFVHS on an ongoing basis to continue to maintain regulatory compliance with the Conditions of Participation.	

LABORATORY DIRECTOR'S PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Michael Magawski | TITLE: CEO | (X6) DATE: 12/8/11

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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A 000	Continued From page 1 hospital. Preliminary results of an autopsy performed revealed the patient's cause of death to be pneumonia secondary to complications related to non-Hodgkin's lymphoma. Review of the hospital's investigation and action plan on 11/30/2011 revealed the facility's event response team (ERT) met 11/23/2011 to discuss the death of Patient #1 while being transported home from being discharged from the hospital. Review revealed "Immediate issues to be disseminated to staff: Continue to follow policies & procedures...Does not appear nor does any staff mention inappropriate discharge. Not a sentinel event, with pt's history, death is not unexpected. Will continue to interview to discern more information...". Other action items presented to the surveyors on 11/30/2011 at 1430 included a process to ensure that all patients were accompanied by nursing staff during the entire discharge process beginning on the afternoon of 11/23/2011, initiated a discharge log requiring nursing staff to attest to their involvement during the entire discharge process (accompany patients to the front door until leaving with transportation home), process to re-educate staff regarding the rapid response process in the transportation, nursing, environmental services and dietary. services departments which began 11/28/2011 and to be completed by 12/02/2011; and, engage an independent third party to audit processes and operations (no date of implementation available). Findings revealed the hospital failed to provide oversight and have systems in place to ensure the protection of patients' rights by providing care in a safe setting and failed to ensure an	A 000		

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A 000	Continued From page 2 organized nursing service by failing to report and respond to a patient's change in condition at the time of discharge from the hospital. Based on evaluation of the immediate corrective action plan, the Immediate Jeopardy was determined to be ongoing.	A 000		
A 043	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, hospital document review and staff, physician, medical examiner and contracted transportation staff interview, the hospital's Governing Body failed to provide oversight and have systems in place to ensure the protection of patients' rights by providing care in a safe setting and failed to ensure an organized nursing service. Findings include: A. The hospital failed to promote and protect patients' rights by failing to ensure a safe setting for patient care. ~ cross refer to 482.13 Patient Rights' Condition Tag 0115. B. The hospital failed to have an organized	A 043	Cape Fear Valley Health System (CFVHS) maintains an organizational chart that demonstrates clear delineation for leadership responsibilities up to and including the Board of Trustees (BOT) (see **CFVHS Organizational Chart "attachment 1"**). The Governing Body provides oversight of health system operations that includes direction of processes to maintain a safe and secure environment for our patients as well as to provide quality care. After the knowledge of the incident, the Chief Executive Officer (CEO) immediately informed the BOT chairperson as well as other members of the Board. The BOT Quality Committee was informed of the incident on November 28, 2011. After the November 29 -30, 2011 survey, findings were reviewed again by the BOT at the BOT Committee meetings on November 30 and December 1, 2011 and the full Board at its meeting on December 7, 2011. The BOT directed management staff to implement and improve existing systems to ensure the protection of patient rights as well as an organized nursing service that provides a safe environment for our patients. Updates will be provided to the BOT on a regular basis on the status and effectiveness of the systems put into place. When the incident was brought to the attention of our Administration, an immediate action plan was put into place to ensure protection of patient rights, an organized nursing staff, and a safe setting **(attachment 2)**. Our analysis of the event referenced in this statement of deficiencies provided an opportunity to improve our systems to ensure a 1) quick and appropriate response to concerns about patient condition 2) appropriate and timely activation of our rapid response team and 3)more	

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A 043	Continued From page 3 nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care. -cross refer to 482.23 Nursing Services Condition Tag A0385. A 115 482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, hospital document review and staff, physician, medical examiner and contracted transportation staff interview, the hospital failed to promote and protect patients' rights by failing to ensure a safe setting for patient care. Findings include: The hospital failed to ensure care in a safe setting by failing to ensure hospital staff evaluated a patient's response to pain medication, failed to reassess a patient once notified of a change in the patient's condition, and failed to initiate the hospital's rapid response team for 1 of 1 inpatient discharge reviewed (#1). - cross refer to 482.13(c)(2) Patient Rights' Standard: Tag 0144. A 144 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting.	A 043	organized inpatient discharge process including routine and appropriate pain reassessment. Furthermore, the action plan includes education on existing policies applicable to this situation. **A. The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** As Administration monitors to assure that this action plan is effective, Nursing Leadership stationed a nurse in the discharge foyer during normal discharge hours as an added resource to recognize changes in patient condition and respond accordingly. The immediate action was to have the nurse transport the patient to the door of the facility for discharge; however Nursing Leadership is transitioning to nursing staff (staff nurse or nursing assistant) since the rapid response education has been completed. This education for nursing staff is to begin on December 9, 2011 and be ongoing. A nursing staff member from the discharging nursing unit will accompany the patient. Upon return from the discharge, the nursing staff member is to sign the discharge log **(attachment 3)**. During hours when the discharge foyer is not open a nursing staff member will accompany the patient and the nursing staff member will wait with the patient until patient departs the facility. A transporter may also accompany the patient for discharge at the discretion of the staff member in addition to the nursing staff. On the afternoon of the event the decision was made to re-educate staff regarding the availability of CFV's existing rapid response team to respond to any change in the medical condition of the patient, visitor or staff member **(see CFVHS Education Plan "attachment 4 & 4A")** targeting transporters, nursing staff, environmental services and dietary services. This included a high level education through the holiday and the weekend with a more in-depth education starting on November 28, 2011. A pocket card for rapid response was provided to the transporters, environmental services and dietary services **(attachment 5)**. The education consisted of the review of the policy and procedure on "Rapid Response Guidelines" **(attachment 6)**. The intent of the education was to ensure that staff members know how and when to call rapid response team when there is a question of a patient's condition worsening including any medical concern of staff or visitors.	Dec. 14, 2011,

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A 144	Continued From page 4 This STANDARD is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, hospital document review and staff, physician, medical examiner and contracted transportation staff interview, the hospital failed to ensure care in a safe setting by failing to ensure hospital staff evaluated a patient's response to pain medication, failed to reassess a patient once notified of a change in the patient's condition, and failed to initiate the hospital's rapid response team for 1 of 1 inpatient discharge reviewed (#1). The findings include: Review of the hospital's policy, "Pain Management", revised 07/26/2010, revealed, "POLICY: (Name of hospital), through its care providers, assesses, intervenes and reassesses the patient's pain on an ongoing basis. ...GUIDELINES: Each patient has the right to expect his/her report of pain to be accepted, to have the pain assessed and reassessed...6. ...Patients are reassessed and effectiveness (including pain scale) is documented by providers after administration of oral pain medication after 60 minutes to 120 minutes. ...". Review of the hospital's policy, "Discharging a Patient", revised 02/19/2009, revealed, "...REQUISITES: RNs/LPNs are responsible for completion of Patient Discharge Instruction...Nursing Assistants may assist by taking vital signs...". Review of the hospital's policy, "Assessment and Reassessment", revised 11/16/2010, revealed,	A 043	**Monitoring:** The Service Line Director of Surgical Services has been assigned the responsibility of staffing the discharge foyer with a nurse. If a nurse is not available due to staffing the discharge foyer will not open. The discharge log will continue to be signed by a nursing staff member which is evidence the patient was transported by a nursing staff member (attachment 3). The Rapid Response Team Audit tool (attachment 7) is being completed by the house Nursing Supervisor whereby staff members of transportation, environmental services and dietary are being audited of their knowledge of rapid response procedures. Effective December 8, 2011, the house nursing supervisor began auditing the nursing assistants prior to the transition from nurse to nurse/nursing assistant for patient discharge. In the event the staff member cannot answer the audit questions, they are to be re-educated immediately and demonstrate understanding of the process. A random audit of the discharge log will be completed by the Service Line Director (SLD) of each nursing unit to ensure the nurse/NA are the staff transporting the patient on discharge. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT B. There is a nursing organization chart (attachment 8) that demonstrates the oversight and responsibility for nursing. For each nursing unit there are Resource Nurses/ charge nurses that report to the Patient Care Manager (PCM). The PCM reports to the Service Line Director (SLD). The SLD reports to the Vice President of Nursing. The positions listed above (with the exception of the resource nurse) have 24 hours per day and 7 days per week accountability and responsibility for nursing care. There is also a house Nursing Supervisor 24 hours per day and 7 days per week with responsibility and oversight of nursing care. There are clinical educators assigned to each inpatient nursing unit (unless vacancy exists) that report to the PCM of that nursing unit. A template with the components of a discharge note is to be developed for use by the staff nurses by December 14, 2011. The recommended components include but are not limited to mental status, color of patient, skin temperature, level of pain when relevant and patient condition. The	Dec. 14, 2011

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A 144	Continued From page 5 "..Procedure: ...3. Assessment and reassessment are completed as patient's condition warrants... 6. Reassessment is any assessment completed after the initial shift assessment. ...The timing,scope and intensity of reassessment is based on the patient's diagnosis, response to any previous care, change in condition and/or diagnosis, as requested by patient or at discretion of the RN. ... A. Reassessment includes: a. Response to medications...b. Response to pain medications and interventions...f. Discharge planning...". Review of the hospital's policy, "Rapid Response Guidelines", revised 04/25/2011, revealed, "POLICY: The Rapid Response Team (RRT) responds to situations where patients at (Hospital Name) are experiencing acute clinical changes or are in a pre-code status. The RRT responds to emergent and pre-emergent situations in all areas...PURPOSE: To provide early intervention for patients who experience acute clinical changes in an effort to stabilize, monitor and transfer to a higher level of care if needed, thereby preventing the progression to cardiopulmonary arrest. ...GUIDELINES: Rapid Response Team Members: 1. RRT member responds within 5 minutes to requests for patient assistance or requests that fall within the following established guidelines for response: a. Staff member concerned about the medical condition of a patient...". Review of the hospital's job description for a Registered Nurse, revised 11/2011, revealed, "...Job Summary: Plans and implements professional nursing care for patients in accordance with hospital policies. ... Major Job	A 043	nurses will be re-educated on the importance of the assessment of the condition on discharge and the importance of reassessment of pain after pain medication during the discharge process. It will also be re-educated that patients are to continue to have physician orders completed such as vital signs; medications etc. until they are physically discharged off the nursing unit. Education will be provided to the inpatient nursing staff beginning no later than Monday, December 12, 2011on the documentation of the discharge note as well as the continuation of physician orders until the discharged patient has left the facility. The discharge note documentation will begin after the education is completed. Also for any patient that refuses discharge, the nurse is to call the physician/provider and inform the physician/provider of the patient refusal. The physician/provider is requested to provide a face to face evaluation prior to the patient discharge. The nursing staff will also be re-educated on the policy "Taxi Service – Patient Discharge" (attachment 9). A key point is the patient is to be able to independently ambulate in and out of the private transportation and provide clear directions. This policy is to be brought to the attention of the Coordination of Care department for further review and education as well. This information "Discharge Talking Points" (attachment 10) is to be provided to the Patient Care Managers and Clinical Educators by the VP of Nursing or designee to educate the nursing staff on these issues. The Patient discharge instruction form is also completed upon patient discharge. **Monitoring:** Until further directed the resource/charge nurse reviews the discharge prior to the patient leaving the nursing unit to ensure the documentation of the discharge note has been completed with the necessary components. Once the education is completed and the implementation is done, the discharge note audit is transitioned from the concurrent process to a retrospective review of charts to be completed by the nursing performance improvement staff. Any noncompliance or issues identified will be followed up and addressed in a timely manner by the VP of Nursing. Furthermore, the BOT will be notified in a timely manner by the CEO of the results of these audits. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERS/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	11/30/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COOC
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P 0 BOX 2000 FAYETTEVILLE, NC 28302

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A 144	Continued From page 6 Functions: 1. Assesses the patient and identifies patient needs. ...3. Plans, organizes, implements and evaluates patient care. ...". Closed record review of Patient #1 revealed a 29 year-old admitted to the hospital 11/15/2011 after presenting to the hospital's emergency department on 11/14/2011 with chief complaint of right-sided chest pain. Review of the admitting physician's dictated history and physical, dated 11/15/2011 at 1858 revealed, "Chief Complaint Right-sided chest pain. History of Present Illness This is a 29-year-old African American male who recently discharged 2 weeks ago. He was actually admitted for sepsis, rule out meningitis, but his meningitis was ruled out, cachetic, anorexia nervosa, malnutrition, worsening chronic pain syndrome, polysubstance abuse. The patient has history of non-Hodgkin's lymphoma, currently in remission...The patient is complaining of mild shortness of breath...The patient has a cough on and off. ...In the emergency department he was evaluated by the ED physicians who did cardiac enzymes which were negative. He had a chest x-ray that was consistent with volume loss. There is an infiltrate within the right upper lobe which is increasing in appearance and early stage of cavitary formation and gradually increasing in density and shape since 10/27/2011. ...Plan The patient will be admitted...in isolation room. The patient will be isolated, droplet and airborne precaution. ...". Review of the physician's discharge summary for Patient #1, dictated 11/22/2011 at 1630 revealed, "...Hospital Course The patient was admitted as a case of right-sided chest pain, cavitary lung lesions, and also query pneumonia, as well as	A 115	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** When the incident was brought to the attention of our Administration, an immediate action plan was put into place to ensure protection of patient rights, an organized nursing staff, and a safe setting (attachment 2). Our analysis of the event referenced in this statement of deficiencies provided an opportunity to improve our systems to ensure a 1) quick and appropriate response to concerns about patient condition 2) appropriate and timely activation of our rapid response team and 3)more organized inpatient discharge process including routine and appropriate pain reassessment. Furthermore, the action plan includes education on existing policies applicable to this situation. A. As Administration monitors to assure that this action plan is effective, Nursing Leadership stationed a nurse in the discharge foyer during normal discharge hours as an added resource to recognize changes in patient condition and respond accordingly. The immediate action was to have the nurse transport the patient to the door of the facility for discharge; however Nursing Leadership is transitioning to nursing staff (staff nurse or nursing assistant) since the rapid response education has been completed. This education for nursing staff is to begin on December 9, 2011 and be ongoing. A nursing staff member from the discharging nursing unit will accompany the patient. Upon return from the discharge, the nursing staff member is to sign the discharge log (attachment 3). During hours when the discharge foyer is not open a nursing staff member will accompany the patient and the nursing staff member will wait with the patient until patient departs the facility. A transporter may also accompany the patient for discharge at the discretion of the staff member. On the afternoon of the event the decision was made to re-educate staff regarding the availability of CFV's existing rapid response team to respond to any change in the medical condition of the patient, visitor or staff member ("attachment 4 & 4A" CFVHS Education Plan) targeting transporters, nursing staff, environmental services and dietary services.	Dec. 14, 2011

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A 144	Continued From page 7 hypokalemia, failure to thrive, malnutrition, and a history of non-Hodgkin's lymphoma. The patient was placed on telemetry monitoring. The patient was placed on droplet precautions and contact isolation. Sputum was sent for acid-fast bacilli, which was negative times two. The patient was also seen by the pulmonary consult. The patient had a bronchoscopy done, without any complications. Cultures from the bronchoscopy and the pathology report just showed mild, chronic inflammation of the bronchial mucosa in the right upper lobe. There was no evidence of any malignant cells. ...Bronchial washing cultures grew fungal elements. The patient received Avelox (antibiotic) for seven days and also Zosyn (antibiotic). This was subsequently discontinued, and the patient was started on Diflucan (anti-fungal), as per infectious disease...He is awake, without altered mentation. He is able to respond appropriately to questions. He is generally weak...the patient is stable and afebrile...He is going to be discharged home...Condition on Discharge Stable...Followup Care The patient is to follow up with the primary MD, as scheduled on an outpatient basis...The plan was communicated to the patient, who verbalized understanding". Further record review for Patient #1 revealed a physician's order dated 11/22/2011 at 0902 for discharge to home. Record review revealed admission orders dated 11/14/2011 at 1910 for vital signs every 4 hours. Record review revealed documentation of vital signs on 11/22/2011 at 0800. Record review revealed no documentation of vital signs at 1200 on 11/22/2011. Record review revealed no documentation of vital signs taken prior to or at the time of discharge on	A 115	This included high level education through the holiday and the weekend with a more in-depth education starting on November 28, 2011. A pocket card for rapid response was provided to the transporters, environmental services and dietary services (attachment 5). The education consisted of the review of the policy and procedure on "Rapid Response Guidelines" (attachment 6). The intent of the education was to ensure that staff members know how and when to call rapid response team when there is a question of a patient's condition worsening including any medical concern of staff or visitors. **Monitoring:** The Service Line Director of Surgical Services has been assigned the responsibility of staffing the discharge foyer with a nurse. If a nurse is not available due to staffing the discharge foyer will not open. The discharge log will continue to be signed by a nursing staff member which is evidence the patient was transported by a nursing staff member (attachment 3). The Rapid Response Team Audit tool (attachment 7) is being completed by the house Nursing Supervisor whereby staff members of transportation, environmental services and dietary are being audited of their knowledge of rapid response procedures. Effective December 8, 2011, the house nursing supervisor began auditing the nursing assistants prior to the transition from nurse to nurse/nursing assistant for patient discharge. In the event the staff member cannot answer the audit questions, they are to be re-educated immediately and demonstrate understanding of the process. A random audit of the discharge log will be completed by the Service Line Director (SLD) of each nursing unit to ensure the nurse/NA are the staff transporting the patient on discharge. Responsibility: VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT	

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A 144	Continued From page 8 11/22/2011 at 1404 (6 hours after last vital signs taken). Record review further revealed RN #1 administered Percocet (narcotic pain medication) on 11/22/2011 at 1005 for generalized pain with pain rated at 10, with 10 being the most severe pain on a scale of 1 to 10. Record review revealed no documentation that the patient's pain was reassessed after administration of the pain medication. Further record review revealed nursing documentation completed by RN #1 on 11/22/2011 at 1000, "Pt refusing morning meds, requests pain meds only, refused breakfast as well, no complaints and no distress noted...monitoring continues". Further record review revealed nursing documentation completed by RN #2 on 11/22/2011 at 1230, "Pt. awake with intermittent spont (spontaneous) eye movement, told of MD order to discharge. Pt. nodded head yes to understanding of order & nodded head yes to transporter on the way". Further record review revealed nursing documentation by RN #2 on 11/22/2011 at 1347, "Pt lying in bed, discharge instructions given, pt refusing to talk or move, transport in to take pt to front lobby, explained to pt that taxi would be coming to pick him up, still would not move, security called to escort pt to front lobby, no distress noted". Review of the hospital's "Event Response Team Checklist" revealed, "Date ERT met: 11-23-11 ERT Members Present: (names of members) Issue discussed: Pt expired after d/c (discharge) on way home...Immediate Issues to be disseminated to staff: Continue to follow policies & procedures...Pt of (MD #1) . Taxi cab owner called (RN #2) , told her the pt has 'flatlined'. Driver was relaying info to owner (of taxi contract	A 115	B. There is a nursing organization chart (attachment 8) that demonstrates the oversight and responsibility for nursing. For each nursing unit there are Resource Nurses/ charge nurses that report to the Patient Care Manager (PCM). The PCM reports to the Service Line Director (SLD). The SLD reports to the Vice President of Nursing. The positions listed above (with the exception of the resource nurse) have 24 hours per day and 7 days per week accountability and responsibility for nursing care. There is also a house Nursing Supervisor 24 hours per day and 7 days per week with responsibility and oversight of nursing care. There are clinical educators assigned to each inpatient nursing unit (unless vacancy exists) that report to the PCM of that nursing unit. A template with the components of a discharge note is to be developed for use by the staff nurses by December 14, 2011. The recommended components include but are not limited to mental status, color of patient, skin temperature, level of pain when relevant and patient condition. The nurses will be re-educated on the importance of the assessment of the condition on discharge and the importance of reassessment of pain after pain medication during the discharge process. It will also be re-educated that patients are to continue to have physician orders completed such as vital signs; medications etc. until they are physically discharged off the nursing unit. Education will be provided to the inpatient nursing staff beginning no later than Monday, December 12, 2011on the documentation of the discharge note as well as the continuation of physician orders until the discharged patient has left the facility: The discharge note documentation will begin after the education is completed. Also for any patient that refuses discharge, the nurse is to call the physician/provider and inform the physician/provider of the patient refusal. The physician/provider is requested to provide a face to face evaluation prior to the patient discharge. The nursing staff will also be re-educated on the policy "Taxi Service – Patient Discharge" (attachment 9). A key point is the patient is to be able to independently ambulate in and out of the private transportation and provide clear directions.	Dec. 14, 2011

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A 144	Continued From page 9 service) who was telling (RN #2). Pt d/c 1347, phone call at 1455. Pt was uncooperative at d/c, was alert. Stopped talking when found out was being d/c, wouldn't make eye contact. Cousin, NA (nursing assistant) who works here, went into room with (RN #2), said he does this everytime it's time for him to be d/c. Transport and security took him downstairs. (MD #1) said he is stable, it's time for him to go. This was minutes before d/c. Does not appear nor does any staff mention inappropriate discharge. Not a sentinel event, with pt's history, death is not unexpected. Will continue to interview to discern more information...". Interview on 11/30/2011 at 0925 with RN #2 revealed the nurse was the charge nurse on 8 South 11/22/2011 (the unit from where Patient #1 was discharged). Interview further revealed, "He (Patient #1) had mood swings. One minute he was upbeat and talkative. The next time he was quiet, wouldn't make eye contact and wouldn't talk. He was withdrawn, especially when he didn't get his way. When his IV pain medication was discontinued, he got upset. He would only eat when he was getting his pain medicine". Interview further revealed, "I went in (to his room) at 1230 because (RN #1) told me that when she told him he was being discharged, he shut down. I had developed rapport with him. I went in and he made eye contact. He nodded yes when I told him he was going home". Interview further revealed, "he has a cousin that works on our floor. She talked with his mother and the mother gave the address to take him to. I saw him in the wheelchair as he was leaving. He seemed fine to me. He was alert". Interview further revealed, "once a patient has discharge orders, we don't do	A 115	This policy is to be brought to the attention of the Coordination of Care department for further review and education as well. This information "Discharge Talking Points" (attachment 10) is to be provided to the Patient Care Managers and Clinical Educators by the VP of Nursing or designee to educate the nursing staff on these issues. The Patient discharge instruction form is also completed upon patient discharge. **Monitoring:** Until further directed the resource/charge nurse reviews the discharge prior to the patient leaving the nursing unit to ensure the documentation of the discharge note has been completed with the necessary components. Once the education is completed and the implementation is done, the discharge note audit is transitioned from the concurrent process to a retrospective review of charts to be completed by the nursing performance improvement staff. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT A 144 **The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** When the incident was brought to the attention of our Administration, an immediate action plan was put into place to ensure protection of patient rights, an organized nursing staff, and a safe setting (attachment 2). Our analysis of the event referenced in this statement of deficiencies provided an opportunity to improve our systems to ensure a 1) quick and appropriate response to concerns about patient condition 2) appropriate and timely activation of our rapid response team and 3)more organized inpatient discharge process including routine and appropriate pain reassessment. Furthermore, the action plan includes education on existing policies applicable to this situation. A. As Administration monitors to assure that this action plan is effective, Nursing Leadership stationed a nurse in the discharge foyer during normal discharge hours as an added resource to recognize changes in patient condition and respond accordingly. The immediate action was to have the	Dec. 14, 2011

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A 144	Continued From page 10 vital signs again unless the condition warrants. His monitor (EKG) stayed on until right before discharge". Interview on 11/30/2011 at 1020 with RN #1 revealed the nurse had been assigned primary care to Patient #1 on previous hospital admissions. Interview revealed 11/22/2011 (the day Patient #1 was discharged) was RN#1's first assignment to Patient #1 for the current hospital admission. Interview revealed, "I assessed him between 7:30 and 8:00. He was in bed, in no distress. He answered all my questions. When I told him he was being discharged, I tried to call his Mom but the phone was disconnected. I told him he had a taxi voucher to go home and was being discharged. He just stopped talking. He was already upset that he didn't have IV pain medication ordered. He had a cough. I brought him his cough medicine and he knocked it out of my hand so I just wasted it and didn't give it to him. I called the taxi service first, then called the transporter. He wasn't being cooperative for us, so I called security to assist with getting him in the wheelchair. I saw him in the wheelchair prior to him getting on the elevator. He was sitting up, alert and in no distress". Interview further revealed, "I got a phone call from (Transporter #2). He said he was slouched down in the wheelchair in the lobby. I told him he was just being uncooperative. They didn't tell me he was in any kind of distress. I figured he was just being uncooperative". Further interview with RN #1 on 11/22/2011 at 1445 revealed, "I did not reassess him after giving him his pain medicine at 1005. He should have been reassessed within an hour". Interview	A 144	nurse transport the patient to the door of the facility for discharge; however Nursing Leadership is transitioning to nursing staff (staff nurse or nursing assistant) since the rapid response education has been completed. This education for nursing staff is to begin on December 9, 2011 and be ongoing. A nursing staff member from the discharging nursing unit will accompany the patient. Upon return from the discharge, the nursing staff member is to sign the discharge log **(attachment 3)**. During hours when the discharge foyer is not open a nursing staff member will accompany the patient and the nursing staff member will wait with the patient until patient departs the facility. A transporter may also accompany the patient for discharge at the discretion of the staff member in addition to the nursing staff. On the afternoon of the event the decision was made to re-educate staff regarding the availability of CFV's existing rapid response team to respond to any change in the medical condition of the patient, visitor or staff member **(see CFVHS Education Plan "attachment 4 & 4A")** targeting transporters, nursing staff, environmental services and dietary services. This included a high level education through the holiday and the weekend with a more in-depth education starting on November 28, 2011. A pocket card for rapid response was provided to the transporters, environmental services and dietary services **(attachment 5)**. The education consisted of the review of the policy and procedure on "Rapid Response Guidelines" **(attachment 6)**. The intent of the education was to ensure that staff members know how and when to call rapid response team when there is a question of a patient's condition worsening including any medical concern of staff or visitors.	

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A 144	Continued From page 11 further revealed, " I received a call from (Transporter #2) when he (Patient #1) was in the lobby. He told me the patient was slouched down in the chair. I didn't ask him any questions about his color or was he breathing". Interview further revealed, "I didn't go down to assess him because he had been discharged and I had five other patients to look after". Interview further revealed, "the transporter should have recognized a problem and called the rapid response team". Interview further revealed, "I should have called rapid response". Interview on 11/30/2011 at 1000 with Transporter #1 revealed the transporter remembered Patient #1. Interview revealed he went to 8 South at approximately 1330 on 11/22/2011 to transport Patient #1 to the lobby for discharge. Interview revealed, "he was alert but non-communicative. When we talked to him, he turned away from us. Security helped me get him in the wheelchair. Security had been called by nursing because he had refused to get in the wheelchair". Interview further revealed, "the taxi van didn't arrive until about 2:05. We waited down there about 15 minutes. He was sitting up straight and then he slouched down in the wheelchair, like he was giving up, he was going home". Interview on 11/30/2011 at 1125 with Transporter #2 revealed the transporter worked in the front lobby discharge area and was working on 11/22/2011. Interview revealed, "when (Transporter #1) brought (Patient #1) down, I asked him, 'Is this guy ok? He doesn't look good. He was sitting, slouched in the wheelchair. I called the nurse on 8 South and asked her was this patient ok. She said, 'he's ok. He just	A 144	**Monitoring:** The Service Line Director of Surgical Services has been assigned the responsibility of staffing the discharge foyer with a nurse. If a nurse is not available due to staffing the discharge foyer will not open. The discharge log will continue to be signed by a nursing staff member which is evidence the patient was transported by a nursing staff member **(attachment 3).** The Rapid Response Team Audit tool **(attachment 7)** is being completed by the house Nursing Supervisor whereby staff members of transportation, environmental services and dietary are being audited of their knowledge of rapid response procedures. Effective December 8, 2011, the house nursing supervisor began auditing the nursing assistants prior to the transition from nurse to nurse/nursing assistant for patient discharge. In the event the staff member cannot answer the audit questions, they are to be re-educated immediately and demonstrate understanding of the process. A random audit of the discharge log will be completed by the Service Line Director (SLD) of each nursing unit to ensure the nurse/NA are the staff transporting the patient on discharge. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT	

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A 144	Continued From page 12 doesn't want to go home. He just wants his meds". Interview further revealed, "(Transporter #1) and I helped him into the van. He would not stand up. We lifted him up and put him in the van. We put his seat belt on him. I think he was breathing. His eyes were open". Further interview with Transporter #1 on 11/30/2011 at 1145 revealed, "we had to lift him up and put him in the van. We had to put his legs into the van. When we put him in the van, the (taxi) driver asked that the nurse be called because he (Patient #1) didn't look right to him. (Transporter #2) called the nurse and he told the driver exactly what the nurse upstairs told me, that this was normal for him". Interview revealed the only call made concerning the change in condition for Patient #1 was the call made by Transporter #2 to nursing on 8 South at the request of the taxi driver. Interview further revealed, "I thought it was a good idea to call the nurse. I thought the nurse should have come down and reassessed him before he drove off". Interview via telephone on 11/30/2011 at 1300 with Taxi Driver #1 revealed the taxi/transport company has a contract with named hospital. Interview revealed, "I was taught to observe the whole patient. Our contract says the patient should be able to board/unboard by himself. When I pulled up, (Patient #1) was slumped over in the wheelchair. He didn't look normal to me. I told the transporter, (Transporter #2) that he didn't look right. He (Transporter #2) called the nurse and the nurse said he was ok. He just didn't want to go home. I told him the patient needed to be able to talk to me because I didn't know exactly where his house was. I got a phone	A 144	B. There is a nursing organization chart (attachment 8) that demonstrates the oversight and responsibility for nursing. For each nursing unit there are Resource Nurses/ charge nurses that report to the Patient Care Manager (PCM). The PCM reports to the Service Line Director (SLD). The SLD reports to the Vice President of Nursing. The positions listed above (with the exception of the resource nurse) have 24 hours per day and 7 days per week accountability and responsibility for nursing care. There is also a house Nursing Supervisor 24 hours per day and 7 days per week with responsibility and oversight of nursing care. There are clinical educators assigned to each inpatient nursing unit (unless vacancy exists) that report to the PCM of that nursing unit. A template with the components of a discharge note is to be developed for use by the staff nurses by December 14, 2011. The recommended components include but are not limited to mental status, color of patient, skin temperature, level of pain when relevant and patient condition. The nurses will be re-educated on the importance of the assessment of the condition on discharge and the importance of reassessment of pain after pain medication during the discharge process. It will also be re-educated that patients are to continue to have physician orders completed such as vital signs; medications etc. until they are physically discharged off the nursing unit. Education will be provided to the inpatient nursing staff beginning no later than Monday, December 12, 2011on the documentation of the discharge note as well as the continuation of physician orders until the discharged patient has left the facility. The discharge note documentation will begin after the education is completed. Also for any patient that refuses discharge, the nurse is to call the physician/provider and inform the physician/provider of the patient refusal. The	Dec. 14, 2011

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERS/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	11/30/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 13 number to his house". Interview further revealed, "He never stood up. Those two men (Transporters #1 and #2) lifted him into the van". Interview further revealed, "I tried to talk to him while in the taxi. I asked him was he ok and did he need assistance. He was non-responsive. I contacted (name of supervisor) and told her he didn't look right. When I arrived at his house, he had closed his eyes. He looked like he was sleeping. I called his house and his mother came out. She called his name. She said, 'he's not acting right'. She called 911. When EMS arrived, they put the monitor on him. He was flatlined, dead. We couldn't move him. It was about 5 hours before they finally got him out of the van. They said because he had died on the way home from the hospital, they had to treat it like a criminal scene". Interview further revealed it was a 45 minute drive from the hospital to Patient #1's house. Interview via telephone on 11/30/2011 at 1315 with the owner of the transport/taxi service revealed she received a call from RN #1 on 11/22/2011 at 1312 for a patient to be transported home. Interview further revealed she received a call at 1352 from Transporter #2 that patient was in the lobby, ready to be picked up. Interview further revealed she received a call from Taxi Driver #1 at 1353 that he was at the hospital and that the patient didn't look right. Interview revealed, "He told me they picked him up and put him in the van and the patient was not saying a word". Interview further revealed, "I called 8 South and spoke to (RN #1). She told me he was ok, he just didn't want to go home". Interview further revealed, "(Taxi Driver #1) called 911 at 2:46 (pm). At 2:51 (pm), I called 8 South and	A 144	physician/provider is requested to provide a face to face evaluation prior to the patient discharge. The nursing staff will also be re-educated on the policy "Taxi Service – Patient Discharge" **(attachment 9)**. A key point is the patient is to be able to independently ambulate in and out of the private transportation and provide clear directions. This policy is to be brought to the attention of the Coordination of Care department for further review and education as well. This information "Discharge Talking Points" **(attachment 10)** is to be provided to the Patient Care Managers and Clinical Educators by the VP of Nursing or designee to educate the nursing staff on these issues. The Patient discharge instruction form is also completed upon patient discharge. **Monitoring:** Until further directed the resource/charge nurse reviews the discharge prior to the patient leaving the nursing unit to ensure the documentation of the discharge note has been completed with the necessary components. Once the education is completed and the implementation is done, the discharge note audit is transitioned from the concurrent process to a retrospective review of charts to be completed by the nursing performance improvement staff. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT	

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A 144	Continued From page 14 talked to (RN #2) and told her that (Patient #1) had died". Interview further revealed, "we have been told by the ER staff not to take patients to the ER (emergency room). (Taxi Driver #1) did that (took a discharged patient to the ER) some time ago and he got fussed out". Interview via telephone on 11/30/2011 at 1400 with the medical examiner in the county where Patient #1 died revealed he had received preliminary autopsy results from the pathologists at UNC. Interview revealed the autopsy results showed that Patient #1 died from pneumonia secondary to complications related to non-Hodgkin's lymphoma. Interview on 11/30/2011 at 1430 with the Chief Medical Officer revealed, "the nurse should have responded to a call that a patient didn't look right". Interview on 11/30/2011 at 1425 with the Interim Chief Nursing Officer revealed Patient #1's record had been reviewed. Interview revealed there were no issues discovered from the hospital's management review of the incident of the discharge of Patient #1 related to policies/procedures being followed. Interview further revealed there were no issues discovered related to reassessment of the patient by the nursing staff.	A 144		
A 385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by:	A 385	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** When the incident was brought to the attention of our Administration, an immediate action plan was put into place to ensure protection of patient rights, an organized nursing staff, and a safe setting (attachment 2). Our analysis of the event referenced in this statement of deficiencies provided an opportunity to improve our systems to ensure a 1) quick and appropriate response to concerns about patient condition 2) appropriate and timely activation of our rapid response team and 3)more organized inpatient discharge process including routine and appropriate pain reassessment. Furthermore, the action plan includes education on existing policies applicable to this situation.	

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A 385	Continued From page 15 Based on review of hospital policy, job descriptions, closed medical record review, hospital document review and staff, physician, medical examiner and contracted transportation staff interview, the hospital failed to have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care. The findings include: The hospital failed to ensure nursing staff supervised and evaluated patient care by failing to ensure nursing staff evaluated a patient's response to pain medication and reassess a patient once notified of a change in the patient's condition for 1 of 1 inpatient discharges reviewed (#1). ~cross refer to 482.23 (b)(3) Nursing Services Standard: Tag A0395	A 385	A. As Administration monitors to assure that this action plan is effective, Nursing Leadership stationed a nurse in the discharge foyer during normal discharge hours as an added resource to recognize changes in patient condition and respond accordingly. The immediate action was to have the nurse transport the patient to the door of the facility for discharge; however Nursing Leadership is transitioning to nursing staff (staff nurse or nursing assistant) since the rapid response education has been completed. This education for nursing staff is to begin on December 9, 2011 and be ongoing. A nursing staff member from the discharging nursing unit will accompany the patient. Upon return from the discharge, the nursing staff member is to sign the discharge log (attachment 3). During hours when the discharge foyer is not open a nursing staff member will accompany the patient and the nursing staff member will wait with the patient until patient departs the facility. A transporter may also accompany the patient for discharge at the discretion of the staff member. On the afternoon of the event the decision was made to re-educate staff regarding the availability of CFV's existing rapid response team to respond to any change in the medical condition of the patient, visitor or staff member ("see attachment 4" CFVHS Education Plan) targeting transporters, nursing staff, environmental services and dietary services. This included a high level education through the holiday and the weekend with a more in-depth education starting on November 28, 2011. A pocket card for rapid response was provided to the transporters, environmental services and dietary services (attachment 5). The education consisted of the review of the policy and procedure on "Rapid Response Guidelines" (attachment 6). The intent of the education was to ensure that staff members know how and when to call rapid response team when there is a question of a patient's condition worsening including any medical concern of staff or visitors.	Dec. 14, 2011,
A 395	482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, hospital document review and staff, physician, medical examiner and contracted transportation staff interview, the hospital failed to ensure nursing staff supervised and evaluated patient care by failing to ensure nursing staff evaluated a patient's response to pain medication and reassess a patient once notified of a change in			

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A 395	Continued From page 16 the patient's condition for 1 of 1 inpatient discharges reviewed (#1). The findings include: Review of the hospital's policy, "Pain Management", revised 07/26/2010, revealed, "POLICY: (Name of hospital), through its care providers, assesses, intervenes and reassesses the patient's pain on an ongoing basis. ...GUIDELINES: Each patient has the right to expect his/her report of pain to be accepted, to have the pain assessed and reassessed...6. ...Patients are reassessed and effectiveness (including pain scale) is documented by providers after administration of oral pain medication after 60 minutes to 120 minutes. ...". Review of the hospital's policy, "Discharging a Patient", revised 02/19/2009, revealed, "...REQUISITES: RNs/LPNs are responsible for completion of Patient Discharge Instruction...Nursing Assistants may assist by taking vital signs...". Review of the hospital's policy, "Assessment and Reassessment", revised 11/16/2010, revealed, "..Procedure: ...3. Assessment and reassessment are completed as patient's condition warrants... 6. Reassessment is any assessment completed after the initial shift assessment. ...The timing,scope and intensity of reassessment is based on the patient's diagnosis, response to any previous care, change in condition and/or diagnosis, as requested by patient or at discretion of the RN. ... A. Reassessment includes: a. Response to medications...b. Response to pain medications	A 385	**Monitoring:** The Service Line Director of Surgical Services has been assigned the responsibility of staffing the discharge foyer with a nurse. If a nurse is not available due to staffing the discharge foyer will not open. The discharge log will continue to be signed by a nursing staff member which is evidence the patient was transported by a nursing staff member **(attachment 3)**. The Rapid Response Team Audit tool **(attachment 7)** is being completed by the house Nursing Supervisor whereby staff members of transportation, environmental services and dietary are being audited of their knowledge of rapid response procedures. Effective December 8, 2011, the house nursing supervisor began auditing the nursing assistants prior to the transition from nurse to nurse/nursing assistant for patient discharge. In the event the staff member cannot answer the audit questions, they are to be re-educated immediately and demonstrate understanding of the process. A random audit of the discharge log will be completed by the Service Line Director (SLD) of each nursing unit to ensure the nurse/NA are the staff transporting the patient on discharge. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT B. There is a nursing organization chart **(attachment 8)** that demonstrates the oversight and responsibility for nursing. For each nursing unit there are Resource Nurses/ charge nurses that report to the Patient Care Manager (PCM). The PCM reports to the Service Line Director (SLD). The SLD reports to the Vice President of Nursing. The positions listed above (with the exception of the resource nurse) have 24 hours per day and 7 days per week accountability and responsibility for nursing care. There is also a house Nursing Supervisor 24 hours per day and 7 days per week with responsibility and oversight of nursing care. There are clinical educators assigned to each inpatient nursing unit (unless vacancy exists) that report to the PCM of that nursing unit.	Dec. 14, 2011,

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A 395	Continued From page 17 and interventions...f. Discharge planning...". Review of the hospital's policy, "Rapid Response Guidelines", revised 04/25/2011, revealed, "POLICY: The Rapid Response Team (RRT) responds to situations where patients at (Hospital Name) are experiencing acute clinical changes or are in a pre-code status. The RRT responds to emergent and pre-emergent situations in all areas...PURPOSE: To provide early intervention for patients who experience acute clinical changes in an effort to stabilize, monitor and transfer to a higher level of care if needed, thereby preventing the progression to cardiopulmonary arrest. ...GUIDELINES: Rapid Response Team Members: 1. RRT member responds within 5 minutes to requests for patient assistance or requests that fall within the following established guidelines for response: a. Staff member concerned about the medical condition of a patient...". Review of the hospital's job description for a Registered Nurse, revised 11/2011, revealed, "...Job Summary: Plans and implements professional nursing care for patients in accordance with hospital policies. ... Major Job Functions: 1. Assesses the patient and identifies patient needs. ...3. Plans, organizes, implements and evaluates patient care. ...". Closed record review of Patient #1 revealed a 29 year-old admitted to the hospital 11/15/2011 after presenting to the hospital's emergency department on 11/14/2011 with chief complaint of right-sided chest pain. Review of the admitting physician's dictated history and physical, dated 11/15/2011 at 1858 revealed, "Chief Complaint	A 385	A template with the components of a discharge note is to be developed for use by the staff nurses by December 14, 2011. The recommended components include but are not limited to mental status, color of patient, skin temperature, level of pain when relevant and patient condition. The nurses will be re-educated on the importance of the assessment of the condition on discharge and the importance of reassessment of pain after pain medication during the discharge physician wrote the discharge orders. It will also be re-educated that patients are to continue to have physician orders completed such as vital signs; medications etc. until they are physically discharged off the nursing unit. Education will be provided to the inpatient nursing staff beginning no later than Monday, December 12, 2011on the documentation of the discharge note as well as the continuation of physician orders until the discharged patient has left the facility. The discharge note documentation will begin after the education is completed. Also for any patient that refuses discharge, the nurse is to call the physician/provider and inform the physician/provider of the patient refusal. The physician/provider is requested to provide a face to face evaluation prior to the patient discharge. The nursing staff will also be re-educated on the policy "Taxi Service – Patient Discharge" **(attachment 9).** A key point is the patient is to be able to independently ambulate in and out of the private transportation and provide clear directions. This policy is to be brought to the attention of the Coordination of Care department for further review and education as well. This information "Discharge Talking Points" **(attachment 10)** is to be provided to the Patient Care Managers and Clinical Educators by the VP of Nursing or designee to educate the nursing staff on these issues. The Patient discharge instruction form is also completed upon patient discharge.	

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A 395	Continued From page 18 Right-sided chest pain. History of Present Illness This is a 29-year-old African American male who recently discharged 2 weeks ago. He was actually admitted for sepsis, rule out meningitis, but his meningitis was ruled out, cachetic, anorexia nervosa, malnutrition, worsening chronic pain syndrome; polysubstance abuse. The patient has history of non-Hodgkin's lymphoma, currently in remission...The patient is complaining of mild shortness of breath...The patient has a cough on and off. ...In the emergency department he was evaluated by the ED physicians who did cardiac enzymes which were negative. He had a chest x-ray that was consistent with volume loss. There is an infiltrate within the right upper lobe which is increasing in appearance and early stage of cavitary formation and gradually increasing in density and shape since 10/27/2011. ...Plan The patient will be admitted...in isolation room. The patient will be isolated, droplet and airborne precaution. ...". Review of the physician's discharge summary for Patient #1, dictated 11/22/2011 at 1630 revealed, "...Hospital Course The patient was admitted as a case of right-sided chest pain, cavitary lung lesions, and also query pneumonia, as well as hypokalemia, failure to thrive, malnutrition, and a history of non-Hodgkin's lymphoma. The patient was placed on telemetry monitoring. The patient was placed on droplet precautions and contact isolation. Sputum was sent for acid-fast bacilli, which was negative times two. The patient was also seen by the pulmonary consult. The patient had a bronchoscopy done, without any complications. Cultures from the bronchoscopy and the pathology report just showed mild, chronic inflammation of the bronchial mucosa in	A 385	**Monitoring:** Until further directed the resource/charge nurse reviews the discharge prior to the patient leaving the nursing unit to ensure the documentation of the discharge note has been completed with the necessary components. Once the education is completed and the implementation is done, the discharge note audit is transitioned from the concurrent process to a retrospective review of charts to be completed by the nursing performance improvement staff. Any noncompliance or issues identified will be followed up and addressed in a timely manner by the VP of Nursing. Furthermore, the BOT will be notified in a timely manner by the CEO of the results of these audits. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT A 395 **The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** When the incident was brought to the attention of our Administration, an immediate action plan was put into place to ensure protection of patient rights, an organized nursing staff, and a safe setting **(attachment 2)**. Our analysis of the event referenced in this statement of deficiencies provided an opportunity to improve our systems to ensure a 1) quick and appropriate response to concerns about patient condition 2) appropriate and timely activation of our rapid response team and 3)more organized inpatient discharge process including routine and appropriate pain reassessment. Furthermore, the action plan includes education on existing policies applicable to this situation. A. As Administration monitors to assure that this action plan is effective, Nursing Leadership stationed a nurse in the discharge foyer during normal discharge hours as an added resource to recognize changes in patient condition and respond accordingly. The immediate action was to have the nurse transport the patient to the door of the facility for discharge; however Nursing Leadership is transitioning to nursing staff (staff nurse or nursing assistant) since the rapid response education has	Dec. 14, 2011

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A 395	Continued From page 19 the right upper lobe. There was no evidence of any malignant cells. ...Bronchial washing cultures grew fungal elements. The patient received Avelox (antibiotic) for seven days and also Zosyn (antibiotic). This was subsequently discontinued, and the patient was started on Diflucan (anti-fungal), as per infectious disease...He is awake, without altered mentation. He is able to respond appropriately to questions. He is generally weak...the patient is stable and afebrile...He is going to be discharged home...Condition on Discharge Stable...Followup Care The patient is to follow up with the primary MD, as scheduled on an outpatient basis...The plan was communicated to the patient, who verbalized understanding". Further record review for Patient #1 revealed a physician's order dated 11/22/2011 at 0902 for discharge to home. Record review revealed admission orders dated 11/14/2011 at 1910 for vital signs every 4 hours. Record review revealed documentation of vital signs on 11/22/2011 at 0800. Record review revealed no documentation of vital signs at 1200 on 11/22/2011. Record review revealed no documentation of vital signs taken prior to or at the time of discharge on 11/22/2011 at 1404 (6 hours after last vital signs taken). Record review further revealed RN #1 administered Percocet (narcotic pain medication) on 11/22/2011 at 1005 for generalized pain with pain rated at 10, with 10 being the most severe pain on a scale of 1 to 10. Record review revealed no documentation that the patient's pain was reassessed after administration of the pain medication. Further record review revealed nursing documentation completed by RN #1 on 11/22/2011 at 1000, "Pt refusing morning meds,	A 395	been completed. This education for nursing staff is to begin on December 9, 2011 and be ongoing...A nursing staff member from the discharging nursing unit will accompany the patient. Upon return from the discharge, the nursing staff member is to sign the discharge log **(attachment 3)**. During hours when the discharge foyer is not open a nursing staff member will accompany the patient and the nursing staff member will wait with the patient until patient departs the facility. A transporter may also accompany the patient for discharge at the discretion of the staff member. On the afternoon of the event the decision was made to re-educate staff regarding the availability of CFV's existing rapid response team to respond to any change in the medical condition of the patient, visitor or staff member **(attachment 4)** CFVHS Education Plan) targeting transporters, nursing staff, environmental services and dietary services. This included a high level education through the holiday and the weekend with a more in-depth education starting on November 28, 2011. A pocket card for rapid response was provided to the transporters, environmental services and dietary services **(attachment 5)**. The education consisted of the review of the policy and procedure on "Rapid Response Guidelines" **(attachment 6)**. The intent of the education was to ensure that staff members know how and when to call rapid response team when there is a question of a patient's condition worsening including any medical concern of staff or visitors. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT **Monitoring:** The Service Line Director of Surgical Services has been assigned the responsibility of staffing the discharge foyer with a nurse. If a nurse is not available due to staffing the discharge foyer will not open. The discharge log will continue to be signed by a nursing staff member which is evidence the patient was transported by a nursing staff member **(attachment 3)**. The Rapid Response	

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A 395	Continued From page 20 requests pain meds only, refused breakfast as well, no complaints and no distress noted...monitoring continues". Further record review revealed nursing documentation completed by RN #2 on 11/22/2011 at 1230, "Pt. awake with intermittent spont (spontaneous) eye movement, told of MD order to discharge. Pt. nodded head yes to understanding of order & nodded head yes to transporter on the way". Further record review revealed nursing documentation by RN #2 on 11/22/2011 at 1347, "Pt lying in bed, discharge instructions given, pt refusing to talk or move, transport in to take pt to front lobby, explained to pt that taxi would be coming to pick him up, still would not move, security called to escort pt to front lobby, no distress noted". Review of the hospital's "Event Response Team Checklist" revealed, "Date ERT met: 11-23-11 ERT Members Present: (names of members) Issue discussed: Pt expired after d/c (discharge) on way home...Immediate Issues to be disseminated to staff: Continue to follow policies & procedures...Pt of (MD #1) . Taxi cab owner called (RN #2) , told her the pt has 'flatlined'. Driver was relaying info to owner (of taxi contract service) who was telling (RN #2). Pt d/c 1347, phone call at 1455. Pt was uncooperative at d/c, was alert. Stopped talking when found out was being d/c, wouldn't make eye contact. Cousin, NA (nursing assistant) who works here, went into room with (RN #2), said he does this everytime it's time for him to be d/c. Transport and security took him downstairs. (MD #1) said he is stable, it's time for him to go. This was minutes before d/c. Does not appear nor does any staff mention inappropriate discharge. Not a sentinel event,	A 395	Team Audit tool (attachment 7) is being completed by the house Nursing Supervisor whereby staff members of transportation, environmental services and dietary are being audited of their knowledge of rapid response procedures. Effective December 8, 2011, the house nursing supervisor began auditing the nursing assistants prior to the transition from nurse to nurse/nursing assistant for patient discharge. In the event the staff member cannot answer the audit questions, they are to be re-educated immediately and demonstrate understanding of the process. A random audit of the discharge log will be completed by the SLD of each nursing unit to ensure the nurse/NA are the staff transporting the patient on discharge. B. There is a nursing organization chart (attachment 8) that demonstrates the oversight and responsibility for nursing. For each nursing unit there are Resource Nurses/ charge nurses that report to the Patient Care Manager (PCM). The PCM reports to the Service Line Director (SLD). The SLD reports to the Vice President of Nursing. The positions listed above (with the exception of the resource nurse) have 24 hours per day and 7 days per week accountability and responsibility for nursing care. There is also a house Nursing Supervisor 24 hours per day and 7 days per week with responsibility and oversight of nursing care. There are clinical educators assigned to each inpatient nursing unit (unless vacancy exists) that report to the PCM of that nursing unit. A template with the components of a discharge note is to be developed for use by the staff nurses by December 14, 2011. The recommended components include but are not limited to mental status, color of patient, skin temperature, level of pain when relevant and patient condition. The nurses will be re-educated on the importance of the assessment of the condition on discharge and the importance of reassessment of pain after pain medication during the discharge process. It will also be re-educated that patients are to continue to have physician orders completed such as vital signs; medications etc. until they are	Dec. 14, 2011

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A 395	Continued From page 21 with pt's history, death is not unexpected. Will continue to interview to discern more information...". Interview on 11/30/2011 at 0925 with RN #2 revealed the nurse was the charge nurse on 8 South 11/22/2011. Interview further revealed, "He (Patient #1) had mood swings. One minute he was upbeat and talkative. The next time he was quiet, wouldn't make eye contact and wouldn't talk. He was withdrawn, especially when he didn't get his way. When his IV pain medication was discontinued, he got upset. He would only eat when he was getting his pain medicine". Interview further revealed, "I went in (to his room) at 1230 because (RN #1) told me that when she told him he was being discharged, he shut down. I had developed rapport with him. I went in and he made eye contact. He nodded yes when I told him he was going home". Interview further revealed, "he has a cousin that works on our floor. She talked with his mother and the mother gave the address to take him to. I saw him in the wheelchair as he was leaving. He seemed fine to me. He was alert". Interview further revealed, "once a patient has discharge orders, we don't do vital signs again unless the condition warrants. His monitor (EKG) stayed on until right before discharge". Interview on 11/30/2011 at 1020 with RN #1 revealed the nurse had been assigned primary care to Patient #1 on previous hospital admissions. Interview revealed 11/22/2011 (the day Patient #1 was discharged) was RN#1's first assignment to Patient #1 for the current hospital admission. Interview revealed, "I assessed him between 7:30 and 8:00. He was in bed, in no	A 395	physically discharged off the nursing unit. Education will be provided to the inpatient nursing staff beginning no later than Monday, December 12, 2011on the documentation of the discharge note as well as the continuation of physician orders until the discharged patient has left the facility. The discharge note documentation will begin after the education is completed. Also for any patient that refuses discharge, the nurse is to call the physician/provider and inform the physician/provider of the patient refusal. The physician/provider is requested to provide a face to face evaluation prior to the patient discharge. The nursing staff will also be re-educated on the policy "Taxi Service – Patient Discharge" **(attachment 10)**. A key point is the patient is to be able to independently ambulate in and out of the private transportation and provide clear directions. This policy is to be brought to the attention of the Coordination of Care department for further review and education as well. This information "Discharge Talking Points" **(attachment 10)** is to be provided to the Patient Care Managers and Clinical Educators by the VP of Nursing or designee to educate the nursing staff on these issues. The Patient discharge instruction form is also completed upon patient discharge. **Monitoring:** Until further directed the resource/charge nurse reviews the discharge prior to the patient leaving the nursing unit to ensure the documentation of the discharge note has been completed with the necessary components. Once the education is completed and the implementation is done, the discharge note audit is transitioned from the concurrent process to a retrospective review of charts to be completed by the nursing performance improvement staff. Any noncompliance or issues identified will be followed up and addressed in a timely manner by the VP of Nursing. Furthermore, the BOT will be notified in a timely manner by the CEO of the results of these audits. **Responsibility:** VP of Nursing, Chief Operating Officer, Chief Executive Officer, BOT	

Attachment 2

Washington Discharge Matter

Situation	Response	Anticipated Completion
At approximately 2 pm on Tuesday, November 22, 2011, patient Adarrin Washington was discharged from CFVHS. At approximately 4 pm, CFVHS was informed that Mr. Washington expired in private transportation on the way home after being discharged.	(1) On the evening of November 22, 2011, CFVHS's CEO, CMO, CNO and Administrator on Call met, reviewed, and discussed the Washington matter and decided to follow CFVHS's existing process and schedule an Event Response Team meeting the next day at 8 am.	November 22, 2011
	(2) An Event Response Team meeting, with the clinical staff involved in the care of Washington, was held to begin the investigation of the Washington matter at 8 am.	November 23, 2011
	(3) Risk Management met with staff involved in the discharge of Washington to collect facts surrounding the discharge at 10:30 am.	November 23, 2011
	(4) CFVHS's CEO, CMO, and CNO met to discuss the Washington matter and potential next steps at approximately 9 am on November 23, 2011.	November 23, 2011
	(5) CFVHS's CEO contacted the Chairman of the CFVHS Board of Trustees to inform him of the Washington matter.	November 23, 2011
	(6) CFVHS's CEO contacted the Division of Health Services Regulation to inform them of the Washington matter.	November 23, 2011
	(7) By the afternoon of November 23, 2011, in an abundance of caution as we conducted our investigation, CFVHS began a process to ensure that all patients were accompanied by nursing staff during the entire discharge process. Throughout the course of the holiday weekend, nursing was educated about the discharge process and CFVHS's Rapid Response process during all shift changes throughout the holiday weekend.	November 28, 2011
	(8) In addition to the education, CFVHS implemented a Discharge Log requiring nursing staff to attest to their involvement during the entire discharge process.	November 28, 2011
	(9) On November 28, 2011 (the first full work day after the holiday weekend), CFVHS began the process of providing in-depth education on its Rapid Response process to all of its staff in the transportation, nursing, environmental services, and dietary services departments.	December 2, 2011
	(10) CFVHS intends to engage an independent third party, possibly the Greely Group, to audit its process and operations.	December 2, 2011

CONFIDENTIAL

Cape Fear Valley Health System

Discharge Log

(Keep in notebook at nurse's station – DO NOT REMOVE)

Name of Unit: _____

Date: _____

By signing below, I attest that I escorted the patient during the entire discharge process.

(Please sign upon return to nursing unit after discharging patient)

Patient sticker	Signature with credentials of discharging nurse/nursing assistant	Time

Created by Nursing Administration on 11/23/11v2
Revised 12/09/11

CONFIDENTIAL

CFVHS Education Plan
Rapid Response

Late afternoon on November 22, 2011, Cape Fear Valley was informed that a patient expired in private transportation after being discharged from Cape Fear Valley. Cape Fear Valley began investigating the matter immediately. On November 23, 2011, in an abundance of caution as we conducted our investigation, the decision was made to further educate staff regarding the availability of CFV's existing rapid response team to respond to any change in the medical condition of a patient, visitor or staff member. Due to the upcoming holiday weekend the plan was to provide high level education to staff about the rapid response during all shift changes throughout the weekend.

On November 28, 2011 (the first full work day after the holiday weekend) the plan was to provide more in-depth education to staff about the rapid response process. Educational pocket cards are being printed with the plan that they would be distributed to transporters, environmental services and dietary services. The VP of nursing met with Department Managers and Directors of transportation, environmental services, dietary services and nursing services and distributed the "Rapid Response Guidelines" policy with the direction that all relevant staff be educated on the policy with a standardized sign in roster and staff acknowledgement. On November 28, 2011, formal education sessions were begun for the following departments:

- Education for the Transporters
- Education for the nursing staff
- Education for Environmental Services staff
- Education for Dietary Services staff

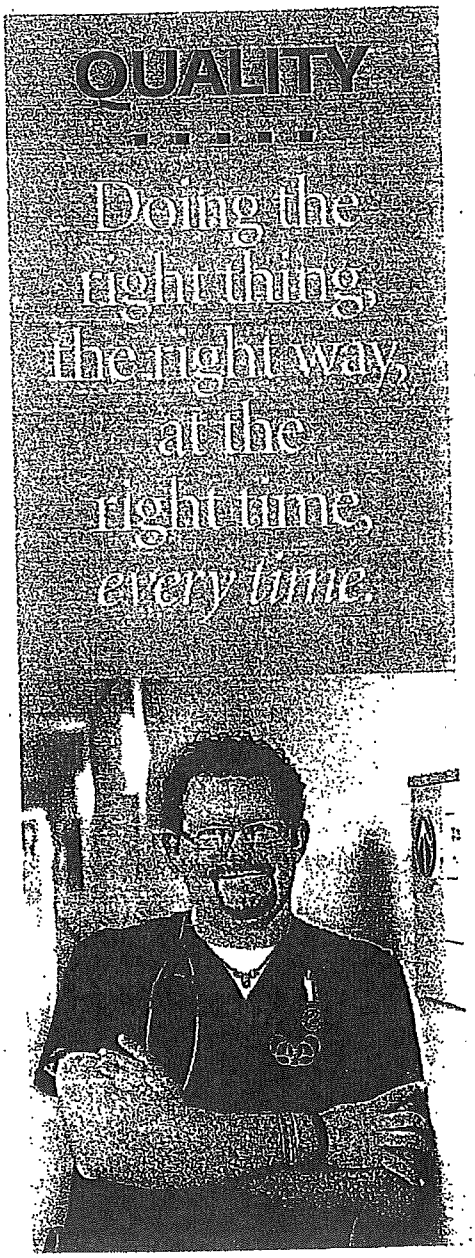
The plan was that all formal education would be completed by December 2, 2011. The final step is to validate the understanding of the education of the staff by utilizing an audit tool to question and track staff's knowledge of the rapid response process. Staff that is not aware of the process will be removed from patient care and re-educated.

Attachment 4A

CAPEability

keeping our PATIENTS SAFE

WINTER 2011



rapid RESPONSE

WHO CAN CALL RAPID RESPONSE?
Anyone can – a patient, family member, nurse or you!

The Rapid Response Team consists of a Critical Care Nurse and Respiratory Therapist who respond immediately when a patient's condition is worsening.

If you are concerned about the medical condition of a patient, visitor or other staff member, the best course of action is to call Rapid Response. At Cape Fear Valley Medical Center or Cape Fear Valley Rehabilitation Center dial 22 and request the Rapid Response Team. Be sure to give your location, including room number and unit or area.

RAPID RESPONSE should be called for:

- Concerns about the medical condition of a patient, visitor or other staff member
- Acute changes in heart rate (less than 40 or greater than 130)
- Acute changes in blood pressure
- Acute changes in respiratory status (respiratory rate less than 9 or greater than 28; pulse oximetry less than 90% or decrease of greater than 8% of the patient's baseline.
- Acute changes in mental status
- Failure to respond to treatment
- Acute significant bleed
- Seizures

AT CAPE FEAR VALLEY MEDICAL CENTER OR CAPE FEAR VALLEY REHABILITATION CENTER DIAL 22

Cape Fear Valley averages about 210 calls a month. Family members can call Rapid Response by dialing 2700 from an in-house phone. We typically have one family activation about every other month.

Is Rapid Response working to increase patient safety? The data speaks for itself. Our rate of Code Blues outside the ICU per 1000 discharges is around 2.

Don't be afraid to call Rapid Response if you are concerned about a patient, visitor or staff member. As your mother always said, "An ounce of prevention is worth a pound of cure." And that's what Rapid Response is all about.

CAPE FEAR VALLEY HEALTH

CAPE*ability*

When It Comes To Patient Safety, ACTIONS Speak Louder Than Words

"That's the way we do things around here."

When staff members say this, are they saying, "we take shortcuts?" Or are they saying, "around here we do the right thing, the right way, at the right time, every time."

If it's the latter, there is a culture of patient safety in that organization. But it's not enough to say it. Staff members must demonstrate it with their actions.

A recent study found that in organizations that had a visible commitment to safety that was evident in the behaviors of its members, it was more likely that safe work practices would be followed. Examples of patient-safety related behaviors include reporting hazards and errors, speaking out about risks, intervening when an error or at-risk behavior is witnessed, and following safety guidelines.

When it comes to patient safety, actions truly speak louder than words. Your professional peers are likely learning from your behaviors on a day-to-day basis, whether it involves taking a shortcut that is thought to be necessary at the time, or speaking up about a risk you observe.

Patient safety—indeed, a culture of safety—begins with YOU leading by example.

MEDICATION RECONCILIATION REMINDER

Cape Fear Valley Health System maintains a process to promote the complete and accurate reconciliation of medications across the continuum of care. Where medications are administered or prescribed, a current medication list is obtained with the involvement of the patient. The list is reconciled against new drug therapies and returned to the patient in updated form.

For the majority of patients in the Emergency Department who are admitted, the Pharmacy Technician obtains a list of medications the patient takes at home. If a patient arrives to a nursing floor without a Medication Reconciliation Form, it is the responsibility of the nursing staff to obtain the list.

INCIVILITY: A HAZARD IN ANY WORKPLACE

The Fall 2011 issue of the N.C. Board of Nursing's Nursing Bulletin has an article titled "Incivility In Nursing." Incivility is just a fancy word for bullying, and the points made in the article are not limited to nursing. Incivility can be seen in all industries; any workplace is a possible setting for workplace bullies.

According to the article, incivility occurs in groups or individual interactions. Common uncivil behaviors include:

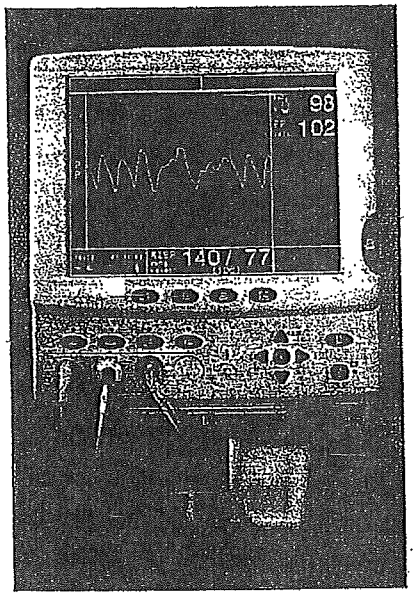
- Using the "silent treatment"
- Spreading rumors
- Rude of obnoxious behavior
- Badgering or back-stabbing
- Sabotaging a project
- Damaging someone's reputation
- Using humiliation, put-downs and intimidation
- Failing to support a co-worker
- Setting someone up for failure
- Undermining of work
- Verbal abuse
- Public reprimands
- Sarcasm
- Destroying confidence
- Losing one's temper or yelling at someone
- Continual criticism
- Encouraging others to turn against a co-worker

The effects of incivility take a toll on all of us. It erodes our self-esteem by wearing down our mental defenses. New graduates who are subject to incivility may experience decreased confidence, anger, frustration, anxiety and worry. And they may in turn emulate that behavior themselves.

The Joint Commission maintains that incivility is a safety issue, and has implemented standards that address intimidating and disruptive behaviors at work. The Joint Commission has also issued a Sentinel Event Alert that specifically addresses this issue.

Incivility should be brought to the attention of management. Do not assume the behavior has already been reported by another staff member. Our shared goal should be the creation of a safe and respectful workplace.

avoid ALARM-RELATED *patient injuries*



...ALARMS CAN VERY EASILY BE DISABLED OR SILENCED. IT CAN ALSO BE EASY TO OVERLOOK ONSCREEN SYMBOLS INDICATING THAT AN IMPORTANT ALARM FEATURE IS NOT TURNED ON OR AVAILABLE.

In the hospital, bedside alarms can be lifesaving. They alert us to dysrhythmias, blood pressure problems, and drops in respiratory rate to mention just a few.

The FDA warns that problems can arise with the use of alarms on monitoring equipment.

From 2005 through 2008, the FDA received 566 reports of patient deaths related to the alarms on monitoring devices. Part of the problem is that alarms can very easily be disabled or silenced. It can also be easy to overlook onscreen symbols indicating that an important alarm feature is not turned on or available.

In many of the FDA reports, users were not familiar with how the monitoring equipment worked, or hadn't checked the monitor's alarm status.
In one FDA report, a patient on continuous cardiac monitoring experienced ventricular fibrillation and died without her monitor sounding or displaying an alarm. It turned out that although the monitor detected the problem, its dysrhythmia processing had been turned off.

In another FDA report, an infant died when staff members did not notice a visual alarm on the screen of the perinatal monitor, warning that the child's heart rate was outside the defined parameters. The equipment had not been set up to provide audible alarms.

Here are some of the things the FDA recommends to avoid alarm-related patient injuries and fatalities:

- Don't silence alarms without first checking on the patient.
- Make sure that all patient alarms are appropriately activated and not suspended, that dysrhythmia detection functions are available and appropriately activated, and that the alarm volume is high enough to be heard outside the patient's room. Perform these checks when assuming care of patients from colleagues, after shift changes, and after patients are transferred.
- Become familiar with all monitor functions, especially dysrhythmia alarms and icons on the screen, and the meanings of various alarm sounds.
- Make sure that new staff members, including agency and supplemental staffing, are adequately trained on the unit's monitors before they care for patients.

COMMUNICATION

We are CAPEable.

WHO CAN CALL RAPID RESPONSE?
Anyone can – a patient, family member, nurse or you!

Don't be afraid to call Rapid Response if you are concerned about a patient, visitor or staff member. As your mother always said, "An ounce of prevention is worth a pound of cure." And that's what Rapid Response is all about.

We're committed to patient safety... We are CAPE*able!*

CAPE FEAR VALLEY HEALTH

Attachment 5

Rapid Response
Dial 22

Who can call Rapid Response?

Anyone can – a patient, family member, nurse or YOU!

The Rapid Response Team consists of a Critical Care Nurse and a Respiratory Therapist who respond immediately when a patient's condition is worsening.

Remember, anyone can call Rapid Response. If you feel something is not right medically with a patient or visitor, the best course of action is to call Rapid Response. Dial 22 and tell the Operator your location and that Rapid Response is needed.

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES			
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERS/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	11/30/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COOC
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P 0 BOX 2000 FAYETTEVILLE, NC 28302

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A 395	Continued From page 22 distress. He answered all my questions. When I told him he was being discharged, I tried to call his Mom but the phone was disconnected. I told him he had a taxi voucher to go home and was being discharged. He just stopped talking. He was already upset that he didn't have IV pain medication ordered. He had a cough. I brought him his cough medicine and he knocked it out of my hand so I just wasted it and didn't give it to him. I called the taxi service first, then called the transporter. He wasn't being cooperative for us, so I called security to assist with getting him in the wheelchair. I saw him in the wheelchair prior to him getting on the elevator. He was sitting up, alert and in no distress". Interview further revealed, "I got a phone call from (Transporter #2). He said he was slouched down in the wheelchair in the lobby. I told him he was just being uncooperative. They didn't tell me he was in any kind of distress. I figured he was just being uncooperative". Further interview with RN #1 on 11/22/2011 at 1445 revealed, "I did not reassess him after giving him his pain medicine at 1005. He should have been reassessed within an hour". Interview further revealed, " I received a call from (Transporter #2) when he (Patient #1) was in the lobby. He told me the patient was slouched down in the chair. I didn't ask him any questions about his color or was he breathing". Interview further revealed, "I didn't go down to assess him because he had been discharged and I had five other patients to look after". Interview further revealed, "the transporter should have recognized a problem and called the rapid response team". Interview further revealed, "I should have called rapid response".	A 395		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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A 395	Continued From page 23 Interview on 11/30/2011 at 1000 with Transporter #1 revealed the transporter remembered Patient #1. Interview revealed he went to 8 South at approximately 1330 on 11/22/2011 to transport Patient #1 to the lobby for discharge. Interview revealed, "he was alert but non-communicative. When we talked to him, he turned away from us. Security helped me get him in the wheelchair. Security had been called by nursing because he had refused to get in the wheelchair". Interview further revealed, "the taxi van didn't arrive until about 2:05. We waited down there about 15 minutes. He was sitting up straight and then he slouched down in the wheelchair, like he was giving up, he was going home". Interview on 11/30/2011 at 1125 with Transporter #2 revealed the transporter worked in the front lobby discharge area and was working on 11/22/2011. Interview revealed, "when (Transporter #1) brought (Patient #1) down, I asked him, 'Is this guy ok? He doesn't look good. He was sitting, slouched in the wheelchair. I called the nurse on 8 South and asked her was this patient ok. She said, 'he's ok. He just doesn't want to go home. He just wants his meds". Interview further revealed, "(Transporter #1) and I helped him into the van. He would not stand up. We lifted him up and put him in the van. We put his seat belt on him. I think he was breathing. His eyes were open". Further interview with Transporter #1 on 11/30/2011 at 1145 revealed, "we had to lift him up and put him in the van. We had to put his legs into the van. When we put him in the van, the (taxi) driver asked that the nurse be called	A 395		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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A 395	Continued From page 24 because he (Patient #1) didn't look right to him. (Transporter #2) called the nurse and he told the driver exactly what the nurse upstairs told me, that this was normal for him". Interview revealed the only call made concerning the change in condition for Patient #1 was the call made by Transporter #2 to nursing on 8 South at the request of the taxi driver. Interview further revealed, "I thought it was a good idea to call the nurse. I thought the nurse should have come down and reassessed him before he drove off". Interview via telephone on 11/30/2011 at 1300 with Taxi Driver #1 revealed the taxi/transport company has a contract with named hospital. Interview revealed, "I was taught to observe the whole patient. Our contract says the patient should be able to board/unboard by himself. When I pulled up, (Patient #1) was slumped over in the wheelchair. He didn't look normal to me. I told the transporter, (Transporter #2) that he didn't look right. He (Transporter #2) called the nurse and the nurse said he was ok. He just didn't want to go home. I told him the patient needed to be able to talk to me because I didn't know exactly where his house was. I got a phone number to his house". Interview further revealed, "He never stood up. Those two men (Transporters #1 and #2) lifted him into the van". Interview further revealed, "I tried to talk to him while in the taxi. I asked him was he ok and did he need assistance. He was non-responsive. I contacted (name of supervisor) and told her he didn't look right. When I arrived at his house, he had closed his eyes. He looked like he was sleeping. I called his house and his mother came out. She called his name. She said, 'he's not acting right'. She called 911. When EMS arrived,	A 395		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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A 395	Continued From page 25 they put the monitor on him. He was flatlined, dead. We couldn't move him. It was about 5 hours before they finally got him out of the van. They said because he had died on the way home from the hospital, they had to treat it like a criminal scene". Interview further revealed it was a 45 minute drive from the hospital to Patient #1's house. Interview via telephone on 11/30/2011 at 1315 with the owner of the transport/taxi service revealed she received a call from RN #1 on 11/22/2011 at 1312 for a patient to be transported home. Interview further revealed she received a call at 1352 from Transporter #2 that patient was in the lobby, ready to be picked up. Interview further revealed she received a call from Taxi Driver #1 at 1353 that he was at the hospital and that the patient didn't look right. Interview revealed, "He told me they picked him up and put him in the van and the patient was not saying a word". Interview further revealed, "I called 8 South and spoke to (RN #1). She told me he was ok, he just didn't want to go home". Interview further revealed, "(Taxi Driver #1) called 911 at 2:46 (pm). At 2:51 (pm), I called 8 South and talked to (RN #2) and told her that (Patient #1) had died". Interview further revealed, "we have been told by the ER staff not to take patients to the ER (emergency room). (Taxi Driver #1) did that (took a discharged patient to the ER) some time ago and he got fussed out". Interview via telephone on 11/30/2011 at 1400 with the medical examiner in the county where Patient #1 died revealed he had received preliminary autopsy results from the pathologists at UNC. Interview revealed the autopsy results	A 395		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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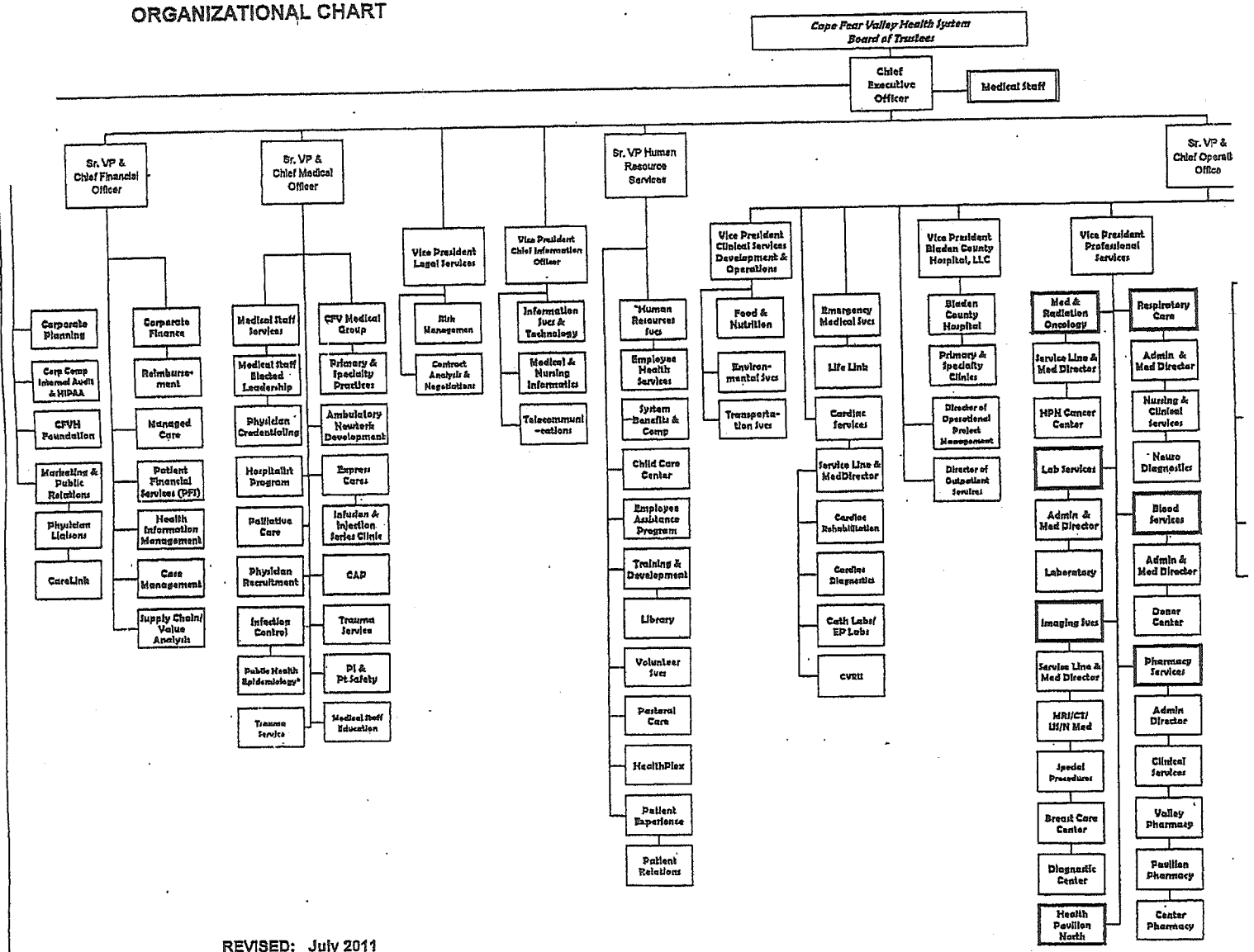
A 395	Continued From page 26 showed that Patient #1 died from pneumonia secondary to complications related to non-Hodgkin's lymphoma. Interview on 11/30/2011 at 1430 with the Chief Medical Officer revealed, "the nurse should have responded to a call that a patient didn't look right". Interview on 11/30/2011 at 1425 with the Interim Chief Nursing Officer revealed Patient #1's record had been reviewed. Interview revealed there were no issues discovered from the hospital's management review of the incident of the discharge of Patient #1 related to policies/procedures being followed. Interview further revealed there were no issues discovered related to reassessment of the patient by the nursing staff. NC00076942	A 395		

Attachment 1

ORGANIZATIONAL CHART



REVISED: July 2011

Cumberland County Hospital System, Inc.
Administrative Policy - Procedure

TITLE: Rapid Response Guidelines	POLICY NUMBER	APPROVED BY MN	EFFECTIVE DATE 3/23/09	Page 1 of 2

POLICY: The Rapid Response Team (RRT) responds to situations where patients at Cape Fear Valley Medical Center (CFVMC) or Cape Fear Valley Rehabilitation Center (CFVRC) are experiencing acute clinical changes or are in a pre-code status. The RRT responds to emergent and pre-emergent situations in all areas of CFVMC and CFVRC. The RRT functions under the direction of the patient's attending physician and uses the appropriate established protocols to provide the initial interventions necessary to assess and stabilize the patient.

PURPOSE: To provide early intervention for patients who experience acute clinical changes in an effort to stabilize, monitor and transfer to a higher level of care if needed, thereby preventing the progression to cardiopulmonary arrest. To encourage patient and family members' involvement in the patient's care.

GUIDELINES:

Rapid Response Team Members:

1. RRT member responds within 5 minutes to requests for patient assistance or requests that fall within the following established guidelines for response:
   a. Staff member concerned about the medical condition of a patient, visitor or other staff member.
   b. Acute changes in heart rate (less than 40 or greater than 130).
   c. Acute changes in Blood Pressure (BP).
   d. Acute changes in respiratory status (Respiratory Rate [RR] less than 9 or greater than 28; pulse oximetry less than 90% or decrease of greater than 8% of the patient's baseline).
   e. Acute changes in mental status.
   f. Failure to respond to treatment.
   g. Acute significant bleed.
   h. Seizures.

2. The responsibilities of the RRT members are:
   a. Assess patient.
   b. Stabilize patient.
   c. Assist with communication to the primary care physician.
   d. Educate and support nursing staff.
   e. Assist with transport of the patient as appropriate.
   f. Continue to monitor patient's condition as appropriate.
   g. Round on all rapid responses from the previous shift/day.
   h. Round on all units offering assistance.
   i. Round on ICU discharges from the previous day.
   j. Respond to and assist with Code Blue if not engaged in a RRT call.

Revised Effective	Reviewed/No Change	Originating Department:	Did this Policy Replace Another Policy? Yes No X	If Yes, Old Policy Title:
4/25/11	8/24/09, 5/24/10	Respiratory Care		

Caller Responsibilities:

1. Utilize the SBARR report tool.
2. Contact physician.
3. Activate RRT.
4. Have available a current list of medications and vital signs.
5. Communicate with RRT the events leading up to call.
6. Assist RRT with procedures and care of patient.
7. Prepare transfer documentation if patient is transferring to a higher level of care (medication reconciliation and transfer orders, etc.).
8. Call report when patient is ready for transfer.
9. Assist RRT with transfer of patient.

Contacting RRT:

1. Call the operator and request the Rapid Response Team, giving the location (room number/unit or area).
2. Family member(s) may activate the RTT by dialing extension 2700 from an in-house phone.

CAPE FEAR VALLEY HEALTH SYSTEM
RAPID RESPONSE TEAM AUDIT

Date: _____ Name Of Employee: _____

Time: _____ Department: _____

1. What are you to do if at any time a patient, staff member or visitor appears in need of assistance or you are concerned about the medical condition of a patient, staff member or visitor?

   Answer: Call Rapid Response Team

2. What is the process for calling Rapid Response Team?

   Answer: Call 22

Instructions for the House Nursing Supervisor

Please conduct 10 interviews days and nights to consist of the following :

2- transporters

2 – dietary staff

2 – environmental services staff

4 – nursing assistants

If staff does not answer questions correctly re-educate the employee immediately and ensure they understand the importance of knowing when and how to contact the Rapid Response Team.

CUMBERLAND COUNTY HOSPITAL SYSTEM, INC.
POLICY - PROCEDURE

TITLE: Taxi Service - Patient Discharge	POLICY NUMBER	APPROVED BY/DATE Nursing Admin 12/03/95	EFFECTIVE DATE 12/03/95	PAGE 1 OF 1 PAGE

POLICY: Under special circumstances, a taxi is used at the Medical Center's expense to transport patients home.

PURPOSE: When no other means of transporting a discharged patient is available, a taxi provides a reasonable, cost-effective alternative to housing the individual in the hospital.

RESPONSIBILITY:
The Nursing Supervisor or Coordination of Care is responsible for assessing, with the patient's assigned nurse, the arrangements for discharging the patient.

PROCEDURE:

1. In the event a patient is discharged and has no means of transportation, the Nursing Supervisor or Coordination of Care issues a Transportation Request Form for a taxi after other alternatives have been explored. The patient is to be able to independently ambulate in and out of the taxi and provide clear directions.

2. If the patient is enrolled in the transportation program with the County Department of Social Services, that agency may provide transportation. The Department of Social Services is contacted Monday-Friday but is not available on weekends.

3. The Transportation Request Form is completed. The blue copy is provided to cab company. The remainder copies (yellow and pink) are returned to Coordination of Care. The yellow copy is kept in Coordination of Care Department and the pink copy is forwarded to Patient Financial Services so patient is billed for taxi service.

Reviewed/Revised	Reviewed/No Change	Department:	Was the Policy Replaced with Another Policy?	If Yes, New Policy Title:
07/28/97 10/16/08 09/30/99 08/18/10 10/01/02 12/14/04	10/24/06 08/27/09 07/25/11	Nursing	_____Yes _____No	

CFVHS NURSING SERVICES

DISCHARGE TALKING POINTS

1) Nurses are responsible for the clinical care of all patients throughout the discharge process.

2) Each patient hospital-wide being discharged will be accompanied by a nursing staff (nurse/nursing assistant) until the patient is discharged and departs from the CFVMC campus. Additionally, when security is called to respond to a patient incident, a nurse will continue to stay with the patient and security throughout the encounter.

3) Staff may discharge patients directly or may take patients to the discharge foyer and transfer care to another nurse. The discharge foyer is only opened if there is a nurse assigned to the area for appropriate hand off from nurse/nursing assistant.

4) Staff will speak with patients that are demanding to leave without completing treatment and request / encourage the patients to complete their treatment plan. If the patient continues to refuse treatment, staff will contact the treating physician, inform the physician of the patient's decision and seek guidance, and document the patient's refusal in the patient's chart.

5) Patients that express that they do not feel that they are ready to be discharged will be given a clinical evaluation for appropriateness of their discharge plan.

6) When a patient's condition changes during their hospital stay and prior to departure from the CFVMC campus, the Rapid Response Team will be called no matter where the patient is currently located. The Rapid Response Team will assume care of the patient.

7) Physician's orders are to be continued until the patient is discharge off the nursing unit.

8) For patients that are being discharged by taxi the patient is to be able to independently ambulate in and out of the taxi and provide clear directions.

9) Upon return to the floor after discharging a patient, staff will sign the CFVHS Discharge Log validating that they completed the discharge process.

10) Policies for review:
Rapid Response Guidelines
Taxi Service – Patient Discharge

Components for discharge note:

Mental status

Patient condition

Color of patient

Skin temperature

Level of pain when relevant

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr
Drexdal Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-3073

** VIA EMAIL **

December 1, 2011

Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive P O Box 2000
Fayetteville, NC 28302

RE: Complaint Investigation - Intake # **NC00076942**

Dear Mr. Nagowski,

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the survey conducted November 29, 2011 through November 30, 2011. The purpose of conducting the complaint survey was to evaluate the Hospital's compliance with the Federal Medicare Conditions of Participation. The complaint investigation resulted in an Immediate Jeopardy (IJ) identification as of **November 30, 2011** at **1600** as a result of incidents occurring on November 22, 2011.

Specifically, pursuant to **482.12 Governing Body, 482.13 Patient's Rights and 482.23 Nursing Services** the facility staff failed to respond and reassess a change in a patient's condition at the time of discharge and the patient expired while being transported home by a contracted taxi service.

As discussed during the survey, the information gathered will be forwarded to the CMS Regional Office in Atlanta (Region IV). Our state agency is recommending 23 day termination due to noncompliance with the **Conditions of Participation: 482.12 Governing Body, 482.13 Patient's Rights and 482.23 Nursing Services.** The Immediate Jeopardy is ongoing. CMS Regional Office in Atlanta will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina:

Ms. Rosemary Robinson
Division of Survey and Certification
CMS Atlanta Regional Office
Sam Nunn Atlanta Federal Center
61 Forsyth Street, SW Suite 4T-20
Atlanta, Georgia 30303-8909
(404) 562-7343

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Doug Stanton, RN

Doug Stanton, RN, BSN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

cc: Azzie Conley, Section Chief (vial email)
Rosemary Robinson, CMS Region IV(vial email)
Lynn Ethridge, Facility Survey Consultant (vial email)

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite. 4T20
Atlanta, Georgia 30303-8909

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

January 3, 2012

Mr. Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive (P O Box 2000)
Fayetteville, NC 28302

RE: CMS Certification Number (CCN): 34-0028

Dear Mr. Nagowski,

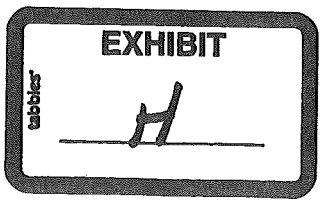
Institutions accredited as hospitals by The Joint Commission (TJC) are deemed to meet all of the Medicare Conditions of Participation for hospitals, with the exception of utilization review. Section 1864 of the Social Security Act authorizes the Secretary of Health and Human Services to conduct surveys of accredited hospitals participating in the Medicare program if there are "substantial allegations" indicating serious deficiencies that could potentially affect the health and safety of patients.

Follow-up, focused and substantial allegation complaint surveys were conducted by the NC State Survey Agency at Cape Fear Valley Medical Center ending December 22, 2011.

1. A follow-up survey to the Full Survey ending November 17, 2011 was concluded on December 22, 2011 and found that the Conditions of Participation listed below were placed back into compliance.

482.55 Emergency Services
482.21 Quality Assessment and Performance Improvement
482.41 Physical Environment (with approved waiver letter dated December 8, 2011.)

2. An additional follow-up survey was performed during this same timeframe to determine whether the Immediate Jeopardy identified on the substantial allegation complaint survey ending November 30, 2011 had been abated and to evaluate the Hospital's compliance with the identified Medicare Conditions of Participation that were out of compliance. It was found that the conditions that led to the determination of Immediate Jeopardy were removed and the termination action as outlined in our letter dated December 5, 2011 was rescinded, however deficiencies remained.



3. Substantial allegation complaint investigations were performed during this same timeframe and resulted in Immediate Jeopardy (IJ) identification on December 22, 2011 as a result of incidents occurring on December 12, 2011. The conditions that led to this determination of Immediate Jeopardy were abated on site and the Immediate Jeopardy was removed on December 22, 2011. However, there was continued noncompliance with the Medicare Conditions of Participation listed below:

42 CFR 482.12 Governing Body
42 CFR 482.13 Patient Rights
42 CFR 482.23 Nursing Services

When a hospital, regardless of its Joint Commission accreditation status, is found to be out of compliance with one or more Conditions of Participation, a determination must be made that the facility no longer meets the requirements for participation as a provider of services in the Medicare program. Such a determination has been made in the case of Cape Fear Valley Medical Center and accordingly, the Medicare provider agreement between Cape Fear Valley Medical Center and the Secretary of the Department of Health and Human Services is being terminated. This termination will be effective **January 19, 2012.**

The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after **January 19, 2012**. For patients admitted prior to January 19, 2012, payment may continue to be made for a maximum of 30 days for inpatient hospital services furnished on or after January 19, 2012. You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your hospital on January 19, 2012, to your fiscal intermediary to facilitate payment for these individuals.

We will publish a public notice in a local newspaper prior to the termination date. Termination can only be averted by correction of these deficiencies prior to **January 19, 2012**. Should we not hear from you, we will assume that the situation has not been corrected. If you believe that compliance has been achieved, you should notify CMS and the North Carolina State Survey Agency in writing on or before **January 13, 2012**, describing in detail the specific corrective measures taken to resolve these problems and include acceptable completion dates. **An acceptable plan of correction should be received NLT 10 days from the date of this notice. Because of the limited time available prior to the termination date, we strongly encourage that you submit an acceptable POC addressing all systemic issues within six days of receipt of this letter.**

An acceptable plan of correction must contain the following elements:

1) The plan of correcting the specific deficiency cited. The plan should address the processes and systems deficiencies that lead to the deficiency cited;
2) The procedure for implementing the acceptable plan of correction for the specific deficiency cited;
3) The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements;

4) The title of the person responsible for implementing the acceptable plan of correction.

If your plan of correction is accepted, the North Carolina State Survey Agency will be authorized to conduct a resurvey to determine if the Medicare Conditions of Participation are back into compliance. Please be advised, however, that failure to come into compliance with the Conditions of Participation will result in your hospital's termination under Medicare, effective **January 19, 2012**. If the Centers for Medicare & Medicaid Services determines that the reasons for termination remain, the effective date of the termination remains **January 19, 2012**, and you will be so informed in writing. If corrections have been made, the termination procedures will be halted, and you will be notified in writing.

If you believe that this termination decision is incorrect, you may request a hearing before an Administrative Law Judge (ALJ) at the Departmental Appeals Board, Department of Health and Human Services. Procedures governing this process are set out in section 42 CFR 498.40, et seq. To be effective, a written request for a hearing must be filed not later than 60 days after the date you receive this letter. Such a request may be made to the following address:

Sandra M. Pace
Associate Regional Administrator
Centers for Medicare & Medicaid Services
61 Forsyth Street, SW, Suite 4T20
Atlanta, Georgia 30303-8909

We will forward your request to the Departmental Appeals Board. The request for a hearing should state why CMS's decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearing, and you may be represented by legal counsel.

If there are any questions, please contact Rosemary L. Robinson at (404) 562-7405 or Rosemary.Robinson@cms.hhs.gov.

Sincerely,

//

Sandra M. Pace
Associate Regional Administrator
Division of Survey & Certification

Enclosure
CMS 2567

cc: TJC
State Agency

DEPARTMENT OF HEALTH AND HUMAN SERVICES — CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

ID: 3VQ111

Facility ID: 943057

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

. MEDICARE/MEDICAID PROVIDER NO.
(L1) 340028
.STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CAPE FEAR VALLEY MEDICAL CENTER
(L4) 1638 OWEN DRIVE P O BOX 2000
(L5) FAYETTEVILLE, NC (L6) 28302

4. TYPE OF ACTION: 6 (L8)
1. Initial 2. Recertification
3. Termination 4. CHOW
5. Validation 6. Complaint
7. On-Site Visit 9. Other
8. Full Survey After Complaint

. EFFECTIVE DATE CHANGE OF OWNERSHIP
(L9)

. DATE OF SURVEY (L34)

. ACCREDITATION STATUS: 1 (L10)
0 NOT ACCREDITED 1 JC 3 DNV

7. PROVIDER/SUPPLIER CATEGORY 01 (L7)

01 Hospital	05 HHA	09 ESRD	13 PTIP	22 CLIA
02 SNF/NF/Dual	06 FRTF	10 NF	14 CORF	
03 SNF/NF/Distinct	07 X-Ray	11 IMR	15 ASC	
04 SNF	08 OPT/SP	12 RHC	16 HOSPICE	

FISCAL YEAR ENDING DATE: (L35)
09/30

1. LTC PERIOD OF CERTIFICATION
From (a):
To (b):

2.Total Facility Beds 597 (L18)

3.Total Certified Beds 597 (L17)

10.THE FACILITY IS CERTIFIED AS:
A. In Compliance With Program Requirements
Compliance Based On:
___1. Acceptable POC

And/Or Approved Waivers Of The Following Requirements:
___2. Technical Personnel
___3. 24 Hour RN
___4. 7-Day RN (Rural SNF)
___5. Life Safety Code
___6. Scope of Services Limit
___7. Medical Director
___8. Patient Room Size
___9. Beds/Room

B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: (L12)

4. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(L37)	(L38)	(L39)	(L42)	(L43)

15. FACILITY MEETS
1861 (e) (1) or 1861 (j) (1): (L15)

6. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):
See Attached Remarks

7. SURVEYOR SIGNATURE Lynn T. Kitteridge Date: 01/03/2012 (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 1/3/2012 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

9. DETERMINATION OF ELIGIBILITY
___ 1. Facility is Eligible to Participate
___ 2. Facility is not Eligible
(L21)

20. COMPLIANCE WITH CIVIL RIGHTS ACT:

21. 1. Statement of Financial Solvency (HCFA-2572)
2. Ownership/Control Interest Disclosure Stmt (HCFA-1513)
3. Both of the Above : ___

22. ORIGINAL DATE OF PARTICIPATION (L24)

23. LTC AGREEMENT BEGINNING DATE (L41)

24. LTC AGREEMENT ENDING DATE (L25)

25. LTC EXTENSION DATE: (L27)

27. ALTERNATIVE SANCTIONS
A. Suspension of Admissions: (L44)
B. Rescind Suspension Date: (L45)

26. TERMINATION ACTION: (L30)
VOLUNTARY 00
01-Merger, Closure
02-Dissatisfaction W/ Reimbursement
03-Risk of Involuntary Termination
04-Other Reason for Withdrawal
INVOLUNTARY
05-Fail to Meet Health/Safety
06-Fail to Meet Agreement
OTHER
07-Provider Status Change
00-Active

28. TERMINATION DATE: (L28)

29. INTERMEDIARY/CARRIER NO.
00000
(L31)

30. REMARKS
Conducted with full Survey.

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

C&T REMARKS - CMS 1539 FORM

A complaint investigation was conducted December 20-22, 2011. The investigation resulted in the identification of an Immediate Jeopardy beginning on December 12, 2011. The SA recommends removal of the IJ on 12/22/2011 at 1630. Condition level deficiencies were cited at: 482.12 Governing Body, 482.13 Patient's Rights and 482.23 Nursing Services. NC00077032, NC00077168, NC00077193, NC00077196, NC00077389, NC00077450, NC00077479 and NC00077288. Based on the outcome of the survey, SA recommends continuance of the termination process of January 19, 2012.

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite. 4T20
Atlanta, Georgia 30303-8909

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Reference: M: 2012.Cape.Fear.Valley.340028.CoNo.71145.01.04.12.com.resc..

1/10/12

January 04, 2012

Mr. Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive
P.O. Box 2000
Fayetteville, North Carolina 28302

Re: Cape Fear Valley Medical Center
CMS Certification Number (CCN): 34-0028
EMTALA Complaint Control Number: NC00071145

Dear Mr. Nagowski:

This letter is written in regards to our letter to you dated September 30, 2011 concerning the non-compliance of Cape Fear Valley Medical Center.

Because of noncompliance, we had advised you that the hospital's Medicare certification would be terminated effective December 29, 2011. Subsequent to our letter, we received documentation from you that adequately addressed the deficiencies cited by the North Carolina State Agency in their survey dated March 3, 2011. The Plan of Correction that was submitted to the Atlanta Regional Office and the revisit conducted by the North Carolina State Agency on December 22, 2011, have determined that action has been taken to correct the cited deficiencies, and procedural changes had been made giving reasonable assurance that a similar violation will not recur.

Based upon the documentation that was submitted, and the revisit survey, we are withdrawing the termination action as stated in the previous correspondence.

The cooperative attitude exhibited by you and your staff in initiating corrective actions is greatly appreciated. Please contact our office if you have any questions and speak with Rosemary Wilder at 404-562-7452.

Sincerely,

Rosemary A Wilder

Sandra M. Pace
Associate Regional Administrator
Division of Survey and Certification

cc: State Agency

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite. 4T20
Atlanta, Georgia 30303-8909

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Reference: M: 2012.Cape.Fear.Valley.340028.CoNo.76789.01.05.12.com.resc..

R 1/10/12

January 05, 2012

Mr. Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive
P.O. Box 2000
Fayetteville, North Carolina 28302

Re: Cape Fear Valley Medical Center
CMS Certification Number (CCN): 34-0028
EMTALA Complaint Control Number: NC00076789

Dear Mr. Nagowski:

This letter is written in regards to our letter to you dated September 30, 2011 concerning the non-compliance of Cape Fear Valley Medical Center.

Because of noncompliance, we had advised you that the hospital's Medicare certification would be terminated effective December 30, 2011. Subsequent to our letter, we received documentation from you that adequately addressed the deficiencies cited by the North Carolina State Agency in their survey dated November 17, 2011. The Plan of Correction that was submitted to the Atlanta Regional Office and the revisit conducted by the North Carolina State Agency on December 22, 2011, have determined that action has been taken to correct the cited deficiencies, and procedural changes had been made giving reasonable assurance that a similar violation will not recur.

Based upon the documentation that was submitted, and the revisit survey, we are withdrawing the termination action as stated in the previous correspondence.

The cooperative attitude exhibited by you and your staff in initiating corrective actions is greatly appreciated. Please contact our office if you have any questions and speak with Rosemary Wilder at 404-562-7452.

Sincerely,

Rosemary Wilder

Sandra M. Pace
Associate Regional Administrator
Division of Survey and Certification

cc: State Agency

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 12/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A000	INITIAL COMMENTS A complaint investigation was conducted December 20-22, 2011 to determine the hospital's compliance with the Medicare Conditions of Participation. The investigation resulted in the identification of an Immediate Jeopardy (IJ) to patients' health and safety beginning on December 12, 2011 related to the failure of hospital nursing staff to report, respond and assess a reported change in the telemetry monitoring (heart monitoring) status of a patient. The hospital's administrative staff was notified on December 22, 2011 at 1555 of the identification of the Immediate Jeopardy. Findings of the investigation revealed a 68 year-old female (Patient #17) admitted 12/08/2011 after presenting to the hospital's emergency department via EMS with altered mental status and a history of congestive heart failure, atrial fibrillation, seizure disorders, schizophrenia, anemia, obesity, chronic debility, pulmonary hypertension and Alzheimers dementia. Record review revealed the patient was admitted to the medical telemetry monitored unit of the hospital. Findings revealed on the day of the patient's death (12/12/2011) a cardiac rhythm strip at 0000 revealed controlled atrial fibrillation and a rhythm strip at 0033 revealed Asystole (rhythm where the heart is not beating and life cannot be sustained). Findings revealed the facility policy was to notify the licensed nurse for telemetry monitor changes such as cardiac leads (connects patient to telemetry) off and rhythm changes. Findings revealed on 12/12/2011 at 0010 the monitor technician (MT) noted the telemetry	A000	Overview. *TELEMETRY:* The report raises issues surrounding an event that was voluntarily reported to CMS and the state: a seven-minute response time for an equipment-related telemetry alert ("leads off"); however, the report also notes that any delay on the hospital's part was either justified or not significant. The hospital's analysis of the event identified two areas to be addressed: 1) the nursing assistants believed the patient fell asleep toward the end of a bed bath when, instead, the patient may have expired; 2) the hospital's telemetry policy may not reflect current accepted practice. The first issue (recognition of signs of distress) was addressed before the survey team arrived, by enhancing training and competency validation practices for nursing assistants. The hospital's telemetry policy was revised to correspond with cardiovascular monitoring standards adopted by the American Heart Association and compliant practices throughout the hospital were assured through a combination of education, concurrent monitoring and reinforcement. *TIMELINESS OF MEDICATIONS:* Concurrent monitoring and reinforcement activities were implemented to assure the timely transmission of new orders to pharmacy. Continuous improvement activities aimed at glycemic control and the timeliness of nebulizer treatments were initiated.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Michael Nagawski — TITLE: CEO — (X5) DATE: 1/6/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See Instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 12/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A000	Continued From page 1	A000		

monitor indicated the leads were off on Patient #17. The MT notified the Nursing Assistant and did not notify the Licensed Nurse that Patient #17's leads were off. Findings revealed the MT at approximately 0033 noted the telemetry monitor indicating Asystole rhythm on Patient #17. Findings revealed the MT first notified the nursing assistant by phone who was in the room with the patient and called the licensed nurse after a conversation with the nursing assistant. Findings revealed the MT notified the nurse by phone at 0034 of the patient's cardiac rhythm change. Findings revealed no rhythm strips were documented from 0000 until 0033 (33 minutes). Findings revealed a code blue (emergency action to be taken immediately) was initiated at 0035. Findings revealed a physician, rapid response team and the patient's primary nurse were at the bedside at 0038 (5 minutes after Asystole noted). Findings revealed the patient was pronounced dead at 0048.

Review of the hospital's investigation and action plan on 12/22/2011 revealed the facility's administrative nursing staff started an investigation of the death of Patient #17 while on a telemetry monitor on 12/19/2011. Review revealed "Conclusions: 1. There was a short delay in reattaching the patient's cardiac monitoring leads. However, the first (approximate 7 minute) portion of the delay was not significant, and the second (approximately 16 minute) portion was justified because the CNA (certified nursing assistant) had to bathe the patient's chest. 2. Both nursing assistants may have misinterpreted signs of cardiac arrest. The following immediate steps have been put in place to address these potential vulnerabilities: 1.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 12/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A000	Continued From page 2	A000	

Rapid response training was given to all clinical personnel on December 14, 2011. 2. The files of all certified nursing assistants were reviewed on December 18, 2011 to assure they reflected evidence of current clinical competence. 3. Training was given to all certified nursing assistants on 4 South on December 17, 2011 and all certified nursing assistants beginning on December 18, 2011 to reinforce indications for summoning a registered nurse or initiating rapid response. The training continued as nursing assistants came on duty to assure 100% contact. 4. Although the training reassures leadership that nursing assistants are sensitive and aware of the issue in the short term, small classes will be held, which will include return demonstration, over the next few weeks. Each nursing assistant will be required to demonstrate competence during this session. Recognizing signs and symptoms of deterioration patient condition will become part of nursing assistant annual competency as on ongoing measure " . Other action items presented to the surveyors on 12/22/2011 at 1600 included a process to re-educate the monitor technicians to the hospital's policy of notifying the nurse for situations such as cardiac leads off and rhythm changes.

Findings revealed the hospital failed to provide oversight and have systems in place to ensure an organized nursing service when a telemetry monitor technician failed to notify a licensed nurse of a change in telemetry monitoring status of a patient (12/12/2011 at 0010 and at 0033) per the facility policy.

Based on evaluation of the immediate corrective action plan, the Immediate Jeopardy was

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 12/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A000	Continued From page 3 determined to be removed on December 22, 2011 at 1630.	A000		
A043	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on policy review, medical record review, staff interview, personnel file review, hospital investigation report review, and Late medication report review, the hospital's Governing Body failed to provide oversight and have systems in place to ensure the protection of patients' rights and an organized nursing service to ensure the safety of patients. The findings include: 1. The hospital failed to ensure care in a safe setting by failing to ensure hospital telemetry monitor technician notified the nurse of a change in telemetry monitoring status of a patient per the facility policy for 1 of 1 patients with a change in cardiac rhythm (Patient #17). ~ cross refer to 482.13 Patient Rights' Condition: Tag 0115. 2. The hospital failed to have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff	A043	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** *1. POLICY REVISION:* The hospital's telemetry policy was reviewed in light of national guidelines for cardiac monitoring (Drew, B.J., et al, 2004, "Practice Standards for Electrocardiographic Monitoring in Hospital Settings," vol 110, pp 2721-2746, *Circulation*). The Vice President of Nursing and the Medical Executive Committee approved the revised Cardiac Monitoring/Telemetry policy **(Attachment 1)**. The revised policy clarifies the scope of telemetry and allows nursing assistants with demonstrated competence to respond to equipment-related alarms (e.g. "leads off", "low battery"). Nurses will continue to respond to all alarms related to changes in a telemetry patient's cardiac rhythm. **Responsible Party:** Vice President of Nursing *STAFF EDUCATION:* Education regarding the requirement of the new policy started on Saturday December 31, 2011 and continued through January 10, 2012. "Talking Points – Telemetry Process, Policy" **(Attachment 2)** was distributed to the Patient Care Managers, Service Line Directors and Clinical Educators so they can provide ongoing reinforcement. **Responsible Party:** Vice President of Nursing	1/11/12 1/11/12

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A043	Continued From page 4 supervised and evaluated patient care. ~ cross refer to 482.23 Nursing Services Condition: Tag 0385.	A043	*NURSING ASSISTANT TRAINING:* Although nursing assistants are certified in cardiopulmonary resuscitation (CPR) (which includes recognition of signs of patient distress), they were re-educated in recognizing patient's change in condition **(Attachment 3).** **Responsible Party:** Vice President of Nursing	1/11/12
A115	482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, staff interview and observation, the hospital failed to promote and protect patients' rights by failing to ensure a safe setting for patient care. Findings include: The hospital failed to ensure care in a safe setting by failing to ensure hospital telemetry monitor technician notified the nurse of a change in telemetry monitoring status of a patient per the facility policy for 1 of 1 patients with a change in cardiac rhythm (Patient #17). ~ cross refer to 482.13(c)(2) Patient Rights' Standard: Tag 0144.		*Monitoring:* A concurrent monitoring process (all patients on adult units with telemetry monitoring) was implemented to assure compliance with the hospital's telemetry policy **(see telemetry audit form – Attachment 5).** Corrections are made and policy requirements are reinforced as they are identified. Data is aggregated and reviewed by nursing leadership on a daily basis to track compliance. **Responsibility:** Vice President of Nursing	
A144	482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on review of review of hospital policy, job descriptions, closed medical record review, staff interview and observation, the hospital failed to ensure care in a safe setting by failing to ensure a		*2. NURSING ORGANIZATION:* There is a nursing organizational chart **(Attachment 4)** that demonstrates the oversight and responsibility of nursing. For each nursing unit there are charge nurses that report to the Patient Care Manager (PCM). The PCM reports to the Service Line Director (SLD). The SLD reports to the Vice President of Nursing. The positions listed above with the exception of the resource nurse have 24 hours per day and 7 days per week and responsibility for nursing care. There is also a house Nursing supervisor 24 hours per day and 7 days per week with responsibility and oversight of nursing care. There are Clinical Educators assigned to each inpatient nursing unit (unless vacancy exists) that report to the PCM of that nursing unit.	

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A115	Continued from page 5	A115	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** *POLICY REVISION:* The hospital's telemetry policy was reviewed in light of national guidelines for cardiac monitoring (Drew, B.J., et al, 2004, "Practice Standards for Electrocardiographic Monitoring in Hospital Settings," vol 110, pp 2721-2746, *Circulation*). The Vice President of Nursing and the Medical Executive Committee approved the revised Cardiac Monitoring/Telemetry policy **(Attachment 1)**. The revised policy clarifies the scope of telemetry and allows nursing assistants with demonstrated competence to respond to equipment-related alarms (e.g. "leads off", "low battery"). Nurses will continue to respond to all alarms related to changes in a telemetry patient's cardiac rhythm. **Responsible Party:** Vice President of Nursing *STAFF EDUCATION:* Education regarding the requirement of the new policy started on Saturday December 31, 2011 and continued through January 10, 2012. "Talking Points – Telemetry Process, Policy" **(Attachment 2)** was distributed to the Patient Care Managers, Service Line Directors and Clinical Educators so they can provide ongoing reinforcement. **Responsible Party:** Vice President of Nursing	1/11/12 1/11/12

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A115	Continued from page 5A	A115	*NURSING ASSISTANT TRAINING:* Although nursing assistants are certified in cardiopulmonary resuscitation (CPR) (which includes recognition of signs of patient distress), they were re-educated in recognizing patient's change in condition **(Attachment 3).** **Responsible Party:** Vice President of Nursing *Monitoring:* A concurrent monitoring process (all patients on adult units with telemetry monitoring) was implemented to assure compliance with the hospital's telemetry policy **(see telemetry audit form – Attachment 5).** Corrections are made and policy requirements are reinforced as they are identified. Data is aggregated and reviewed by nursing leadership on a daily basis to track compliance. **Responsibility:** Vice President of Nursing	1/11/12

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	Continued From page 5B telemetry monitor technician notified a licensed nurse of a change in telemetry monitoring status of a patient per the facility policy for 1 of 1 patients sampled with a change in cardiac rhythm (Patient #17).	A115		
A144	The findings include: Review of the hospital's policy, "Telemetry Policy", effective 07/11/2011, revealed, "PURPOSE : To provide guidelines for cardiac monitoring and nursing care of the patient requiring telemetry monitoring in a non-ICU unit and documenting telemetry information in the medical record. ...I. Communication: ...MT (monitor technician)-to-Nurse Troubleshooting: Notify nurse for situations such as but not limited to leads off, low battery, and rhythm changes. If nurse is not available or does not respond within 5 minutes, notify resource/charge nurse. If resource/charge nurse is not available or does not respond within 5 minutes, notify patient care manager if on duty or the nursing supervisor if the manager is not on duty. ...II. Monitoring Practices - Monitor Technician Role: ...Record continuous strips from telemetry monitor or defibrillator during: Codes, Critical Situations...Notify primary nurse for changes in patient's usual heart rate/rhythm. ...V. Nursing Care- Temporary Interruption of Telemetry: ... Notify MT that patient is being temporarily removed from telemetry...Remove telemetry electrodes as described above. Confirm with MT that patient's rhythm is transmitting...". Review of the hospital's job description for a Registered Nurse, revised 11/2011, revealed, "...Job Summary: Plans and implements	A144	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** *POLICY REVISION:* The hospital's telemetry policy was reviewed in light of national guidelines for cardiac monitoring (Drew, B.J., et al, 2004, "Practice Standards for Electrocardiographic Monitoring in Hospital Settings," vol 110, pp 2721-2746, *Circulation*). The Vice President of Nursing and the Medical Executive Committee approved the revised Cardiac Monitoring/Telemetry policy **(Attachment 1)**. The revised policy clarifies the scope of telemetry and allows nursing assistants with demonstrated competence to respond to equipment-related alarms (e.g. "leads off", "low battery"). Nurses will continue to respond to all alarms related to changes in a telemetry patient's cardiac rhythm. **Responsible Party:** Vice President of Nursing	1/11/12

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A144	Continued From page 6 professional nursing care for patients in accordance with hospital policies. ... Major Job Functions: 1. Assesses the patient and identifies patient needs. ...3. Plans, organizes, implements and evaluates patient care. ...". Review of the hospital's job description for a monitor technician, revised 11/2011, revealed, "Major Job Functions : ...10. Assumes responsibility for maintaining and monitoring cardiac rhythms and alerting assigned nurse of any arrhythmia or change in EKG pattern (rate, rhythm, configuration)...". Closed record review of Patient #17 revealed a 68 year-old female admitted 12/08/2011 with altered mental status, congestive heart failure, atrial fibrillation and a history of seizure disorders, schizophrenia, anemia, obesity, chronic debility, pulmonary hypertension and Alzheimer dementia. Record review revealed the patient was admitted to the medical telemetry monitored unit of the hospital. Record review revealed an order dated 12/08/2011 at 0620 for soft wrist restraints and an order dated 12/09/2011 at 1010, 12/10/2011 at 1100 and 12/11/2011 at 1100 for a vest restraint. Further record review revealed a cardiac rhythm strip dated for Patient #17, on 12/12/2011 at 0000. Review of the rhythm strip revealed, "Atrial Fib (fibrillation) controlled" electronically printed on the bottom of the strip. Record review revealed the next rhythm strip dated 12/12/2011 at 0033 was electronically printed with "Asystole" (rhythm where the heart is not beating and life cannot be sustained). Record review revealed no rhythm strips from 12/12/2011 at 0000 until 12/12/2011 at 0033 (33 minutes). Record review revealed nursing documentation by RN	A144	*STAFF EDUCATION:* Education regarding the requirement of the new policy started on Saturday December 31, 2011 and continued through January 10, 2012. "Talking Points – Telemetry Process, Policy" **(Attachment 2)** was distributed to the Patient Care Managers, Service Line Directors and Clinical Educators so they can provide ongoing reinforcement. **Responsible Party:** Vice President of Nursing *NURSING ASSISTANT TRAINING:* Although nursing assistants are certified in cardiopulmonary resuscitation (CPR) (which includes recognition of signs of patient distress), they were re-educated in recognizing patient's change in condition **(Attachment 3)**. **Responsible Party:** Vice President of Nursing *Monitoring:* A concurrent monitoring process (all patients on adult units with telemetry monitoring) was implemented to assure compliance with the hospital's telemetry policy (see telemetry audit form – **Attachment 5**). Corrections are made and policy requirements are reinforced as they are identified. Data is aggregated and reviewed by nursing leadership on a daily basis to track compliance. **Responsibility:** Vice President of Nursing	1/11/12 1/11/12

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A144	Continued From page 7 (Registered Nurse) #1 dated 12/12/2011 at 0213, "At 0034 monitor Tech (Monitor Tech #1) alerted staff of EKG change. Noted patient not breathing nor responding. Called Code immediately and initiated CPR. At 0038 (Physician's Name), Rapid response team, Primary Nurse, supportive staff and family at the bedside. ...0000 @ V/S (vital signs) Pulse-77, resp (respirations) - 20, BP- 105/70 and 02 (oxygen) 94%. MD pronounced patient at 0048. No pulse, no respirations, no blood pressure". Review of the physician's final summary, dictated 12/14/2011 at 1825 revealed, "...The patient succumbed to PEA (pulseless electrical activity) and a code blue was done on 12/12/2011 at 1250 with CPR, which could not revive the patient and the patient was pronounced expired at 1250 a.m. on 12/12/2011...". Telephone interview 12/15/2011 at 1250 with monitor technician (MT#1) revealed she was assigned duties as the MT on 12/12/2011 for the 3 South unit. The interview revealed on 12/12/2011 at 0010 she paged the nursing assistant (NA #1) assigned to patient #17. The interview revealed she paged her because it appeared her telemetry leads were off. The interview revealed the page came back as "OT" meaning NA#1 had not responded to the page. The interview revealed the paging system automatically notified the MT after 3 to 5 minutes when the page was not responded to. The interview revealed she heard NA#1 in the "nursery" area talking. The interview revealed she verbally told NA#1 to go and check the leads on Patient #17 and NA #1 told her "No". The interview revealed MT #1 asked her why she would not go and put the leads back on patient	A144	

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A144	Continued From page 8 #17 and NA #1 told her the patient had been "agitated pulling off the monitor". The interview revealed MT #1 told her the patient had been on telemetry her "whole shift". MT #1 stated that NA #1 had never before told her she would not respond to check on a patient on telemetry. The interview revealed MT #1 heard NA #1 ask NA #2 to help in Patient #17's room. The interview revealed she knew the patient's son was in the room but did not remember who told her. Interview revealed she knew the NA's were in patient #17's room bathing the patient. The interview revealed it was no more than 10 minutes from the first page until both NA's were in the room bathing patient. The interview revealed she called into patient #17's room to ask the NA what they were doing with the patient. She stated NA #1 told her they had just "hooked" the patient back on the monitor. MT #1 asked what the patient was doing and was told that the patient was sleeping. The interview revealed MT #1 knew that patient had been agitated earlier and was concerned the patient was sleeping now. The interview revealed she thought the patient was in the heart rhythm Asystole. She stated she called the nursing station for the charge nurse (RN #1). Stated RN #1 immediately answered the phone and she told her to check on patient #17 because the NA said the patient was sleeping and she (MT #1) thought she saw Asystole on the heart monitor. The interview revealed it was approximately 10 minutes from the first page (0010) before NA #1 got into patient #17's room and approximately another 10 minutes that the patient was finished being bathed. The interview revealed she called RN #1 at 0033. The interview revealed she had concern about NA #1 not properly putting the leads on	A144		

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A144	Continued From page 9 patients. She stated she had spoken to the nurse manager (NM) and he had shown NA #1 how to correctly place the leads. The interview revealed she had not spoken to anyone about NA #1 not improving since then. The interview revealed she had written a statement about concerns about NA #1 the morning of 12/12/2011. The interview revealed she had not stated her written concerns correctly. Her concern was NA #1 did not properly place the monitor leads on the patient and she did not have concerns with NA #1 not responding to pages. Telephone interview on 12/15/2011 at 1320 revealed RN #1 was assigned as charge nurse on 12/12/2011 for the 3 South unit. The interview revealed she did not have a patient assignment on 12/12/2011, she had only charge nurse duties. The interview revealed on 12/12/2011 she was coming out of a patient room and noted the light on outside patient #17's door. The interview revealed the hospital had a "no pass policy" which meant when you saw a light on you went to see why the light was on. Interview revealed she went to patient #17's room and NA #1 and NA #2 were in the room bathing the patient and questioned why the light was on and was told MT #1 had called in the room and told them it looked like the patient's (telemetry) lead was not on. She told them to put the leads back on. Stated she noted the patient was breathing. Stated she left, went into another patient room and then went to the nursing station. Stated MT #1 called the station and told her to check the leads on "22" (patient # 17) that it looked like the rhythm "could be" Asystole. The interview revealed she immediately went to patient # 17's room, the son was in the room behind a chair and the patient	A144		

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A144	Continued From page 10 did not appear to be breathing or responsive so she called a "code". The interview revealed she thought MT #1 said the leads were not on properly and it "looked like Asystole". The interview revealed the maximum time between when she first saw the NA's in the room bathing the patient and receiving the phone call from MT #1 was 15-20 minutes. The interview revealed she talked to the NM at the end of shift about NA #1 telling MT #1 "no" that the patient had been taking her leads off. The interview revealed when the patient was being bathed and the leads were off the patient NA #1 should have told MT # 1. The interview revealed she was aware of concerns regarding NA's not placing the leads correctly on patients. There was no specific NA and was "Hit/miss". The interview revealed she was aware of the NM responding to this concern. The interview revealed one time the NM showed the NA how to place the leads correctly and the NA did return demonstration of correct placement. The interview revealed she was not aware of any further concerns. The interview revealed no staff had voiced any further concerns to her. The interview revealed the name of the NA that the NM had worked with was NA #1. Telephone interview with NA #2 on 12/15/2011 at 1620 revealed she had assisted NA #1 with bathing patient #17 on 12/12/2011. The interview revealed she was asked by NA #1 to help her change a soiled diaper on patient #17 on 12/12/2011. Stated she went with NA #1 into the room and patient #17's son was in the room. Interview revealed NA #2 had worked with patient #17 earlier in the week and knew she would be combative and kicking. Interview revealed she	A144		

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A144	Continued From page 11 stayed at the foot of the bed while NA #1 explained to patient #17 that they were going to clean and change her soiled diaper. Interview revealed patient #17 had her gown on and she could not see if the patient had all the telemetry leads on. Interview revealed the patient told them to "leave " her alone and was not cooperative. Interview revealed the son told the patient the NA's wanted to change her diaper. Interview revealed the patient calmed down and they changed her diaper. Stated NA#1 turned patient on her back and was cleaning the "Peri" (front of groin area) area. Stated she asked had the nurse given something to the patient and no one responded. Stated the patient was turned to her side and patient was continuing to have an active bowel movement. Interview revealed the patient was pushing the stool out and she told NA #1 they "might as well wait" until she finished her bowel movement before continuing to clean her. Interview revealed this took about 2 minutes. She watched her "grimace and grunt about five times" while the patient had the bowel movement. Interview revealed they cleaned the patient after the stool. Stated they had to change her draw sheet and pad under the patient and put a clean diaper back on. Interview revealed the patient looked like she was "drifting" off to sleep. She asked a second time had the nurse given the patient something and the son responded the nurse had given patient #17 a "Sweet tasting medicine". Interview revealed when she asked earlier had the patient been given anything she did observe the patient was breathing because she was flat on her back. Interview revealed NA #1 was checking that the telemetry leads were connected. Interview revealed she saw the red and brown leads on and when the gown was up	A144		

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A144	Continued From page 12 she saw the black and white lead on. Interview revealed she was not sure but did see NA #1 touching the green lead and did not know if she reattached it or just touched it. Interview revealed as soon as she saw NA #1 touch the green lead MT #1 called into the room and asked what were they doing with the patient. NA #1 told MT #1 they bathed the patient and had put the leads back on. MT #1 asked what was the patient doing and NA #1 told her the patient was resting sleeping. Interview revealed almost immediately RN #1 the charge nurse came to the door and asked what was going on. RN #1 said to call a code. Interview revealed RN #3 was standing in the hall and told her to check the patient's pulse. Interview revealed she checked the patient's radial pulse and it was in the "50's" and the patient was warm. Interview revealed she could not tell if the patient was breathing while she taking her pulse but thought she was still. Telephone interview with LPN #1 on 12/16/2011 at approximately 0900 revealed she was the primary care nurse assigned patient #17 on 12/12/2011. Interview revealed she was taking her break and when she stepped back onto the floor she heard the code called. Interview revealed she went into the room at the same time as RN #1. Interview revealed she heard RN #1 say call a code. Interview revealed she thought the secretary called the code. Interview revealed she started assisting with putting the back board under the patient. Interview reveals she did not remember all the staff in the room but she saw NA #1 and NA #2 both at the bedside one on each side of the patient. She saw NA #2 with the patient's arm in her hand and she heard NA #1 say "I feel a pulse". Interview revealed she	A144		

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A144	Continued From page 13 reached for the patient's arm and a member of the rapid response team asked her to move. Interview revealed she did not remember if the patient was breathing because the patient was a "heavy lady" and her focus was on getting the back board under the patient for time she was in the room.	A144		
A385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, staff interview, Late medication report review and observation, the hospital failed to have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care. The findings include: 1. The telemetry monitor technician failed to notify the nurse of a change in telemetry monitoring status of a patient per the facility policy. ~cross refer to 482.23 (b)(3) Nursing Services Standard: Tag A0395 2. The nursing and respiratory therapy staff failed obtain and/or administer medications per the physicians' order	A385	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** *1. POLICY REVISION:* The hospital's telemetry policy was reviewed in light of national guidelines for cardiac monitoring (Drew, B.J., et al, 2004, "Practice Standards for Electrocardiographic Monitoring in Hospital Settings," vol 110, pp 2721-2746, *Circulation*). The Vice President of Nursing and the Medical Executive Committee approved the revised Cardiac Monitoring/Telemetry policy **(Attachment 1)**. The revised policy clarifies the scope of telemetry and allows nursing assistants with demonstrated competence to respond to equipment-related alarms (e.g. "leads off", "low battery"). Nurses will continue to respond to all alarms related to changes in a telemetry patient's cardiac rhythm. **Responsible Party:** Vice President of Nursing *STAFF EDUCATION:* Education regarding the requirement of the new policy started on Saturday December 31, 2011 and continued through January 10, 2012. "Talking Points – Telemetry Process, Policy" **(Attachment 2)** was	1/11/12

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A385	Continued from page 14	A385	distributed to the Patient Care Managers, Service Line Directors and Clinical Educators so they can provide ongoing reinforcement. **Responsible Party:** Vice President of Nursing	1/11/12
			NURSING ASSISTANT TRAINING: Although nursing assistants are certified in cardiopulmonary resuscitation (CPR) (which includes recognition of signs of patient distress), they were re-educated in recognizing patient's change in condition **(Attachment 3).** **Responsible Party:** Vice President of Nursing	1/11/12
			Monitoring: A concurrent monitoring process (all patients on adult units with telemetry monitoring) was implemented to assure compliance with the hospital's telemetry policy **(see telemetry audit form – Attachment 5).** Corrections are made and policy requirements are reinforced as they are identified. Data is aggregated and reviewed by nursing leadership on a daily basis to track compliance. **Responsibility:** Vice President of Nursing	1/11/12
			2. TIMELINESS OF MEDICATIONS: *a. Insulin Administration:* Communication challenges between the nursing assistants and licensed nurses was an underlying factor in the missed insulin doses identified. Two floors have been selected to improve insulin management, in part by making the nurse responsible for obtaining glucose levels. **Responsible Party:** Vice President of Nursing	1/11/12

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A385	Continued from page 14A	A385	*b. Nebulizer Treatments:* Data collection and aggregation processes to track early, late and missed nebulizer treatments have been implemented. This data will be used to support focused improvements (beginning on high-utilization units and moving through the rest of the house) aimed at reducing the incidence of potential medication errors. Senior leadership oversees these improvement projects **Responsible Party:** Chief Operating Officer ***Monitoring:*** Concurrent monitoring and reinforcement activities were implemented to assure the timely transmission of new orders to pharmacy. Continuous improvement activities aimed at glycemic control and the timeliness of nebulizer treatments were initiated.	1/11/12

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A385	Continued From page 14B ~cross refer to 482.23 (c)(1) Nursing Services Standard: Tag A0405	A385		
A395	482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on review of hospital policy, job descriptions, closed medical record review, staff interview and observation, the telemetry monitor technician failed to notify the nurse of a change in telemetry monitoring status of a patient per the facility policy for 1 of 1 patients with a change in cardiac rhythm (Patient #17). The findings include: Review of the hospital's policy, "Telemetry Policy", effective 07/11/2011, revealed, "PURPOSE : To provide guidelines for cardiac monitoring and nursing care of the patient requiring telemetry monitoring in a non-ICU unit and documenting telemetry information in the medical record. ...I. Communication: ...MT (monitor technician)-to-Nurse Troubleshooting : Notify nurse for situations such as but not limited to leads off, low battery, and rhythm changes. If nurse is not available or does not respond within 5 minutes, notify resource/charge nurse. If resource/charge nurse is not available or does not respond within 5 minutes, notify patient care manager if on duty or the nursing supervisor if the manager is not on duty. ...II. Monitoring Practices - Monitor Technician Role: ...Record continuous strips from telemetry monitor or defibrillator during: Codes, Critical Situations...Notify primary	A395	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** *POLICY REVISION:* The hospital's telemetry policy was reviewed in light of national guidelines for cardiac monitoring (Drew, B.J., et al, 2004, "Practice Standards for Electrocardiographic Monitoring in Hospital Settings," vol 110, pp 2721-2746, *Circulation*). The Vice President of Nursing and the Medical Executive Committee approved the revised Cardiac Monitoring/Telemetry policy **(Attachment 1)**. The revised policy clarifies the scope of telemetry and allows nursing assistants with demonstrated competence to respond to equipment-related alarms (e.g. "leads off", "low battery"). Nurses will continue to respond to all alarms related to changes in a telemetry patient's cardiac rhythm. **Responsible Party:** Vice President of Nursing *STAFF EDUCATION:* Education regarding the requirement of the new policy started on Saturday December 31, 2011 and continued through January 10, 2012. "Talking Points – Telemetry Process, Policy" **(Attachment 2)** was distributed to the Patient Care Managers, Service Line Directors and Clinical Educators so they can provide ongoing reinforcement. **Responsible Party:** Vice President of Nursing	1/11/12 1/11/12

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A395	Continued From page 15 nurse for changes in patient's usual heart rate/rhythm. ...V. Nursing Care- Temporary Interruption of Telemetry: ... Notify MT that patient is being temporarily removed from telemetry...Remove telemetry electrodes as described above. Confirm with MT that patient's rhythm is transmitting...". Review of the hospital's job description for a Registered Nurse, revised 11/2011, revealed, "...Job Summary: Plans and implements professional nursing care for patients in accordance with hospital policies. ... Major Job Functions: 1. Assesses the patient and identifies patient needs. ...3. Plans, organizes, implements and evaluates patient care. ...". Review of the hospital's job description for a monitor technician, revised 11/2011, revealed, "Major Job Functions : ...10. Assumes responsibility for maintaining and monitoring cardiac rhythms and alerting assigned nurse of any arrhythmia or change in EKG pattern (rate, rhythm, configuration)...". Closed record review of Patient #17 revealed a 68 year-old female admitted 12/08/2011 with altered mental status, congestive heart failure, atrial fibrillation and a history of seizure disorders, schizophrenia, anemia, obesity, chronic debility, pulmonary hypertension and Alzheimer dementia. Record review revealed the patient was admitted to the medical telemetry monitored unit of the hospital. Record review revealed an order dated 12/08/2011 at 0620 for soft wrist restraints and an order dated 12/09/2011 at 1010, 12/10/2011 at 1100 and 12/11/2011 at 1100 for a vest restraint. Further record review revealed a cardiac rhythm	A395	*NURSING ASSISTANT TRAINING:* Although nursing assistants are certified in cardiopulmonary resuscitation (CPR) (which includes recognition of signs of patient distress), they were re-educated in recognizing patient's change in condition (Attachment 3). **Responsible Party:** Vice President of Nursing *Monitoring:* A concurrent monitoring process (all patients on adult units with telemetry monitoring) was implemented to assure compliance with the hospital's telemetry policy (see telemetry audit form – attachment 5). Corrections are made and policy requirements are reinforced as they are identified. Data is aggregated and reviewed by nursing leadership on a daily basis to track compliance. **Responsibility:** Vice President of Nursing	1/11/12

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A395	Continued From page 16 strip dated 12/12/2011 at 0000. Review of the rhythm strip revealed, "Atrial Fib (fibrillation) controlled" electronically printed on the bottom of the strip. Record review revealed the next rhythm strip dated 12/12/2011 at 0033 was electronically printed with "Asystole" (rhythm where the heart is not beating and life cannot be sustained). Record review revealed no rhythm strips from 12/12/2011 at 0000 until 12/12/2011 at 0033 (33 minutes). Record review revealed nursing documentation by RN (Registered Nurse) #1 dated 12/12/2011 at 0213, "At 0034 monitor Tech (Monitor Tech #1) alerted staff of EKG change. Noted patient not breathing nor responding. Called Code immediately and initiated CPR. At 0038 (Physician's Name), Rapid response team, Primary Nurse, supportive staff and family at the bedside. ...0000 @ V/S (vital signs) Pulse-77, resp (respirations) - 20, BP- 105/70 and 02 (oxygen) 94%. MD pronounced patient at 0048. No pulse, no respirations, no blood pressure". Review of the physician's final summary, dictated 12/14/2011 at 1825 revealed, "...The patient succumbed to PEA (pulseless electrical activity) and a code blue was done on 12/12/2011 at 1250 with CPR, which could not revive the patient and the patient was pronounced expired at 1250 a.m. on 12/12/2011...". Telephone interview 12/15/2011 at 1250 with monitor technician (MT#1) revealed she was assigned duties as the MT on 12/12/2011 for the 3 South unit. The interview revealed on 12/12/2011 at 0010 she paged the nursing assistant (NA #1) assigned to patient #17. The interview revealed she paged her because it appeared her telemetry leads were off. The interview revealed the page came back as "OT"	A395		

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A395	Continued From page 17 meaning NA#1 had not responded to the page. The interview revealed the paging system automatically notified the MT after 3 to 5 minutes when the page was not responded to. The interview revealed she heard NA#1 in the "nursery" area talking. The interview revealed she verbally told NA#1 to go and check the leads on Patient #17 and NA #1 told her "No". The interview revealed MT #1 asked her why she would not go and put the leads back on patient #17 and NA #1 told her the patient had been "agitated pulling off the monitor". The interview revealed MT #1 told her the patient had been on telemetry her "whole shift". MT #1 stated that NA #1 had never before told her she would not respond to check on a patient on telemetry. The interview revealed MT #1 heard NA #1 ask NA #2 to help in Patient #17's room. The interview revealed she knew the patient's son was in the room but did not remember who told her. Stated she knew the NA's were in patient #17's room bathing the patient. The interview revealed it was no more than 10 minutes from the first page until both NA's were in the room bathing patient. The interview revealed she called into patient #17's room to ask the NA what they were doing with the patient. She stated NA #1 told her they had just "hooked" the patient back on the monitor. MT #1 asked what the patient was doing and was told that the patient was sleeping. The interview revealed MT #1 knew that patient had been agitated earlier and was concerned the patient was sleeping now. The interview revealed she thought the patient was in the heart rhythm Asystole. She stated she called the nursing station for the charge nurse (RN #1). Stated RN #1 immediately answered the phone and she told her to check on patient #17 because the NA said	A395		

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A395	Continued From page 18 the patient was sleeping and she (MT #1) thought she saw Asystole on the heart monitor. The interview revealed it was approximately 10 minutes from the first page (0010) before NA #1 got into patient #17's room.. It was approximately another 10 minutes that the patient was finished being bathed. The interview revealed she called RN #1 at 0033. The interview revealed she had concerns about NA #1 not properly putting the leads on patients. She stated she had spoken to the nurse manager (NM) and he had shown NA #1 how to correctly place the leads. The interview revealed she had not spoken to any one about NA #1 not improving since then The interview revealed she had written a statement about concerns about NA #1 the morning of 12/12/2011. The interview revealed she had not stated her written concerns correctly. Her concern was NA #1 did not properly place the monitor leads on the patient and she did not have concerns with NA #1 not responding to pages. Telephone interview on 12/15/2011 at 1320 revealed RN #1 was assigned as charge nurse on 12/12/2011 for the 3 South unit. The interview revealed she did not have a patient assignment on 12/12/2011, she had only charge nurse duties. The interview revealed on 12/12/2011 she was coming out of a patient room and noted the light on outside patient #17's door. The interview revealed the hospital had a "no pass policy" which meant when you saw a light on you went to see why the light was on. Stated she went to patient #17's room and NA #1 and NA #2 were in the room bathing the patient. She question why the light was on and was told MT #1 had called in the room and told them it looked like the patient's lead was not on. She told them to put the leads	A395		

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A395	Continued From page 19 back on. Stated she noted the patient was breathing. Stated she left, went into another patient room and then went to the nursing station. Stated MT #1 called the station and told her to check the leads on "22" (patient # 17) that it looked like the rhythm "could be" Asystole. The interview revealed she immediately went to patient # 17's room, the son was in the room behind a chair and the patient did not appear to be breathing or responsive so she called a "code". The interview revealed she thought MT #1 said the leads were not on properly and it "looked like Asystole". The interview revealed the maximum time between when she first saw the NA's in the room bathing the patient and receiving the phone call from MT #1 was 15-20 minutes. The interview revealed she talked to the NM at the end of shift about NA #1 telling MT #1 "no" that the patient had been taking her leads off. The interview revealed when the patient was being bathed and the leads were off the patient NA #1 should have told MT # 1. The interview revealed she was aware of concerns regarding NA's not placing the leads correctly on patients. There was no specific NA and was "Hit/miss". The interview revealed she was aware of the NM responding to this concern. The interview revealed one time the NM showed the NA how to place the leads correctly and the NA did return demonstration of correct placement. The interview revealed she was not aware of any further concerns. The interview revealed no staff had voiced any further concerns to her. The interview revealed the name of the NA that the NM had worked with was NA#1. Telephone interview with NA #2 on 12/15/2011 at 1620 revealed she had assisted NA #1 with	A395		

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A395	Continued From page 20 bathing patient #17 on 12/12/2011. The interview revealed she was asked by NA #1 to help her change a soiled diaper on patient #17 on 12/12/2011. Stated she went with NA #1 into the room and patient #17's son was in the room. Interview revealed NA #2 had worked with patient #17 earlier in the week and knew she would be combative and kicking. Interview revealed she stayed at the foot of the bed while NA #1 explained to patient #17 that they were going to clean and change her soiled diaper. Interview revealed patient #17 had her gown on and she could not see if the patient had all the telemetry leads on. Interview revealed the patient told them to "leave" her alone and was not cooperative. Interview revealed the son told the patient the NA's wanted to change her diaper. Interview revealed the patient calmed down and they changed her diaper. Stated NA#1 turned patient on her back and was cleaning the "Peri" (front of groin area) area. Stated she asked had the nurse given something to the patient and no one responded. Stated the patient was turned to her side and patient was continuing to have an active bowel movement. Interview revealed the patient was pushing the stool out and she told NA #1 they "might as well wait" until she finished her bowel movement before continuing to clean her. Interview revealed this took about 2 minutes. She watched her "grimace and grunt about five times" while the patient had the bowel movement. Interview revealed they cleaned the patient after the stool. Stated they had to change her draw sheet and pad under the patient and put a clean diaper back on. Interview revealed the patient looked like she was "drifting" off to sleep. She asked a second time had the nurse given the patient something and the son responded the	A395		

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A395	Continued From page 21 nurse had given patient #17 a "Sweet tasting medicine". Interview revealed when she asked earlier had the patient been given anything she did observe the patient was breathing because she was flat on her back. Interview revealed NA #1 was checking that the telemetry leads were connected. Interview revealed she saw the red and brown leads on and when the gown was up she saw the black and white lead on. Interview revealed she was not sure but did see NA #1 touching the green lead and did not know if she reattached it or just touched it. Interview revealed as soon as she saw NA #1 touch the green lead MT #1 called into the room and asked what were they doing with the patient. NA #1 told MT #1 they bathed the patient and had put the leads back on. MT #1 asked what was the patient doing and NA #1 told her the patient was sleeping. Interview revealed almost immediately RN #1 the charge nurse came to the door and asked what was going on. RN #1 said to call a code. Interview revealed RN #3 was standing in the hall and told her to check the patient's pulse. Interview revealed she checked the patient's radial pulse and it was in the "50's" and the patient was warm. Interview revealed she could not tell if the patient was breathing while she taking her pulse but thought she was still. Telephone interview with LPN #1 on 12/16/2011 at approximately 0900 revealed she was the primary care nurse assigned patient #17 on 12/12/2011. Interview revealed she was taking her break and when she stepped back onto the floor she heard the code called. Interview revealed she went into the room at the same time as RN #1. Interview revealed she heard RN #1 say call a code. Interview revealed she thought	A395		

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A395	Continued From page 22 the secretary called the code. Interview revealed she started assisting with putting the back board under the patient. Interview reveals she did not remember all the staff in the room but she saw NA #1 and NA #2 both at the bedside one on each side of the patient. She saw NA #2 with the patient's arm in her hand and she heard NA #1 say "I feel a pulse". Interview revealed she reached for the patient's arm and a member of the rapid response team asked her to move. Interview revealed she did not remember if the patient was breathing because the patient was a "heavy lady" and her focus was on getting the back board under the patient for time she was in the room. Telephone interview with RN #2 on 12/16/2011 at 0950 revealed she was a staff nurse on the unit 12/12/2011. Interview revealed she was not sure of the time on 12/12/2011 but around 0100 RN #1 running into the nursery room where the crash cart is stored. Interview revealed RN #1 told her to call a code and she used the desk phone to call a code. Interview revealed within 30 seconds she then went to patient #17's room. Interview revealed NA # 1 was standing in the doorway of the room. Interview revealed a nurse was with the patient and there were 3 to 4 people already in the room. Interview revealed she immediately took the patient's blood sugar. Interview revealed she was not sure if she beat the crash cart in the room. Interview revealed the patient's blood sugar results were 119. The interview revealed she did not look at the patient's chest and could not say if the patient was breathing when she was doing the blood sugar. The interview revealed it was about 30 minutes before the code when MT #1 called into the desk asking for LPN #1 (Patient	A395		

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A395	Continued From page 23 #17's primary nurse) and she told her that LPN #1 had gone on break. Telephone interview on 12/16/2011 at 1020 revealed RN #3 was on duty 12/12/2011 in the unit where patient #17 was a patient. Interview revealed she was walking down the hall and saw the door open to patient #17's room. Interview revealed she looked into the room while in the hall and did a "quick assessment". Interview revealed her "quick assessment" consisted of her looking at the patient from the hall. Interview revealed she could see that the patient was not breathing. Interview revealed when looking into the room she saw NA #1 and NA #2 at the bedside. Interview revealed NA #1 was on the right side of the bed and NA #2 was on the left side of the bed. Interview revealed both NA's were looking at the patient. Interview revealed she was not sure if the light outside the room was activated or not. Interview revealed she told the NA's they "had a code". Interview revealed NA #1 tried to shake the patient for a response and NA #2 did not move. Interview revealed RN #1 was in the hall and heard her say this. Interview revealed she went into the room and saw the son in the room after entering the room. Interview revealed she tried to feel for a femoral pulse and could not feel a pulse. Interview revealed the head of the bed was slightly elevated and she did not see any indication of the patient breathing. Interview revealed there was no back board under the patient and a nurse was at the head of the bed suctioning the patient. Interview revealed she did not know where NA #1 and NA #2 were during the code. Interview revealed LPN # 1 checked for a pulse and said she had a pulse. Interview revealed when RN #1 got there with the	A395	

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A395	Continued From page 24 back board she told her she was "shocked" they (NA #1 and NA #2) were looking at the patient when she first looked into the room. Interview revealed when LPN #1 felt a pulse the patient was not having chest compressions. Interview revealed she thought that 50 percent of the NA's did not recognize when a patient was in trouble. Interview revealed she had talked with the charge nurse about patients calling out for the bathroom and the NA's taking too long and "basic things". Interview revealed she had not talked with anyone about 50 percent of the NA's did not recognize a patient in trouble. Interview with the Nurse Manager (NM) on 12/16/2011 at 1126 revealed RN #2 and LPN #1 had clarified that both NA's were at the patient's bedside on 12/12/2011. Second telephone interview on 12/15/2011 at 1705 with RN #1 revealed the first time she went to patient #17's room was when she saw the light above the door was "blinking". The interview revealed she knocked on the door and when she opened the door NA #1 and NA #2 were bathing the patient. The interview revealed the patient had a large bowel movement. The interview revealed when a white light is on it means nursing staff need to assess the patient and when the green light is on it means the telemetry has activated the light. Interview on 12/20/2011 at 1310 with monitor technician #2 on the medical telemetry unit revealed the rhythm strips are run every four hours. Interview further revealed once a patient is discharged, the patient's profile in the telemetry recording system is deleted after 96 hours.	A395	

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A395	Continued From page 25 Interview further revealed, "when a lethal rhythm is detected, the printer automatically starts printing the strips". Interview revealed, "if the leads are off, I would call the nursing assistant. If it is a lethal rhythm, I would call the nurse and call the desk". Observation during tour of 4 South (a Telemetry Unit) on 12/22/2011 at 1324 revealed a telemetry monitoring room. Observation within the room revealed a Monitor Technician (MT#3) sitting in front of multiple monitor screens displaying patient heart rhythms. Further observation revealed an paging system control unit adjacent and to the right of the monitoring screens. Interview during tour with MT#3 revealed he has the capability of monitoring up to 32 patients at the same time. Interview revealed the MT monitors the patient in Lead II. Interview revealed the monitoring system alarms when a patient's monitor lead(s) has been disconnected or when there has been a change in the patient's heart rhythm. Interview revealed the monitoring system automatically prints rhythm strips when "lethal" changes in heart rhythms are detected (i.e. Asystole, Ventricular Fibrillation or V-Tachycardia, Supraventricular Tachycardia or Bradycardia et al). Interview revealed the system does not print out a rhythm strip when a lead is off. Interview revealed if the monitoring system identifies a "lead off" a message is displayed on the screen and an audible alarm signals. Interview revealed "If a lead comes off, I call the nursing assistant." Interview revealed the MT uses the paging system located adjacent to the monitors to page the nursing assistant (NA) to go check on the patient. Interview revealed the NA has a "5 minute window" to respond to the page. Interview revealed if the NA does not respond within the 5	A395	

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A395	Continued From page 26 minute window (delay) the system goes into "overtime" and alarms again then the patient's nurse is paged using the same system. Interview revealed all the nursing assistants and nurses carry pagers. Interview during tour with a Resource Nurse (supervisor) revealed "according to hospital policy, the monitor tech. should page the nurse for leads off, battery changes, and rhythm changes."	A395		
A405	482.23(c)(1) ADMINISTRATION OF DRUGS All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures. This STANDARD is not met as evidenced by: Based on policy and procedure review, Late medication report review, medical record review and staff interviews the nursing and respiratory therapy staff failed to obtain and/or administer medications per the physicians' order in 1 of 1 sampled patients with missed medications. (Patient #5). The findings include: Review of hospital policy 207-A, reviewed 08/11 revealed "Medication Administration Policy: Medications are administered per physician order". Review of hospital; policy 126-A revised 8/18/2011 revealed "Medication Administration check...17. CHARTING A LATE MEDICATION.	A405	*TIMELINESS OF MEDICATIONS:* *a. Nebulizer Treatments:* Data collection and aggregation processes to track early, late and missed nebulizer treatments have been implemented. This data will be used to support focused improvements (beginning on high-utilization units and moving through the rest of the house) aimed at reducing the incidence of potential medication errors. Senior leadership oversees these improvement projects **Responsible Party:** Chief Operating Officer *b. Insulin Administration:* Communication challenges between the nursing assistants and licensed nurses was an underlying factor in the missed insulin doses identified. Two floors have been selected to improve insulin management, in part by making the nurse responsible for obtaining glucose levels. **Responsible Party:** Vice President of Nursing	1/11/12 1/11/12

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A405	Continued From page 27 1. Respiratory will have a one-hour window prior to the time the medication is scheduled, and a one-hour window after the scheduled time to administer a medication."(minimum 3 hours and maximum 5 hours). Review of the respiratory "Medications Charted Late" report, revealed the treatments on 11/27/2011 at 2051 was administered late, 11/28/2011 at 0903 was late. Closed medical record review of patient #5 on 12/21/2011 revealed a 66 year old admitted on 11/25/2011 with a diagnosis of SOB (shortness of breath), COPD (chronic obstructive pulmonary disease), Atrial fibrillation COPD precipitated by acute bronchitis. Record review revealed the patient was discharged on 11/30/2011. Record review revealed admission orders on 11/25/2011 at 0140 for Xenopax nebulizer treatments (to assist the patient in breathing) every 4 hours. Medical record review revealed on 11/27/2011 at 2051 documentation of 5 hours and 38 minutes between medical respiratory treatments (38 minutes beyond the maximum 5 hours). Further record review revealed on 11/28/2011 at 0903 documentation of 5 hours and 43 minutes between medical respiratory treatments (44 minutes beyond the maximum 5 hours). Record review revealed on 11/28/2011 at 1834 documentation of 2 hours and 3 minutes between medical respiratory treatments (57 minutes prior to the minimum of 3 hours). Interview with the Director of Respiratory care on 12/21/2011 at 1010 revealed the treatments on 11/27 and 11/28/2011 at 2051,0903 and 1834 respectively were not given within the facility	A405	*c. Transmission of Orders to Pharmacy:* The process of scanning orders to pharmacy was reviewed to identify and remediate potential weakness. A data collection process was implemented to track "missed scans" with remedial actions taken when indicated. **Responsible Party:** Vice President of Nursing **Monitoring:** Concurrent monitoring and reinforcement activities were implemented to assure the timely transmission of new orders to pharmacy. Continuous improvement activities aimed at glycemic control and the timeliness of nebulizer treatments were initiated.	1/11/12 1/11/12

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 12/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A405	Continued From page 28 policy. The interview revealed the treatments were late or early due to the staff providing care with another patient. The interview confirmed the treatments noted on the Medications Charted Late report were correct in that the treatments were late. Record review revealed admission orders on 11/25/2011 at 0140 for Low dose insulin regimen for fingerstick blood glucose on a sliding scale of 61-150--0 units; 151-200--1 unit of insulin to be administered ; 201-250--3 units; 251-300--5 units; 301-350--7 units; 351-400 --9 units and greater than 400--11 units, call MD. Record review revealed on 11/25/2011 at 1810, the patient's blood sugar was 173 and there was no documentation of 1 unit of insulin given per the sliding scale physician orders. Record review revealed on 11/28/2011 at 1845 the patient's blood sugar was 226 and there was no documentation of 3 units of insulin given per the sliding scale physician orders. Record review revealed on 11/29/2011 at 1835 the patient's blood sugar was 153 and there was no documentation of 1 unit of insulin given per the sliding scale physician orders. Record review did not reveal why the patient was not administered insulin per the physician's sliding scale order. Interview on 12/21/2011 at 0930 with administrative nursing staff revealed the 3 units of insulin was not given on 11/28/2011 at 1843 because the nurse misread the results as 96. The interview revealed the patient should have been given 3 units per the physician's order. The interview also confirmed the patient was not given insulin on 11/25/2011 at 1810 and on 11/29/2011 at 1835. The interview revealed the patient	A405		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 12/22/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

A405	Continued From page 29 should have been administered 1 unit of insulin each on both dates/times. Record review revealed a physicians' order on 11/29/2011 at 1530 for Lidocaine Viscous (for pain in mouth) 15 cc's rinse and spit "QID PRN" (four times per day as needed). Record review revealed the order to the pharmacy was not sent until 11/30/2011 at 0129 (10 hours after physician's order written). Record review revealed the patient was administered on 11/30/2011 at 0151. Record review did not reveal why the physician's order was not scanned to the pharmacy after being written. Interview with Clinical Pharmacist #1 on 12/21/2011 at 0840 revealed the turnaround time between orders received and medications sent is 12 to 30 minutes. The interview confirmed 10 hours is beyond the hospital standard for a medication to be available after the physician's order is written. Interview revealed the hours for medications ordered as QID is at 0830, 1230,1730 and 2200. NC00077032, NC00077168, NC00077193, NC00077196, NC00077288, NC00077389, NC00077450, NC00077479	A405		

TITLE: TELEMETRY POLICY	POLICY NUMBER:	APPROVED BY/DATE: Nursing Policy Committee Med Executive	EFFECTIVE DATE: 01/06/12	PAGE 1 of 2 PAGES

I. POLICY

This policy addresses telemetry or centralized cardiac monitoring on inpatient nursing units. This policy does not address cardiac monitoring for inpatients in the emergency department, intensive/critical care units or procedural areas.

Telemetry shall be initiated and continued upon the order of a Physician, Physician Assistant or Advance Practice Nurse.

Telemetry may be temporarily discontinued while the patient is off the floor. However, the Practitioner may separately order continuous cardiac monitoring for high risk patients. Cardiac monitoring may be temporarily discontinued to accommodate patient bathing, toilet, etc.

Nursing staff members shall be notified to resolve/address alarms identified at the central monitoring station. A Registered Nurse shall be notified and respond to alarms resulting from rhythm changes. A Nursing Aid or other Nursing staff member with current clinical competence may be notified and respond to equipment or reception alarms (such as "leads off" or "low battery.")

II. REQUIRED STEPS

None

III. RESOURCES

A. External Requirements: Regulations and accreditation standards do not address cardiovascular monitoring outside critical care and procedural areas.

B. Literature: American Heart Association guidelines "Practice Standards for Electrocardiographic Monitoring in Hospital Settings" suggests continuous cardiac monitoring for Class I patients, which are typically cared for in critical care setting (intensive care, emergency department, etc.). The guidelines suggest that lower risk patients (Class II and III) may benefit from telemetry monitoring but that such monitoring may be suspended while the patient is off the floor.

IV. GUIDELINES

Monitoring Practices of the Nurse or Monitor Technician (MT) assigned to a central monitoring unit:

- Select the monitoring lead that best displays patient's rhythm. Lead II is preferred, unless patient's clinical condition warrants otherwise or as specified by Clinical Personnel.
- Set heart rate alarm limits. Default alarm limits are:
  - Lower limit of 50 bpm
  - Upper limit of 150 bpm
  - Adjust alarm limits by 20 bpm above or 20 bpm below patient's usual rate if the default limits do not coincide with the patient's usual rate.
- Print a 6-second telemetry strip:
  - Upon admission
  - Every 4 hrs
  - With rhythm changes or dysrhythmias.

Reviewed/Revised:	Reviewed/No Change:	Department: Inpatient Telemetry Nursing Units	Does this Policy replace Another Policy? [X] Yes [] No	If yes, Old Policy Title: Telemetry Policy Effective Date 7/11/11

TITLE: TELEMETRY POLICY	POLICY NUMBER:	APPROVED BY/DATE: Nursing Policy Committee Med Executive	EFFECTIVE DATE:	PAGE 2 of 2 PAGES

- Record continuous strips from telemetry monitor or defibrillator during:
    - Codes
    - At the request of the bedside Nurse, Physician or Rapid Response Team
- Observe monitor to identify abnormal variations in heart rate and/or rhythm such as but not limited to:
    - Presence or absence of component waves (PQRST)
    - Changes in configuration of P waves, QRS complex, T waves and ST segments
    - Premature atrial, ventricular beats or junctional rhythms
- Interpret rhythm strip
- Record date, time, and name of MT performing measurements and interpretation
- Notify Primary Nurse for changes in patient's usual heart rate/rhythm
- Provide copies of strips to Primary Nurse
- Complete QCC on all Telemetry Boxes that go for repair
- Notify Resource/Charge Nurse or Manager when a telemetry box is lost.
- Notify Resource/Charge Nurse or Manager when a telemetry box is returned from decontamination or repair.

Attachment: Telemetry Lead/Electrode Placement Competency Checklist

COMPETENCY CHECKLIST

TELEMETRY LEAD/ELECTRODE PLACEMENT

NOTE: Please place the date of the observation that indicates the staff member has completed all critical elements of competency. In the Evaluation Code column, place the appropriate code used in the evaluation and in the Observer Comment Code column indicate the staff's proficiency of the competency.

Observer Evaluation Code: DO = Direct Observation S = Simulation
Comments Code: CD= Demonstraies age specific knowledge/skill and critical thinking for competency
NI = Needs improvement (staff referred to educational resources must re-demonstrate

CRITICAL ELEMENTS	Date	Evaluator Code	Comment Code	Initials
1. Verify telemetry order with nurse. 2. Identify the patient per hospital procedure. 3. Explain procedure to patient. 4. Obtain transmitter and insert battery. 5. Check the leads for fraying, broken wires or discoloration. 6. Prepare skin for electrode placement: A. Cleans the areas for application of electrodes with alcohol pads or soap and water and allow to dry. B. Abrade the skin with a washcloth or gauze pad. C. Clip chest hair as needed. 7. Remove the backing from the pre-gelled electrodes and test the center of the pads for moistness. Attach electrode to lead prior to placing in skin. Avoid pushing on the gel pads. 8. Apply electrodes to the sites by pressing around the entire edge of the electrode, ensuring a seal. Avoid pressing directly on the gel pad. Apply Electrodes: **3-Electrode Placement.** See Figure 1. Right Arm (RA), just below the right clavicle. Left Arm (LA) just below the left clavicle. Left Leg (LL) on the lower chest, just above and left of the umbilicus. **5-Electrode Placement:** See Figure 2. Right Arm (RA), just below the right clavicle. Left Arm (LA) just below the left clavicle. Left Leg (LL) on the lower chest, just above and left of the umbilicus. Right Leg (RL) on the lower chest, just above and right of the umbilicus. Chest (CH) on the mid-chest just right of the sternum.				

CRITICAL ELEMENTS	Date	Evaluator Code	Comment Code	Initials
9. Verify lead transmission on monitor screen with the MT. 10. Reinforce education about telemetry to include purpose, bathing, movement, restrictions. 11. Evaluate skin integrity around the electrodes on a daily basis. 12. Monitor the skin for any allergic reaction to the adhesive or gel. 13. Change the electrodes every 48 hrs and as needed. 14. Rotate sites when changing electrodes. 15. Change all electrodes if a problem occurs with one. 16. Check electrode placement every shift. 17. Coordinate with nurse regarding temporary removal of telemetry for personal hygiene/transport. 18. Clean transmitter with antimicrobial wipes using universal precautions. Send soiled transmitters to Central Processing for decontamination. 19. Remove battery from transmitter prior to returning the clean transmitter to designated storage area when telemetry is discontinued 20. Complete a QCC to include the CTS number of transmitters that are sent for repair.				
Observer's Signature:				
Observer's Printed Name:				

I have read and understand the **Telemetry Policy dated** _____.

_____ _____

Signature/Title Date

She/He has successfully demonstrated this procedure and is competent to perform telemetry lead/electrode placement without supervision.

_____ _____

Final Observer's Signature Participant's Signature/Date

Attachment 2

Cape Fear Valley Health System
Talking Points – Telemetry Process, Policy & Audit Tool
Telemetry Monitor Technicians/Licensed Nurses/
Unit Secretaries/Nursing Assistants

- Revisions to the Cardiac Monitoring/Telemetry Policy
  - A nurse is notified and responds to rhythm alert alarms.
  - A nursing aid or other nursing staff member with current clinical competence may be notified and responds to equipment or reception alarms (such as 'leads off' or 'low battery').

- Use of staff audit tool
- Staff responsiveness – chain of command
  - It is always our responsibility to respond to our patient when requested. We always want to keep our patients safe and secure in our hospital. Utilize chain of command if there are concerns regarding our patients.
- Recognition of patient's change in condition
  - Be alert for signs and symptoms such as unresponsiveness, changes in vital signs (pulse/respiration/blood pressure), change in mental status, change in skin color.

Talking Points for Nursing Assistants

It is always our responsibility to respond to our patients when requested. We always want to keep our patients safe and secure in our hospital.

The clinical nurse is always responsible for the patient.

Question: How can I recognize a change in patient's condition? What are the signs and symptoms?
Answer: Unresponsiveness, absence of peripheral pulse, absence of respirations, absence of blood pressure, skin color, change in mental status

Question: What do I do if I have a question about a patient's condition?
Answer: Call rapid response. Also always notify the nurse in charge of the patient.

Question: What do I do when a monitor tech calls me to respond to a patient for telemetry reasons (leads off, asystole, low battery)?
Answer: You are to respond immediately to the patient

Question: What is my role when I call for help and no one responds?
Answer: Stay with the patient. Report the situation immediately to the charge nurse. If the charge nurse does not respond, call the PCM or the house supervisor if the PCM is not available.

Any concern regarding our patients is to be reported to the charge nurse on duty. The next step is the charge nurse is to report to the PCM and the PCM is to report to the Service Line Director.

When in doubt, always ask for assistance!

Attachment 5

Cape Fear Valley Health System
Telemetry Audit Form

Room Number:

Place Patient Identification Sticker

Is this the initial telemetry order? ____ No ____ Yes
If yes, completed the following related to the order and beginning of telemetry.

Ordering Practitioner	
Date/Time of Order	
Date/Time of First Strip	
Date/Time Patient Arrived on the Unit	

Today's Date	Time	Rhythm Change	Nurse Resp	Strip
	07:00			
	08:00			
	09:00			
	10:00			
	11:00			
	12:00			
	13:00			
	14:00			
	15:00			
	16:00			
	17:00			
	18:00			
	19:00.			
	20:00			
	21:00			
	22:00			
	23:00			
	00:00			
	01:00			
	02:00			
	03:00			
	04:00			
	05:00			
	06:00			
		Tele Tech	Charge Nurse	US

Timeliness of Telemetry Instructions

1. Please fill this out once per shift per patient before the nurse goes off duty. This will provide immediate feedback and reinforce correct documentation of tele monitoring.
2. Use one sheet per patient. Place patient ID sticker on sheet.
3. If there was a rhythm alert, check (√) in the hour column.
4. If the nurse writes a note in the chart regarding alert, place a check (√). If not, place an X in the column. If corrected by the nurse, draw a circle around the X. (X)
5. For all telemetry patients document if there were missing strips by an "X". If patient off unit note N/A.
6. If all strips are then placed correctly in the chart, draw a circle around the "X" to document the correction. (X)

√= completed
X=incomplete
O=completed with reminder

Revised: 1/4/12

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite 4T20
Atlanta, Georgia 30303-8909

January 11, 2012

Mr. Michael Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive (P O Box 2000)
Fayetteville, NC 28302

RE: CMS Certification Number (CCN): 34-0028

Dear Mr. Nagowski;

We are pleased to inform you that Cape Fear Valley Medical Center's credible allegation of compliance for its Medicare deficiencies has been found acceptable.

We are requesting that the North Carolina State Survey Agency conduct a follow up survey of all outstanding Medicare conditions. In this regard we are requesting that you provide the North Carolina State Survey Agency with a copy of your credible allegation of compliance at the following address:

Ms. Azzie Conley
Acute & Home Care Licensure & Certification Section
North Carolina Division of Facility Services
P.O. Box 2712
Raleigh, North Carolina 27699-2712
Phone: (919) 855-4646 Fax: (919) 715-3073

Since the North Carolina State Survey Agency will need to make their follow-up visit before the effective date of the termination of your Medicare agreement the document should be sent by the fastest means possible if you have not done so already.

If you have any questions concerning this, please contact Janetta Booker at (404) 562-7343.

Sincerely,

/s/

Sandra M. Pace
Associate Regional Administrator
Division of Survey & Certification

Cc: State Agency

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr
Drexdal Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-3073

January 30, 2012

Mike Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive P O Box 2000
Fayetteville, NC 28302

RE: Follow up survey and Complaint investigation - Intake numbers NC00077782, NC00077788, NC00077877, and NC00077965

Dear Mr. Nagowski

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the follow up and complaint surveys conducted on January 24-26, 2012. The surveys were conducted in order to evaluate the Hospital's compliance with the Federal Medicare Conditions of Participation, to validate the complaint allegations, and to follow up on the Condition-level deficiencies cited during the survey conducted on December 20-22, 2011.

As discussed in the exit conference, 1 of 8 complaint allegations was substantiated. The State Agency recommends compliance with 482.13 Patients' Rights, previously out of compliance. Furthermore, as discussed in the exit conference, the State Agency recommends Condition Level deficiencies in the areas of **482.12 Governing Body, 482.21 Quality Assessment and Performance Improvement, 482.23 Nursing Services, and 482.42 Infection Control.** The CMS Regional Office in Atlanta will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina:

Ms. Rosemary Robinson
Division of Survey and Certification
CMS Atlanta Regional Office
Sam Nunn Atlanta Federal Center
61 Forsyth Street, SW Suite 4T-20
Atlanta, Georgia 30303-8909
(404) 562-7343

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Tammy Holleman RN

Tammy Holleman, RN
Facility Survey Consultant
Acute and Home Care Licensure and Certification Section

CC: Azzie Conley, DHSR Acute and Home Care Section Chief
Rosemary Robinson, CMS Representative for NC

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary
919-855-4620

http://www.ncdhhs.gov/dhsr
Drexdal Pratt, Division Director

Azzie Y. Conley, Chief
Phone:

Fax: 919-715-3073

December 28, 2011

Mike Nagowski, CEO
Cape Fear Valley Medical Center
1638 Owen Drive P O Box 2000
Fayetteville, NC 28302

RE: Follow-Up Survey and Complaint Investigations- Intake # **NC00077288, NC00077479, NC00077450, NC000389, NC00077196, NC00077193, NC00077168, NC00077032**

Dear Mr. Nagowski:

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the complaint and follow-up survey conducted December 20, 2011 through December 22, 2011. The purpose of conducting the survey was to evaluate the Hospital's compliance with the Federal Medicare Conditions of Participation. The complaint investigation resulted in an Immediate Jeopardy (IJ) identification as of **December 22, 2011 at 1555;** as a result of incidents occurring on December 12, 2011.

Specifically, pursuant to **482.12 Governing Body, 482.13 Patient's Rights, 482.23 Nursing Services** the facility nursing failed to report, respond and assess a reported change in the telemetry monitoring status of a patient.

As discussed during the survey, the information gathered was forwarded to the CMS Regional Office in Atlanta (Region IV). Our state agency is recommending removal of the Immediate Jeopardy as of December 22, 2011 at 1630. Our state agency is recommending continued noncompliance with the **Conditions of Participation: 482.12 Governing Body, 482.13 Patient's Rights, 482.23 Nursing Services.** CMS Regional Office in Atlanta will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

Also, as discussed in the exit conference, the State Agency is also recommending removal of the Immediate Jeopardy, identified during the complaint survey conducted November 30, 2011, as of December 22, 2011 at 1630.

We also conducted a follow-up survey to the Full Survey conducted at the facility on November 9-17, 2011. The State Agency is recommending compliance with the **Condition of Participation 482.55 Emergency Services and 482.21 Quality Assessment and Performance Improvement. Condition of Participation 482.41 Physical Environment** will remain out of compliance based on the Life Safety survey.

Federal Regulations prohibit the State Agency from recommending Certification of a provider when it has been determined there are one or more Conditions of Participation out of compliance. Based on overall survey findings and due to noncompliance with the Condition(s) of Participation **482.12 Governing Body, 482.13 Patient's Rights and 482.23 Nursing Services** the State Agency is recommending termination from the Medicare and Medicaid program ***effective***

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina:

Ms. Rosemary Robinson
Division of Survey and Certification
CMS Atlanta Regional Office
Sam Nunn Atlanta Federal Center
61 Forsyth Street, SW Suite 4T-20
Atlanta, Georgia 30303-8909
(404) 562-7343

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Lynn Ethridge

Lynn Ethridge, RN,BSN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

cc: Azzie Conley, Section Chief
Rosemary Robinson, CMS Regional Office IV, Atlanta

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth Street, SW, Suite 4T20
Atlanta, Georgia 30303-8909

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Refer:M.2011.Cape/Fear.Valley.340028.Co.No.71145.09.30.11.205

November 2, 2011

Mr. Michael Nagowski, CEO
Cape Fear Valley
1638 Owen Drive
P.O. Box 2000
Fayetteville, North Carolina 28302

Re: Cape Fear Valley
CMS Certification Number: 34-0028
Complaint Number: NC00071145

Dear Mr. Nagowski:

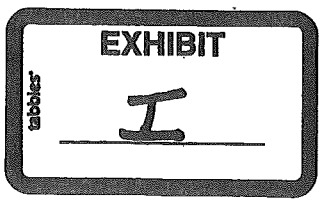
To participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act) and the regulations established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) of the Act authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

Your hospital was surveyed on March 3, 2011 by the North Carolina Survey Agency based on an allegation of noncompliance with the requirements of 42 CFR 489.24, Special responsibilities of Medicare hospitals in emergency cases and/or the related requirements at 42 CFR 489.20. After a careful review of the findings, we have determined that your hospital violated:

- The requirements of 42 CFR 489.24 based on failure to appropriately transfer your Emergency Room patients.

- The related anti-dumping provisions found at 42 CFR 489.20 based on the hospital's failure to have and enforce policies to ensure compliance with the requirements of 42 CFR 489.24.

The deficiencies identified are listed on the enclosed form CMS-2567, Statement of Deficiencies.



Under 42 CFR 489.53, a hospital that violates the provisions of 42 CFR 489.20 or 42 CFR 489.24 is subject to termination of its provider agreement. Consequently, we plan to terminate name of hospital participation in the Medicare program.

This preliminary determination letter serves to notify you of the violation. The projected date on which your agreement will terminate is December 29, 2011.

You will receive a "notice of termination letter" on December 14, 2011. This final notice will be sent to you concurrently with notice to the public, in accordance with regulations at 42 CFR 489.53.

You may avoid termination action and notice to the public by providing a plan of correction/ credible allegation of correction of the deficiencies within 10 days of the receipt of this notice. A credible allegation of correction by the hospital requires a resurvey within 45 calendar days of the original survey. If we verify your corrective action, or determine that the findings contained in this letter were in error, your planned termination from the Medicare program will be rescinded.

If you have any questions concerning this preliminary determination letter, please contact Rosemary Wilder at 404 562-7452 or, **rosemary.wilder@cms.hhs.gov.**

Sincerely yours,

Sandra M. Pace
Associate Regional Administrator

Enclosure: Form CMS-2567, Statement of Deficiencies

cc's:
State *Survey* Agency
OIG
QIO
Complainant

DEPARTMENT OF HEALTH AND HUMAN VICES — CENTERS F MEDICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

ID: TZMF11

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

Facility ID: 943057

1. MEDICARE/MEDICAID PROVIDER NO. (L1) 340028
2. STATE VENDOR OR MEDICAID NO. (L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CAPE FEAR VALLEY MEDICAL CENTER
(L4) 1638 OWEN DRIVE P O BOX 2000
(L5) FAYETTEVILLE, NC (L6) 28302

4. TYPE OF ACTION: 6 (L8)
1. Initial 2. Recertification
3. Termination 4. CHOW
5. Validation 6. Complaint
7. On-Site Visit 9. Other
8. Full Survey After Complaint

5. EFFECTIVE DATE CHANGE OF OWNERSHIP (L9)

5. DATE OF SURVEY 01/26/2012 (L34)

8. ACCREDITATION STATUS: 1 (L10)
0 NOT ACCREDITED 1 JC 3 DNV

7. PROVIDER/SUPPLIER CATEGORY 01 (L7)

01 Hospital	05 HHA	09 ESRD	13 PTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	15 ASC
04 SNF	08 OPT/SP	12 RHC	16 HOSPICE

FISCAL YEAR ENDING DATE: (L35) 09/30

11. LTC PERIOD OF CERTIFICATION
From (a):
To (b):

12. Total Facility Beds (L18)

13. Total Certified Beds (L17)

10. THE FACILITY IS CERTIFIED AS:

A. In Compliance With Program Requirements
Compliance Based On:
___1. Acceptable POC

And/Or Approved Waivers Of The Following Requirements:
___2. Technical Personnel
___3. 24 Hour RN
___4. 7-Day RN (Rural SNF)
___5. Life Safety Code
___6. Scope of Services Limit
___7. Medical Director
___8. Patient Room Size
___9. Beds/Room

B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: (L12)

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(L37)	(L38)	(L39)	(L42)	(L43)

15. FACILITY MEETS
1861 (e) (1) or 1861 (j) (1): (L15)

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):

A complaint investigation was conducted in conjunction with a follow-up survey (reference Event 3VQ112) on January 24-26, 2012. Condition level deficiencies were cited in 482.12 Governing Body, 482.21 QAPI, 482.23 Nursing Services, and 482.42 Infection Control. Findings forwarded to the RO for final determination. NC00077782, NC00077788, NC00077877, and NC00077965.

17. SURVEYOR SIGNATURE Date: 01/30/2012 (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 1/30/2012 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY
___ 1. Facility is Eligible to Participate
___ 2. Facility is not Eligible
(L21)

20. COMPLIANCE WITH CIVIL RIGHTS ACT:

21. 1. Statement of Financial Solvency (HCFA-2572)
2. Ownership/Control Interest Disclosure Stmt (HCFA-1513)
3. Both of the Above: ___

22. ORIGINAL DATE OF PARTICIPATION (L24)

23. LTC AGREEMENT BEGINNING DATE (L41)

24. LTC AGREEMENT ENDING DATE (L25)

25. LTC EXTENSION DATE: (L27)

27. ALTERNATIVE SANCTIONS
A. Suspension of Admissions: (L44)
B. Rescind Suspension Date: (L45)

26. TERMINATION ACTION: (L30)
VOLUNTARY 00
01-Merger, Closure
02-Dissatisfaction W/ Reimbursement
03-Risk of Involuntary Termination
04-Other Reason for Withdrawal
INVOLUNTARY
05-Fail to Meet Health/Safety
06-Fail to Meet Agreement
OTHER
07-Provider Status Change
00-Active

28. TERMINATION DATE: (L28)

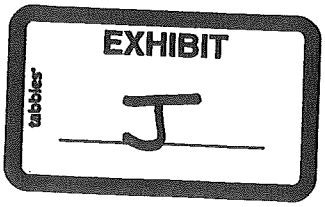
29. INTERMEDIARY/CARRIER NO. 00000 (L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL



Department of Health and Human Services

Medicare/Medicaid/CLIA Complaint Form

Control Number: 1F11 (NC00077788 NC00077782 NC00077877 NC00077965)

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number

3 4 0 0 2 8

Facility Name and Address

CAPE FEAR VALLEY MEDICAL CENTER
1638 OWEN DRIVE P O BOX 2000
FAYETTEVILLE, NC 28302

3. Date Complaint Received

0 1 1 7 1 2
M M D D Y Y

4. Receiving Component

1 State Survey Agy.
[1] 2 RO

5. Date Acknowledged

0 1 2 3 1 2
M M D D Y Y

6A. Source of Complaint

1 [1]
2 [4]
3 [ ]

1 Resident/Patient Family
2 Ombudsman
3 Facility Employee/Ex-Employ
4 Anonymous
5 Other

6B. Total Number of Complainants

0 5

7. Allegations

7.A. Category

1	1	8
2	0	6
3	0	3
4	0	5
5		

1 Resident Abuse
2 Resident Neglect
3 Resident Rights
4 Patient Dumping
5 Environment
6 Care or Services
7 Dietary
8 Misuse of Funds/ Property
9 Certification/Un-authorized Testing
10 Proficiency Test
11 Falsification of Records / Reports
12 Unqualified Personnel
13 Quality Control
14 Specimen Handling
15 Diagnostic Erroneous Test Results
16 Fraud/False Billing
17 Fatality/Transfusion Fatality
18 Other (Specify) Infection Control,Resident/Patient/Client Assessment
19 Life Safety Code
20 State Monitoring

7.B. Findings (To be completed following investigation)

1	0 1
2	0 2
3	0 2
4	0 2
5	

01 Substantiated
02 Unsubstantiated/ Unable to Verify

7.C. Number of Complainants per Allegation

1	0 3
2	0 2
3	0 2
4	0 2
5	

8. Action (if multiple actions, indicate earliest action)

[3]
1 Investigate within 2 working days
2 Investigate within 10 working days
3 Investigate within 45 working days
4 Investigate during next onsite
5 Referral (Specify) _____
6 Other Action (Specify) _____
7 None

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by

[1] 1 State Survey Agency
2 RO
3 Other (Specify) _____

10. Complaint Survey Date

0 1 2 6 1 2
M M D D Y Y

11. Findings (Under 7B Above)

12. Proposed Actions Taken by SA or RO

1:	0 4
2:	
3:	

1 Recommend Termination (23-day)
2 Recommend Termination (90-day)
3 Recommend Intermediate Sanction
4 POC (No Sanction)
5 Fine
6 Denial of Payment for New Admissions
7 License Revocation
8 Receivership
9 Provisional License
10 Special Monitor
11 Directed POC
12 Limitation of Certificate
13 Suspension of Certificate
14 Revocation of Certificate
15 Injunction
16 Civil Monetary Penalty
17 TA & Training for Unsuccessful PT
18 State Onsite Monitoring
19 Suspension of Part of Medicare Payments
20 Suspension of All Medicare Payments
21 None
22 Other (Specify) _____
23 Enforcement Action

13. Date of Proposed Action

0 1 2 6 1 2
M MD D Y Y

14. Parties Notified and Dates

1 Facility
2 Complainant
3 Representative
4 Other (Specify) _____

Party	Date
1. [1]	0 1 3 0 1 2
2. [2]	0 2 0 6 1 2
3. [ ]	

M M D D Y Y

15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567)

M MD DY Y

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt

M M D D Y Y

17. CMS RO/MSA Action

[ ]

1 None
2 Termination (23-day)
3 Termination (90-day)
4 Intermediate Sanction
5 Move Routine Survey Date Forward
6 Limitation of Certificate
7 Suspension of Certification
8 Revocation of Certificate
9 Injunction
10 Civil Monetary Penalty
11 TA & Training For Unsuccessful PT
12 Cancellation of Medicare Approval
13 Other (Specify) _____
14 Enforcement Action

18. Date of Final Action Sign-off

M M D D Y Y

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 01/26/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAT	PROVIDER PLAN OF CORRECTION (EACH CORRCTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 043	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on policy review, Performance Improvement plan review, staff interview, open medical record review, telemetry audit tool review, infection control data review, job description review, and patient interview, the hospital's Governing Body failed to provide oversight and have systems in place to ensure an effective quality assessment and performance improvement program, an organized nursing service, and an effective infection control program to ensure the safety of patients. The findings include: 1. The hospital failed to implement and maintain an effective quality assessment and performance improvement program to ensure the safety of patients. ~cross refer to 482.21 Quality Assessment/Performance Improvement Condition: Tag A0263 2. The hospital failed to have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care and administered medications per physician's orders.	A 043	**Overall Approach:** The statement of deficiencies identifies five issues: 1) inconsistencies between the isolation precautions documented for some patients and those called for in the hospital's infection control policy; 2) inconsistencies in the Infection Control Committee's oversight of isolation precautions in the emergency department; 3) a discrepancy between the findings of an internal audit and the content of a medical record; 4) a dosage calculation error on a sliding scale insulin; and 5) three missing telemetry strips. Rather than treat these issues in isolation, they have been given enhanced priority and workgroups will work on resolutions for each issue during the first phases on the CMS-approved agreement and action plan. **The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 1. There is an ongoing overall review and restructuring of the Performance Improvement Department (PI) to include providing additional oversight to patient safety and quality and infection control issues hospital wide. With the assistance of the Greeley consultants, the re-design of the Performance Improvement Department has begun and one consideration is the Infection Control Department will report to the Patient Safety Officer, Associate Chief Medical Officer as is the current status with the Performance Improvement Department. The PI Department along with other members of leadership to include the VP of Nursing is to review occurrences (incident reports) in the hospital as well as Patient Grievances on a scheduled basis 5-6 days per	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Michael Magowski — TITLE: CEO — (X6) DATE: 2/12/12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See Instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 043	Continued From page 1 ~cross refer to 482.23 Nursing Services Condition: Tag A0385 3. The hospital failed to have a system in place to ensure the prevention and control of infections and communicable diseases.	A 043	week. Occurrences will be tracked and trended by the PI Department. As quality and patient safety issues are identified, these issues will be prioritized by Leadership. The PI department is responsible for coordinating the Event Response Team process and the Patient Safety Response Team process to address immediate concerns related to patient safety. **Monitoring:** The PI Department along with other members of leadership to include the VP of Nursing is to review occurrences (incident reports) in the hospital as well as Patient Grievances on a scheduled basis 5-6 days per week. Occurrences will be tracked and trended by the PI Department. As quality and patient safety issues are identified, these issues will be prioritized by Leadership. The PI department is responsible for coordinating the Event Response Team process and the Patient Safety Response Team process to address immediate concerns related to patient safety. **Responsibility:** Associate Chief Medical Officer and Chief Executive Officer	4/9/2012

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A 043	Continued From page 1A	A 043	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 2. The isolated dosage calculation error reflected in the statement of deficiencies will be augmented by a complete review of glycemic control practices, from ordering through dispensing to administration and monitoring. The changes in blood glucose monitoring promised in an earlier plan of whereby the nurse completed his/her own accucheck have been proven positive for the nursing staff on the 2 test nursing units. An Insulin/Glycemic Control Improvement Team is being established to make recommendations regarding nurse and physician practice in regards to insulin which is recognized as a high alert medication. The recommendations are to be designed, tested and implemented over the next 90 days. The Insulin/Glycemic Control Improvement Team will report to the Medication Safety subcommittee of Pharmacy and Therapeutics. **Monitoring:** A report for high alert medications is to be sent by pharmacy to all of the nursing units. Any patient receiving insulin will be on this report for review by the nurse manager. An auditing process will be in place for random auditing of insulin administration. In the case of telemetry monitoring, the audit process is being revised whereby the telemetry audit is to be completed by an "off the unit" audit person. This will provide a representative sampling of the telemetry process on the nursing units with validation to ensure the integrity of data collection. Reliable oversight data will be a key to the success of the improvements necessary to fulfill the hospital's obligations under agreement with CMS.	4/9/2012

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A 043	Continued From page 1B	A 043	**Monitoring:** The revised audit tool is being developed for telemetry monitoring to be used for the (off the unit) audit person. Part of the audit will include the interview of the monitor tech to ensure the appropriate person is called for an event rhythm. **Responsibility:** Vice President of Nursing **The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 3. A comprehensive review of the hospital's infection control program is underway and the findings will be reported to CMS as specified in our agreement with CMS. In the mean time, two work groups have been formed to address isolation precautions on a priority basis: one group (under the auspices of hospital-wide interdisciplinary team) will focus on the emergency department; the other group (reporting to Nursing Services) will focus on the inpatient service. The process design and testing phase will be completed within 30 days. **Monitoring:** Monitoring will be put in place for assuring stable compliance. **Responsibility:** Chief Medical Officer and Chief Executive Officer The Governing Body is always kept informed of the ongoing DHSR reviews and action plans to be implemented at the Board of Trustees meeting as well as direct communication from the Chief Executive Officer (CEO).	4/9/2012

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	Continued From page 1C			
A 263	~Cross refer to 482.41 Infection Control Condition: Tag A0747 482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on policy review, Performance Improvement plan review, staff interview, open medical record review, telemetry audit tool review, and infection control data review, the hospital failed to implement and maintain an effective quality assessment and performance improvement program to ensure the safety of patients.	A 263	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 1. There is an ongoing overall review and restructuring of the Performance Improvement Department (PI) to include providing additional oversight to patient safety and quality and infection control issues hospital wide. With the assistance of the Greeley consultants, the re-design of the Performance Improvement Department has begun and one consideration is the Infection Control Department will report to the Patient Safety Officer, Associate Chief Medical Officer as is the current status with the Performance Improvement Department. The PI Department along with other members of leadership to include the VP of Nursing is to review occurrences (incident reports) in the hospital as well as Patient Grievances on a scheduled basis 5-6 days per week. Occurrences will be tracked and trended by the PI Department. As quality and patient safety issues are identified, these issues will be prioritized by Leadership. The PI department is responsible for coordinating the Event Response Team process and the Patient Safety Response Team process to address immediate concerns related to patient safety.	

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A 263	Continued From page 2 The findings include: 1. The hospital failed to track identified quality indicators for telemetry patients by failing to accurately complete telemetry audit tools. ~cross refer to 482.21(a)(2) QAPI Standard: Tag A0267 2. The hospital failed to ensure quality of care by failing to monitor compliance with isolation policies and procedures in the hospital's Emergency Department.		for patient safety and quality. There is also a Patient Safety Response Team process whereby there is an immediate follow up needed for concern for patient safety and quality. The PI Department is also responsible for trending patient quality and safety issues as to prioritize action needed based on the PI Department oversight responsibility. **Monitoring:** The PI Department along with other members of leadership to include the VP of Nursing is to review occurrences (incident reports) in the hospital as well as Patient Grievances on a scheduled basis 5-6 days per week. Occurrences will be tracked and trended by the PI Department. As quality and patient safety issues are identified, these issues will be prioritized by Leadership. The PI department is responsible for coordinating the Event Response Team process and the Patient Safety Response Team process to address immediate concerns related to patient safety. **Responsibility:** Associate Chief Medical Officer and Chief Executive Officer **The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 2. There is an ongoing overall review and restructuring of the Performance Improvement Department (PI) to include providing additional oversight to patient safety and quality and infection control issues hospital wide. With the assistance of the Greeley consultants, the re-design of the Performance Improvement Department has begun and one consideration is the Infection Control Department will report to the Patient Safety Officer, Associate Chief Medical Officer as is the current status with the Performance Improvement Department. The	4/9/2012

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A 263	Continued From page 2A		PI Department along with other members of leadership to include the VP of Nursing is to review occurrences (incident reports) in the hospital as well as Patient Grievances on a scheduled basis 5-6 days per week. Occurrences will be tracked and trended by the PI Department. As quality and patient safety issues are identified, these issues will be prioritized by Leadership. The PI department is responsible for coordinating the Event Response Team process and the Patient Safety Response Team process to address immediate concerns related to patient safety. **Monitoring:** The PI Department along with other members of leadership to include the VP of Nursing is to review occurrences (incident reports) in the hospital as well as Patient Grievances on a scheduled basis 5-6 days per week. Occurrences will be tracked and trended by the PI Department. As quality and patient safety issues are identified, these issues will be prioritized by Leadership. The PI department is responsible for coordinating the Event Response Team process and the Patient Safety Response Team process to address immediate concerns related to patient safety. **Responsibility:** Associate Chief Medical Officer and Chief Executive Officer	4/9/2012

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	Continued From page 2B			
A 267	~cross refer to 482.21(c)(1) QAPI Standard: Tag A0285 482.21(a)(2) QAPI QUALITY INDICATORS The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations. This STANDARD is not met as evidenced by: Based on policy review, Performance improvement plan review, staff interview, open medical record review, and telemetry audit tool review the hospital failed to track identified quality indicators for telemetry patients by failing to accurately complete telemetry audit tools for 2 of 9 sampled patients on telemetry monitors (Patients #10 and #9). The findings include: Review of current hospital policy entitled	A 267	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** In the case of telemetry monitoring on the inpatient nursing units the audit process is being revised whereby the telemetry audit is to be completed by an "off the unit" audit person. This will provide a representative sampling of the telemetry process on the nursing units with validation to ensure the integrity of data collection. Reliable oversight data will be a key to the success of the improvements necessary to fulfill the hospital's obligations under our improvement agreement with CMS. Following the last DHSR visit an overall re-education was completed for the monitor technicians. The monitor technicians have been reminded to always print the report that details which patient on a particular nursing unit has a physician order for telemetry. A report is to be printed at shift change by the monitor technicians to ensure each patient that has a physician order for telemetry is completed and the monitor technician is	

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A 267	Continued From page 3 "Telemetry Policy" dated 01/06/2012 revealed, "...Monitoring Practices of the Nurse or Monitor Technician (MT) assigned to a central monitoring unit:...Print a 6-second telemetry strip:...Every 4 hrs (hours)....Interpret rhythm strip. Record date, time, and name of MT/Nurse performing measurements and interpretation. Notify Primary Nurse for changes in patient's usual heart rate/rhythm. Provide copies of strips to Primary Nurse...." Review of current hospital "PI (Performance Improvement) Plan 2011-2012" approved by the Board of Trustees 12/2011 revealed, "...Data will be collected and performance monitored regularly as determined by the leaders, for the following areas: Priorities identified by leaders....When an indicator detects or suggests significant undesirable performance or variation, intense analysis is initiated to determine where best to focus changes for improvement...." Interview on 01/24/2012 at 1400 with the Interim Chief Nursing Officer (CNO) revealed an action plan to improve quality of care to patients on telemetry monitors had been implemented and audits to monitor the process were currently in process. Interview revealed all patients on telemetry monitors on inpatient units are audited each day. Interview revealed the Monitor Tech completes the Telemetry Audit Form for the previous 24 hour period every morning and gives it to the manager. Interview revealed the Telemetry Audit Form includes documentation of cardiac rhythm changes, nurses' responses to rhythm changes, and presence of a rhythm strip (printed, interpreted and signed) in the medical record every 4 hours. Further interview revealed	A 267	printing the monitor strips per policy. Part of the audit will ensure the monitor technician will know to always call the nurse for an event rhythm and understand the nursing assistant can be called for leads off or battery change based on the telemetry policy. **Monitoring:** The revised audit tool is being developed for telemetry monitoring to be used for the (off the unit) audit person. Part of the audit will include the interview of the monitor tech to ensure the appropriate person is called for an event rhythm. **Responsibility:** VP of Nursing	4/9/2012

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A 267	Continued From page 4 the manager reviews all of the Telemetry Audit Forms daily and completes the Nursing Telemetry Summary Audit Tool. Interview revealed the manager documents rhythm alerts and staff follow up, as well as whether or not any rhythm strips were missing from the medical record. Further interview revealed all completed Nursing Telemetry Summary Audit Tools are sent to nursing administration daily data aggregation and review. 1. Medical record review on 01/25/2012 during tour of the 8-South Unit for Patient #10 revealed a 79 year-old female that was admitted on 01/17/2012 from a skilled nursing facility with sepsis, urinary tract infection, bilateral lower extremity cellulitis, and renal failure. Record review revealed a physician's order dated 01/17/2012 at 1515 for telemetry monitoring (continuous heart monitoring) of the patient. Record review revealed no documentation of a printed 6-second telemetry strip, interpreted and signed by a MT or nurse, between 01/23/2012 at 1559 and 01/24/2012 at 0430 (12 hours and 31 minutes - 2 rhythm strips missing from record). Record review revealed a physician's order dated 01/24/2012 at 1100 to discontinue telemetry monitoring of the patient. Review of Telemetry Audit Forms for Patient #10 revealed no form dated 01/23/2012. Review of the Nursing Telemetry Summary Audit Tool for 8-South dated 01/24/2012 revealed documentation of the nurse manager's review of Telemetry Audit Forms from the previous day (01/23/2012). Review of the Tool revealed no documentation Patient #10 had been reviewed.	A 267		

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A 267	Continued From page 5 Interview on 01/25/2012 at 1500 with the Nurse Manager of the 8-South Unit revealed the Unit has 34 rooms, numbered 1 through 34. Interview revealed all of the beds have telemetry monitoring capability, but rooms 1 through 32 are routinely used for telemetry patients. Interview revealed Patient #10 was in room 33, which was not a room that usually had telemetry patients in it. Interview revealed, "I didn't audit (room) 33 (on 01/24/2012) because I stopped at (room) 32 and I didn't have an audit sheet (Telemetry Audit Form). I'm not sure why I didn't have an audit sheet for her. The monitor tech on night shift going off (duty) should have given it to the dayshift Unit Secretary to check and make sure the strips were in the chart and signed by the (monitor) tech." Interview revealed the telemetry audit process did not detect the fact that telemetry strips were missing from the patient's medical record. 2. Medical record review on 01/25/2012 during tour of the 6-South Unit for Patient #9 revealed a 26 year-old female that was admitted on 01/18/2012 with diabetes and sickle cell crisis. Record review revealed a physician's order dated 01/18/2012 at 1815 for telemetry monitoring (continuous heart monitoring) of the patient. Record review revealed no documentation of a printed 6-second telemetry strip, interpreted and signed by a MT or nurse, on 01/20/2012 between 1207 and 1951 (7 hours and 44 minutes). Record review revealed a physician's order dated 01/22/2012 at 2115 to discontinue telemetry monitoring of the patient. Review of a Telemetry Audit Form dated 01/20/2012 for Patient #9 revealed no	A 267		

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A 267	Continued From page 6 documentation of any missing telemetry strips on 01/20/2012. Review of the Nursing Telemetry Summary Audit Tool for 6-South dated 01/21/2012 revealed documentation of the nurse manager's review of Telemetry Audit Forms from the previous day (01/20/2012). Review of the Tool revealed documentation Patient #9 had been audited and found to have no missing telemetry strips. Interview on 01/25/2012 at 1320 with the Nurse Manager of the 6-South Unit revealed, "Resource nurses do audits of telemetry patients every shift." Interview confirmed the missing telemetry strip from 01/20/2012 was not noted on either the Telemetry Audit Form or the Nursing Telemetry Summary Audit Tool. Interview revealed the telemetry audit process did not detect the fact that a telemetry strip was missing from the patient's medical record.	A 267		
A 285	482.21(c)(1) QAPI PATIENT SAFETY The hospital must set priorities for its performance improvement activities that – Focus on high-risk, high-volume, or problem-prone areas; Consider the incidence, prevalence, and severity of problems in those areas; and Affect health outcomes, patient safety, and quality of care. This STANDARD is not met as evidenced by: Based on review of hospital policy, infection control data and staff interviews, the hospital failed to ensure quality of care by failing to	A 285	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** Once the patient arrives in the ED there is a current notification in the computer system for VRE and/or MRSA for patients that have a history from a previous hospital visit utilized by the access registration personnel. A blue armband is placed on the patient by the access registration personnel. There is also a notation by the access registration personnel on the consent form that is being implemented to demonstrate they placed the blue armband on the patient. A new step added in the process is the access registration personnel will access the EmStat computer documentation system for the ED and order the isolation in the drop down menu which will note on the EmStat medical record the contact isolation that is needed for these patients. Also on the EmStat patient tracking board the color green will show	

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A 285	Continued From page 7 monitor compliance with isolation policies and procedures in the hospital's Emergency Department. The findings include: Review of the hospital's Patient Safety Plan, effective 12/2011, revealed, "....(Name of Hospital) integrates activities to improve patient safety and to proactively address and reduce medical/health care occurrences and other factors that contribute to unintended and/or unanticipated adverse patient outcomes. It is our responsibility to question if we can do things in a better, more efficient, and safer manner and be relentless in our pursuit of finding ways to improve our systems and to establish patient safety priorities for the health system....In the organization's commitment to quality, there is a focus on improving these systems and processes...." Review of the hospital's infection control data dated 07/18/2011, 08/23/2011, 09/19/2011, 10/19/2011, 11/14/2011 and 01/02/2012 revealed "Contact Isolation Compliance Scores" for patient care units of the hospital. Review of the data revealed no contact isolation compliance score for the hospital's Emergency Department (ED). Interview on 01/25/2012 at 1030 with the hospital's Interim Emergency Department Director revealed, "We are not monitoring compliance with isolation in the ED. We haven't done that in months." Interview on 01/24/2012 at 1515 with the Infection	A 285	under the previous visit (PV) column which will call attention to the staff of the needed isolation precautions needed for the patient. The ED Information Technology representative worked with the EmStat programmer to link a work task message that populates in the ED secretaries work list to order isolation in Valley Link (in-patient system for hospital). There is work that has started so a pop-up message will generate when C diff tests are ordered and it will instruct the staff to order "Contact Special Enteric Precautions". The isolation stations will be placed on the patient door with the patients that are positive for VRE and/or MRSA and C diff when ordered. There are current flags in the nursing documentation system that informs the nurse the patient is positive for VRE and/or MRSA. As the practices in the ED improve the patients will already be on isolation prevention when the admitted patients arrive on the nursing unit. Good hand washing practices are to be reviewed again with the nursing staff at shift change in the ED as well as infection control practices. The same information is to be shared with the providers that work in the ED. **Monitoring:** There is a report that has been made available to show patients in the ED as well as inpatient nursing units that are VRE and/or MRSA positive. It is a verification process for review so checks can be done by all levels of leadership in the hospital to know if contact isolation procedures have been implemented. If not, the process for notification and ordering the appropriate isolation is done immediately. The Infection Control Staff will check the ED Valleylink Isolation report at the beginning and	4/9/2012

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A 285	Continued From page 8 Control Practitioner revealed, "The ED patients are not really included on the Infection Control log. There is no monitoring for compliance with isolation in the ED. We don't have a really good handle on this." Further interview on 01/26/2012 at 1150 revealed, "The last time the ED was monitored for compliance with isolation was in April (2011 - 9 months ago). I knew this sometime between June (2011) and August (2011). I had a conversation with (ED resource nurse). I haven't followed up." Interview further revealed the contact isolation compliance data is reported to the Patient Safety/Quality Council. Interview revealed the Patient Safety/Quality Council has not questioned the lack of monitoring for isolation precautions in the ED. Interview on 01/26/2012 at 1140 with the hospital's Director of Quality revealed, "Compliance with isolation falls with the Infection Control Department. They have weekly Infection Control meetings and quarterly meetings with the Infection Control Committee. The Infection Control Committee reports to the Patient Safety/Quality Council and the information is then reported to the Board Quality Committee." Interview further revealed, "We did not realize the ED was not being monitored for compliance."	A 285	end of the work day to validate that isolation has been ordered until the ED leadership has fully implemented the real time process. The inpatient Valleylink Isolation report will be provided to the nursing leadership for review on a daily basis. An audit will be done by an assigned "off the unit" auditor by the VP of Nursing for validation purposes. The Supervisor of ED Registration checks the documentation on the consent form for validation of the placement of the blue arm band. **Responsibility:** Chief Medical Officer and Chief Executive Officer	
A 385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on policy review, open medical record review, and staff interview the hospital failed to	A 385	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 1. In the case of telemetry monitoring on the inpatient nursing units the audit process is being revised whereby the telemetry audit is to be completed by an "off the unit" audit person. This will provide a representative sampling of the telemetry process on the nursing units with validation to ensure the integrity of data collection. Reliable oversight data will be a key to the success of the improvements necessary to fulfill the hospital's obligations under our agreement with CMS. Following the last	

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A 385	Continued From page 9 have an organized nursing service providing oversight of day-to-day operations to ensure registered nursing staff supervised and evaluated patient care and administered medications per physician's orders. The findings include: 1. The hospital's nursing staff failed to supervise and evaluate patient care by failing to review and interpret telemetry monitor tracings to assess cardiac rhythms of patients on telemetry monitors per policy. ~cross refer to 482.23 (b)(3) Nursing Services Standard: Tag A0395 2. The hospital failed to ensure nursing staff administered insulin as ordered by the physician.	A 385	DHSR visit an overall re-education was completed for the monitor technicians. The monitor technicians have been reminded to always print the report that details which patient on a particular nursing unit has a physician order for telemetry. A report is to be printed at shift change by the monitor technicians to ensure each patient that has a physician order for telemetry is completed and the monitor technician is printing the monitor strips per policy. Part of the audit will ensure the monitor technician will know to always call the nurse for an event rhythm and understand the nursing assistant can be called for leads off or battery change based on the telemetry policy. **Monitoring:** The revised audit tool is being developed for telemetry monitoring to be used for the (off the unit) audit person. Part of the audit will include the interview of the monitor tech to ensure the appropriate person is called for an event rhythm. **Responsibility:** Vice President of Nursing **The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** 2. The isolated dosage calculation error reflected in the statement of deficiencies will be augmented by a complete review of glycemic control practices, from ordering through dispensing to administration and monitoring. The changes in blood glucose monitoring promised in an earlier plan of correction whereby the nurse completed his/her own accucheck have been proven positive for the nursing staff on the 2 test nursing units. An Insulin/Glycemic Control Improvement Team is being established to make recommendations regarding nurse and physician practice in regards to insulin which	

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A 385	Continued From page 9A	A 385	is recognized as a high alert medication. The recommendations are to be designed, tested and implemented over the next 90 days. The Insulin/Glycemic Control Improvement Team will report to the Medication Safety subcommittee of Pharmacy and Therapeutics. **Monitoring:** A report for high alert medications is to be sent by pharmacy to all of the nursing units. Any patient receiving insulin will be on this report for review by the nurse manager. An auditing process will be in place for random auditing of insulin administration. **Responsibility:** Vice President of Nursing	4/9/2012
A 395	~cross refer to 482.23 (c) Nursing Services Standard: Tag A0404 482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on policy review, open medical record review, and staff interview the hospital's nursing staff failed to supervise and evaluate patient care by failing to review and interpret telemetry monitor tracings to assess cardiac rhythms of patients on telemetry monitors per policy for 2 of 9 sampled patients on telemetry monitors (Patients #10 and #9).	A 395	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** In the case of telemetry monitoring on the inpatient nursing units the audit process is being revised whereby the telemetry audit is to be completed by an "off the unit" audit person. This will provide a representative sampling of the telemetry process on the nursing units with validation to ensure the integrity of data collection. Reliable oversight data will be a key to the success of the improvements necessary to fulfill the hospital's obligations under our agreement with CMS. Following the last DHSR visit an overall re-education was completed for the monitor technicians. The monitor technicians have been reminded to always print the report that details which patient on a particular nursing unit has a physician order for telemetry. A report is to be printed at shift change by the monitor	

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A 395	Continued From page 10 The findings include: Review of current hospital policy entitled "Telemetry Policy" dated 01/06/2012 revealed, "...Monitoring Practices of the Nurse or Monitor Technician (MT) assigned to a central monitoring unit:...Print a 6-second telemetry strip:...Every 4 hrs (hours)....Interpret rhythm strip. Record date, time, and name of MT/Nurse performing measurements and interpretation. Notify Primary Nurse for changes in patient's usual heart rate/rhythm. Provide copies of strips to Primary Nurse...." 1. Medical record review on 01/25/2012 during tour of the 8-South Unit for Patient #10 revealed a 79 year-old female that was admitted on 01/17/2012 from a skilled nursing facility with sepsis, urinary tract infection, bilateral lower extremity cellulitis, and renal failure. Record review revealed a physician's order dated 01/17/2012 at 1515 for telemetry monitoring (continuous heart monitoring) of the patient. Record review revealed no documentation of a printed 6-second telemetry strip, interpreted and signed by a MT or nurse, between 01/23/2012 at 1559 and 01/24/2012 at 0430 (12 hours and 31 minutes). Record review revealed a physician's order dated 01/24/2012 at 1100 to discontinue telemetry monitoring of the patient. Interview on 01/25/2012 at 1500 with the Nurse Manager of the 8-South Unit revealed monitor tech or nurse should print, interpret, and sign telemetry monitor strips every 4 hours. Interview revealed the strips should then be placed in the medical record. Interview confirmed there was no available documentation of a printed 6-second	A 395	technicians to ensure each patient that has a physician order for telemetry is completed and the monitor technician is printing the monitor strips per policy. Part of the audit will ensure the monitor technician will know to always call the nurse for an event rhythm and understand the nursing assistant can be called for leads off or battery change based on the telemetry policy. **Monitoring:** The revised audit tool is being developed for telemetry monitoring to be used for the (off the unit) audit person. Part of the audit will include the interview of the monitor tech to ensure the appropriate person is called for an event rhythm. **Responsibility:** Vice President of Nursing	4/9/2012

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A 395	Continued From page 11 telemetry strip, interpreted and signed by a MT or nurse, between 01/23/2012 at 1559 and 01/24/2012 at 0430 (12 hours and 31 minutes). 2. Medical record review on 01/25/2012 during tour of the 6-South Unit for Patient #9 revealed a 26 year-old female that was admitted on 01/18/2012 with diabetes and sickle cell crisis. Record review revealed a physician's order dated 01/18/2012 at 1815 for telemetry monitoring (continuous heart monitoring) of the patient. Record review revealed no documentation of a printed 6-second telemetry strip, interpreted and signed by a MT or nurse, on 01/20/2012 between 1207 and 1951 (7 hours and 44 minutes). Record review revealed a physician's order dated 01/22/2012 at 2115 to discontinue telemetry monitoring of the patient. Interview on 01/25/2012 at 1320 with the Nurse Manager of the 6-South Unit revealed monitor tech or nurse should print, interpret, and sign telemetry monitor strips every 4 hours. Interview revealed the strips should then be placed in the medical record. Interview confirmed there was no available documentation of a printed 6-second telemetry strip, interpreted and signed by a MT or nurse, on 01/20/2012 between 1207 and 1951 (7 hours and 44 minutes).	A 395		
A 404	482.23(c) ADMINISTRATION OF DRUGS Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.	A 404	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** The isolated dosage calculation error reflected in the statement of deficiencies will be augmented by a complete review of glycemic control practices, from ordering through dispensing to administration and monitoring. The changes in blood glucose monitoring promised in an earlier plan of correction whereby the nurse completed his/her own accucheck have been proven	

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A 404	Continued From page 12 This STANDARD is not met as evidenced by: Based on policy review, open medical record review, and staff interview the hospital failed to ensure nursing staff administered insulin as ordered by the physician for 1 of 5 sampled patients with physicians' orders for sliding scale insulin (Patient #9). The findings include: Review of current hospital policy entitled "Medication Administration" dated 01/11/2012 revealed, "I. GENERAL POLICY:...B. Medication orders are originated by a License independent Practitioner....F. Remove medications from the Pyxis for one patient at a time and administer to each patient separately, adhering to the 'five fights of medication' administration as follows:...3) right dose....II. SECOND NURSE VERIFICATION:....A. High alert medications and specific critical medications require a second licensed nurse, one being a RN (registered nurse), to check the five rights before administration...." Medical record review on 01/25/2012 during tour of the 6-South Unit for Patient #9 revealed a 26 year-old female that was admitted on 01/18/2012 with diabetes and sickle cell crisis. Review of physician's orders dated 01/18/2012 at 1815 revealed, "...sliding scale insulin BS-100/30 (BS level minus 100 and then divided by 30 to get the dose of insulin to be administered) & accucheck (blood sugar test) Q ACHS (before each meal and at bedtime)...." Record review revealed on 01/24/2012 at 2344 (bedtime) the patient's blood sugar was 308. Record review revealed RN #5 administered 10 units of insulin to the patient on	A 404	positive for the nursing staff on the 2 test nursing units. An Insulin/Glycemic Control Improvement Team is being established to make recommendations regarding nurse and physician practice in regards to insulin which is recognized as a high alert medication. The recommendations are to be designed, tested and implemented over the next 90 days. The Insulin/Glycemic Control Improvement Team will report to the Medication Safety subcommittee of Pharmacy and Therapeutics. **Monitoring:** A report for high alert medications is to be sent by pharmacy to all of the nursing units. Any patient receiving insulin will be on this report for review by the nurse manager. An auditing process will be in place for random auditing of insulin administration. **Responsibility:** Vice President of Nursing	4/9/2012

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A 404	Continued From page 13 01/24/2012 at 2353 (blood sugar of 308 minus 100 and then divided by 30 equals 6.9, so the dose of insulin that should have been administered was 7 units). Record review revealed RN #6 checked the insulin dose with RN #5 prior to administration. Interview on 01/25/2012 at 1320 with the Nurse Manager of the 6-South Unit revealed, based on the patient's blood sugar of 308, the patient should have been given 7 units of insulin on 01/24/2012 at 2353. Interview confirmed RN #5 administered 10 units of insulin to the patient on 01/24/2012 at 2353. Interview revealed, "This was a med(ication) error."	A 404		
A 747	482.42 INFECTION CONTROL The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases. This CONDITION is not met as evidenced by: Based on policy review, job description review, staff interview, open medical record review, and patient interview, the hospital failed to have a system in place to ensure the prevention and control of infections and communicable diseases. The findings include: 1. The hospital's Infection Control Officer failed to ensure the control of infections by failing to ensure isolation precautions were initiated per hospital policy.	A 747	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** Once the patient arrives in the ED there is a current notification in the computer system for VRE and/or MRSA for patients that have a history from a previous hospital visit utilized by the access registration personnel. A blue armband is placed on the patient by the access registration personnel. There is also a notation by the access registration personnel on the consent form that is being implemented to demonstrate they placed the blue armband on the patient. A new step added in the process is the access registration personnel will access the EmStat computer documentation system for the ED and order the isolation in the drop down menu which will note on the EmStat medical record the contact isolation that is needed for these patients. Also on the EmStat patient tracking board the color green will show under the previous visit (PV) column which will call attention to the staff of the needed isolation precautions needed for the patient. The ED Information Technology representative worked with the EmStat programmer to link a work task message that	

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A 747	Continued From page 14	A 747	populates in the ED secretaries work list to order isolation in Valley Link (in-patient system for hospital). There is work that has started so a pop-up message will generate when C diff tests are ordered and it will instruct the staff to order "Contact Special Enteric Precautions". The isolation stations will be placed on the patient door with the patients that are positive for VRE and/or MRSA and C diff when ordered. There are current flags in the nursing documentation system that informs the nurse the patient is positive for VRE and/or MRSA. As the practices in the ED improve the patients will already be on isolation prevention when the admitted patients arrive on the nursing unit. Good hand washing practices are to be reviewed again with the nursing staff at shift change in the ED as well as infection control practices. The same information is to be shared with the providers that work in the ED. **Monitoring:** There is a report that has been made available to show patients in the ED as well as inpatient nursing units that are VRE and/or MRSA positive. It is a verification process for review so checks can be done by all levels of leadership in the hospital to know if contact isolation procedures have been implemented. If not, the process for notification and ordering the appropriate isolation is done immediately. The Infection Control Staff will check the ED Valleylink Isolation report at the beginning and end of the work day to validate that isolation has been ordered until the ED leadership has fully implemented the real time process. The inpatient Valleylink Isolation report will be provided to the nursing leadership for review on a daily basis. An audit will be done by an assigned "off the unit" auditor by the VP of Nursing for validation purposes.	4/9/2012

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A 747	Continued From page 14A	A 747	The Supervisor of ED Registration checks the documentation on the consent form for validation of the placement of the blue arm band. **Responsibility:** Chief Medical Officer and Chief Executive Officer	
A 749	~Cross refer to 482.41 (a)(1) Infection Control Standard: Tag A0749 482.42(a)(1) INFECTION CONTROL OFFICER RESPONSIBILITIES The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on policy review, job description review, staff interview, open medical record review, and patient interview, the hospital's Infection Control Officer failed to ensure the control of infections by failing to ensure isolation precautions were initiated per hospital policy for 7 of 9 patients presenting to the hospital with a history of infectious/communicable disease (#13, #14, #12, #20, #9, #10, #21). The findings include: Review of the hospital's policy, "Isolation Precautions", revised 01/2011, revealed, "Policy: Isolation Precautions are used in addition to Standard Precautions when patients have or are suspected of having a highly communicable disease or a disease of epidemiological importance....The nurse may place the patient on isolation without a physician's order per this policy....Purpose: To utilize control measures, which decrease the risk of transmission of microorganisms within the Health System....Guidelines:...II. Transmission-Based Precautions: A. General Principles: 1. In addition to Standard Precautions, use Isolation	A 749	**The corrective action(s) and the systems that have been or will be implemented to correct the deficiency are as follows:** Once the patient arrives in the ED there is a current notification in the computer system for VRE and/or MRSA for patients that have a history from a previous hospital visit by the access registration personnel. A blue armband is placed on the patient utilized by the access registration personnel. There is also a notation by the access registration personnel on the consent form that is being implemented to demonstrate they placed the blue armband on the patient. A new step added in the process is the access registration personnel will access the EmStat computer documentation system for the ED and order the isolation in the drop down menu which will note on the EmStat medical record the contact isolation that is needed for these patients. Also on the EmStat patient tracking board the color green will show under the previous visit (PV) column which will call attention to the staff of the needed isolation precautions needed for the patient. The ED Information Technology representative worked with the EmStat programmer to link a work task message that populates in the ED secretaries work list to order isolation in Valley Link (in-patient system for hospital). There is work that has started so a pop-up message will generate when C diff tests are ordered and it will instruct the staff to order "Contact Special Enteric Precautions". The isolation stations will be placed on the patient door with the patients that are positive for VRE	

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A 749	Continued From page 15 Precautions for patients with documented or suspected infection or colonization with highly transmissible or epidemiologically important pathogens for which additional precautions are needed to prevent transmission....B. Contact Precautions: There are two types of Contact Precautions. Contact Precautions and Contact-Special Enteric Precautions. Use Contact Precautions, for specified patients known or suspected to be infected, colonized, or known exposure to communicable diseases which may spread prior to development of signs or symptoms with epidemiological important microorganisms that can be transmitted by direct contact with the patient (hand or skin-to-skin contact that occurs when performing patient-care activities that require touching the patient's dry skin) or indirect contact (touching) with environmental surfaces or patient-care items in the patient's environment. Contact-Special Enteric Precautions are used for highly transmittable diarrhea illnesses caused by Clostridium difficile or Norovirus. 1. Automatically place patient on Contact Precautions when patients are identified as having Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin Resistant Enterococcus (VRE)...2. Patients flagged in SMS or Valley Link (hospital computer system), as MRSA, VRE...positive are to be automatically placed on Contact Precautions with each visit to the Health System per order of the Infection Prevention and Control Committee. Registration staff places blue armband on these patients. Nursing is responsible for placing the blue armband on patients identified during their hospital stay. 3. Patients flagged as having a history of MRSA are to remain on Contact	A 749	and/or MRSA and C diff when ordered. There are current flags in the nursing documentation system that informs the nurse the patient is positive for VRE and/or MRSA. As the practices in the ED improve the patients will already be on isolation prevention when the admitted patients arrive on the nursing unit. Good hand washing practices are to be reviewed again with the nursing staff at shift change in the ED as well as infection control practices. The same information is to be shared with the providers that work in the ED. **Monitoring:** There is a report that has been made available to show patients in the ED as well as inpatient nursing units that are VRE and/or MRSA positive. It is a verification process for review so checks can be done by all levels of leadership in the hospital to know if contact isolation procedures have been implemented. If not, the process for notification and ordering the appropriate isolation is done immediately. The Infection Control Staff will check the ED Valleylink Isolation report at the beginning and end of the work day to validate that isolation has been ordered until the ED leadership has fully implemented the real time process. The inpatient Valleylink Isolation report will be provided to the nursing leadership for review on a daily basis. An audit will be done by an assigned "off the unit" auditor by the VP of Nursing for validation purposes. The Supervisor of ED Registration checks the documentation on the consent form for validation of the placement of the blue arm band. **Responsibility:** Chief Medical Officer and Chief Executive Officer	4/9/2012

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A 749	Continued From page 16 Precautions until 6 months has lapsed from the last positive MRSA culture and there are 2 negative cultures for MRSA from nares and other site of infection (if present)....4. Patients flagged, as having a history of VRE are to remain on Contact Precautions until 1 year has lapsed from last positive culture, and there are 3 successive rectal swabs obtained for VRE at least 1 week apart. 5. Automatically place patient on Contact-Special Enteric Precautions when Clostridium difficile toxin is ordered or patient is known or suspected as having Clostridium difficile or Norovirus as the cause of diarrhea...." Review of the hospital's policy, "Triage Policy-Adult", revised 06/20/2011, revealed, "POLICY: Patients presenting to the Emergency Department are evaluated by a Registered Nurse to determine the nature of their presenting complaints, their condition...B. Initial Intake Process:...Secondary Triage includes:...f. Pertinent past medical history...." Review of the hospital's job description for the director of infection prevention and control, revised 03/2010, revealed, "...Job Summary: The Director of Infection Prevention and Control is a registered professional nurse who is responsible for supervising the multiple facets of the Infection Prevention and Control Program in the institution....Major Job Functions:...B. Surveillance and Reporting Functions:...4. Oversees Infection Preventionists, Infection Prevention and Control Coordinator's surveillance rounds and accuracy of surveillance....C. Prevention Functions:...2. Coaches and mentors Infection Preventionists and Infection Prevention and Control Coordinator with assisting	A 749		

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A 749	Continued From page 17 department manager in achieving compliance with established infection control and prevention priorities and/or system goals...." Interview on 01/24/2012 at 1400 with the hospital's infection control practitioner revealed patients that present to the hospital with a history of MRSA or VRE should be placed on Contact Isolation precautions as soon as possible. Interview revealed patients that present to the hospital and are suspected to have Clostridium difficile toxin (C-Diff) should be placed on Special Enteric precautions as soon as possible. Interview revealed, "When a patient is registered in the ED, the business office uses INVISION (computer system) to register the patient." Interview revealed the alert for isolation precautions related to a history of infectious disease is displayed in the INVISION computer system. Interview further revealed, "The registrar places a blue arm band on the patient and tells the nurse. The nurse should document in the ED record. The alert for isolation precautions is not in EMSTAT (ED clinical computer system)." 1. Medical record review of Patient #13 revealed a 41 year-old who presented to the hospital's emergency services department via EMS (emergency medical services) on 01/19/2012 at 1427 with chief complaint of right lower abdominal pain and fever. Review of the ED record revealed the patient's temperature was 102.8 degrees when assessed by the triage nurse at 1431. Review of the ED record revealed documentation by RN #1 at 1433, "...TB Screening: Have you been exposed to TB- no, Have you had a cough or resp (respiratory) illness -no, Fever greater than 100.4 Fh (Fahrenheit) or	A 749		

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A 749	Continued From page 18 38 C (Celsius)- No...Isolation Recommended: No...." Record review revealed Patient #13 was admitted to an inpatient unit on 01/20/2012 at 1426. Review of the SBARR (nurse-to-nurse communication tool) ED Admission Report for Patient #13 revealed, "...Pt. Status & Alerts: Isolation: *Standard Precautions...." Review of the electronic medical record for Patient #13 revealed a red exclamation mark (!) in the left upper corner of the screen. Review of the "Alert Description" that opened after clicking on the exclamation mark (!) revealed, "....MRSA Present: flank on 10/23/2009. Place on Contact Precautions with each visit...." Further record review revealed Contact Isolation was ordered by a nurse on 01/23/2012 at 0909 (3 days, 18 hours after presentation to the hospital). Interview on 01/25/2012 at 0915 with RN #1 revealed the nurse was working in the hospital's ED on 01/19/2012 as the triage nurse. Interview revealed the nurses in the ED do not have access to the computer system that displays alerts for isolation precautions. Interview revealed ED registration personnel have access to the alerts and the nurses depend on the registrars to place blue arm bands on patients that should be isolated. Interview revealed Patient #13 did not have a blue arm band on when triaged. Interview revealed, "If I had known, I would have notified the provider so the doctor could order precautions." Interview further revealed, "Nurses can initiate contact precautions." Interview further revealed, "The hospital infection control policy applies to the ED." Interview further revealed Patient #13 had a history of MRSA and temperature of 102.8 degrees Fahrenheit and should have been placed on Contact Precautions	A 749		

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A 749	Continued From page 19 in the ED. Interview revealed the hospital's isolation policy was not followed. Interview on 01/25/2012 with the hospital's infection control practitioner revealed, "One of the Infection Control nurses found that (Patient #13) had a history of MRSA when reviewing the Isolation Log on Monday (01/23/2012). She notified the unit to place the patient on Contact Precautions." Interview further revealed Patient #13 should have been placed on Contact Precautions upon presentation to the hospital's ED on 01/19/2012. 2. Medical record review of Patient #14 revealed a 65 year-old who presented to the hospital's ED on 01/19/2012 at 1652 via EMS with altered mental status and pneumonia. Review of the ED record revealed documentation by RN #2 at 1718, "...Isolation Recommended: No...." Record review revealed Patient #14 was admitted to an inpatient unit on 01/20/2012 at 1718. Review of the SBARR ED Admission Report for Patient #14 revealed, "...Pt. Status & Alerts: Isolation: *Standard Precautions...." Review of the electronic medical record for Patient #14 revealed a red exclamation mark (!) in the left upper corner of the screen. Review of the "Alert Description" that opened after clicking on the exclamation mark (!) revealed, "....MRSA Present penis, nares on 06/03/2011. VRE Present urine on 01/24/2009. Place on Contact Precautions with each visit...." Further record review revealed Contact Isolation was ordered by a nurse on 01/23/2012 at 0937 (3 days, 16 hours after presentation to the hospital). Interview on 01/25/2012 at 0915 with RN #1	A 749		

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A 749	Continued From page 20 revealed the nurse was working in the hospital's ED on 01/19/2012 as the triage nurse. Interview revealed the nurses in the ED do not have access to the computer system that displays alerts for isolation precautions. Interview revealed ED registration personnel have access to the alerts and the nurses depend on the registrars to place blue arm bands on patients that should be isolated. Interview revealed Patient #14 did not have a blue arm band on when triaged. Interview revealed, "If I had known, I would have notified the provider so the doctor could order precautions". Interview further revealed, "Nurses can initiate contact precautions." Interview revealed, "The hospital infection control policy applies to the ED". Interview further revealed Patient #14 had a history of MRSA and VRE and should have been placed on Contact Precautions in the ED. Interview revealed the hospital's isolation policy was not followed. Interview on 01/25/2012 with the hospital's infection control practitioner revealed, "One of the Infection Control nurses found that (Patient #14) had a history of MRSA when reviewing the Isolation Log on Monday (01/23/2012). She notified the unit to place the patient on Contact Precautions". Interview further revealed Patient #14 should have been placed on Contact Precautions upon presentation to the hospital's ED on 01/19/2012. 3. Medical record review of Patient #12 revealed a 26 year-old who presented to the hospital's ED on 01/18/2012 at 0640 via EMS with altered mental status, chronic renal failure and a history of cryptococcal meningitis. Review of the ED record revealed documentation by RN #3 at	A 749		

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A 749	Continued From page 21 0648, "...Isolation Recommended: Unobtainable due to condition...." Record review revealed Patient #12 was admitted to an inpatient unit on 01/19/2012 at 0044. Review of the SBARR ED Admission Report for Patient #12 revealed, "...Pt. Status & Alerts: Isolation: *Standard Precautions...." Review of the electronic medical record for Patient #14 revealed a red exclamation mark (!) in the left upper corner of the screen. Review of the "Alert Description" that opened after clicking on the exclamation mark (!) revealed, "....VRE Present: Blood on 04/13/2011. Place on Contact Precautions with each visit...." Further record review revealed Contact Isolation was ordered by a nurse on 01/19/2012 at 0140 (19 hours after presentation to the hospital). RN #3 was not available for interview. Interview on 01/24/2012 at 1510 with the ED's clinical educator confirmed there is no documentation that a blue arm band was placed on Patient #12 at registration and no documentation that Patient #12 was placed on contact precautions in the ED. Interview revealed Patient #12 should have been placed on contact precautions due to history of VRE. Interview on 01/25/2012 at 1000 with RN #7 revealed the nurse admitted Patient #12 to the inpatient floor on 01/19/2012 and ordered contact precautions for the patient. Interview further revealed, "Contact precautions should have been initiated in the ED." 4. Medical record review of Patient #20 revealed a 25 year-old who presented to the hospital's ED on 01/20/2012 at 2049 via EMS with paraplegia,	A 749		

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A 749	Continued From page 22 anoxic brain injury, back pain and a history of a sacral decubitus ulcer. Review of the ED record revealed documentation by RN #4 at 0648, "...Isolation Recommended: No...." Record review revealed Patient #20 was admitted to an inpatient unit on 01/21/2012 at 2152. Review of the SBARR ED Admission Report for Patient #12 revealed, "...Pt. Status & Alerts: Isolation: *Standard Precautions...." Review of the electronic medical record for Patient #20 revealed a red exclamation mark (!) in the left upper corner of the screen. Review of the "Alert Description" that opened after clicking on the exclamation mark (!) revealed, "....MRSA Present: Buttocks on 08/04/2011. Place on Contact Precautions with each visit...." Further record review revealed Contact Isolation was ordered by a nurse on 01/21/2012 at 2236 (25 hours after presentation to the hospital). RN #4 was not available for interview. Interview on 01/25/2012 at 1330 with administrative nursing staff confirmed there is no documentation that a blue arm band was placed on Patient #20 at registration and no documentation that Patient #20 was placed on contact precautions in the ED. Interview confirmed Patient #20 should have been placed on contact precautions due to history of MRSA. FORM CMS-2567(02-99) Previous Versions Obsolete Event ID:TZMF11 Facility ID: 943057 If continuation sheet	A 749		

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A 749	Continued From page 23 5. Medical record review on 01/25/2012 for Patient #9 revealed a 26 year-old female that presented to the hospital's ED on 01/18/2012 at 1526 with diabetes and sickle cell crisis. Review of the ED record revealed nursing documentation at 1613, "...Isolation Recommended: No...." Record review revealed the patient was admitted to an inpatient unit (6-South) on 01/19/2012 at 1804. Review of the SBARR ED Admission Report (nursing report from the ED nurse to the inpatient unit nurse) for the patient revealed, "...Pt. Status & Alerts: Isolation: *Standard Precautions...." Review of the electronic medical record for the patient revealed a red exclamation mark (!) in the left upper corner of the screen. Review of the "Alert Description" that opened after clicking on the exclamation mark (!) revealed, "....VRE Present: rectal on 09/15/2011. Place on Contact Precautions with each visit. After 09/15/2012 the patient can be cleared...." Further record review revealed Contact Isolation was ordered by a nurse on 01/20/2012 at 0111 (33 hours after presentation to the hospital). Interview with the Medical Service Line Director revealed the process for initiating Contact Isolation precautions was for the nursing staff to order Contact Isolation in the computer to request the necessary supplies. Interview revealed the time of the order was the time isolation was initiated. Interview confirmed the first available documentation the patient was placed on Contact Isolation precautions was on 01/20/2012 at 0111 (33 hours after presentation to the hospital). Interview revealed, "(The patient) should have been placed on isolation within a couple of hours of being in the hospital."	A 749		

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A 749	Continued From page 24 6. Medical record review on 01/25/2012 for Patient #10 revealed a 79 year-old female that presented to the hospital's ED on 01/17/2012 at 0812 from a skilled nursing facility with sepsis, urinary tract infection, bilateral lower extremity cellulitis, and renal failure. Review of the ED record revealed nursing documentation at 0830, "...Isolation Recommended: No...." Record review revealed the patient was admitted to the Intensive Care Unit (ICU) on 01/18/2012 at 1312. Review of the SBARR ED Admission Report (nursing report from the ED nurse to the ICU nurse) for the patient revealed, "...Pt. Status & Alerts: Isolation: *Standard Precautions...." Review of the electronic medical record for the patient revealed a red exclamation mark (!) in the left upper corner of the screen. Review of the "Alert Description" that opened after clicking on the exclamation mark (!) revealed, "...VRE Present: RECTAL on 06/02/2008. Place on Contact Precautions with each visit. After 06/02/2009 the patient can be cleared...." Record review revealed Contact Isolation was ordered by an ICU nurse on 01/18/2012 at 1435 (30 hours after presentation to the hospital). Further record review revealed a VRE culture (first one during the admission) was obtained on 01/19/2012 (negative results). Record review revealed the patient was scheduled for a second VRE culture on 01/26/2012. Interview with the Medical Service Line Director revealed the process for initiating Contact Isolation precautions was for the nursing staff to order Contact Isolation in the computer to request the necessary supplies. Interview revealed the time of the order was the time isolation was initiated. Interview confirmed the first available	A 749		

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A 749	Continued From page 25 documentation the patient was placed on Contact Isolation precautions was on 01/18/2012 at 1435 (30 hours after presentation to the hospital). Interview revealed the patient needed to remain on Contact Isolation precautions until 3 successive negative VRE cultures were obtained. 7. Medical record review on 01/25/2012 for Patient # 21 revealed a 53 year old female who presented to the ED (Emergency Department) on 01/23/2012 at 1735, from her physician's office, for direct admission. Patient #21 presented with Dehydration and vomiting and had with her physician's orders from the office. One of the orders was for a "stool for C.difficile" (Clostridium Difficile). Record review revealed nursing staff acknowledged and signed the order on 01/24/2012 at 0014. Review of ED nursing notes dated 01/23/2012 at 1759 revealed, "...Isolation Recommended : No....". Further review of the ED record shows Patient #21 was either in the waiting room or being reassessed in Triage from 1739 to 2146, at which time she was placed in the "Gateway" section awaiting admission to the floor. Record review shows Patient #21 was discharged from the ED Gateway section to the inpatient unit (2-North) on 01/24/2012 at 0100. Record review revealed the first documentation the patient was placed on Special Enteric Isolation precautions on 01/24/2012 at 1155 (18 hours after she presented to the ED with orders for C. difficile testing). Interview on 01/25/2012 at 1530 with Patient #21 revealed she had been in the ED around 4 hours, part of that time in the "Gateway" section of the	A 749		

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A 749	Continued From page 26 ED, and was never placed on any isolation precautions there. Interview on 01/26/2012 at 1005 with the Interim ED Director confirmed the patient was not placed on isolation precautions while in the ED (18 hours). Interview on 01/25/2012 at 1540 with the Nursing administration staff on 2-North revealed whenPatient #21 arrived on the floor on 01/24/2012 at 0100 the patient had not been placed on Isolation precautions. Interview confirmed the first available documentation the patient was placed on Isolation precautions was on 01/24/2012 at 1155, (18 hours after she presented to the ED with orders for C. difficile testing). NC00077782 NC00077788 NC00077877 NC00077965	A 749		

HHA 2012 Tier

2/7/12

	A	B	C	D	E	F	G
1	CCN	NAME	ADDRESS	CITY	ZIP	PHONE	LAST SURVEY
2	347002	WELL CARE HOME HEALTH	2715 ASHTON DRIVE, SUITE 201	WILMINGTON	28412	9103629405	06/18/2009
3	347007	HOME HEALTH OF RANDOLPH HOSPITAL	127 MACARTHUR STREET	ASHEBORO	27203	3366298896	01/15/2009
4	347017	ALBEMARLE HOME CARE	311 CEDAR ST.	ELIZABETH CITY	27909	2523384066	11/16/2006
5	347021	BAYADA NURSES INC A + MJ	280 CONCORD PARKWAY STE 110B	CONCORD	28027	7049201150	04/30/2009
6	347024	LIBERTY HOME CARE	300 W PENNSYVANIA AVENUE28387	SOUTHERN PINES	28387	9108153122	02/26/2009
7	347031	GENTIVA HEALTH SERVICES A + E	1970 WEST ARLINGTON BLVD B2	GREENVILLE	27858	2523533300	05/27/2009
8	347035	MED WEST HAYWOOD HOME CARE	560 LEROY GEORGE DR	CLYDE	28721	8284528292	09/02/2009
9	347042	CARTERET HOME HEALTH SERVICES	302 MEDICAL PARK COURT	MOREHEAD CITY	28557	2528086081	11/14/2008
10	347049	HERTFORD-GATES HOME HEALTH AGENCY	704 EVANS STREET	AHOSKIE	27910	2523326747	01/26/2009
11	347065	NHRMC HOME CARE	7864 US HIGHWAY 117 S SUITE C	ROCKY POINT	28457	9102591224	06/25/2009
12	347075	GENTIVA HEALTH SERVICES	1002 N CHURCH STREET	GREENSBORO	27402	3363797413	04/16/2009
13	347089	HARNETT COUNTY HOME HEALTH AGE	307 CORNELIUS HARNETT BLVD.	LILLINGTON	27546	9108937544	06/10/2009
14	347102	ALEXANDER COUNTY HOME HEALTH A	338 1ST AVENUE SW	TAYLORSVILLE	28681	8286329704	07/09/2008
15	347105	JOHNSTON MEMORIAL HOME CARE & HOSPICE	514 NORTH BRIGHTLEAF BLVD, SUITE 1502	SMITHFIELD	27577	9199387580	06/26/2009
16	347113	HOME CARE OF THE CAROLINAS	907 NORTH SECOND STREET	ALBEMARLE	28001	7049822273	05/07/2009
17	347124	GENTIVA HEALTH SERVICES	2111-C NORTH QUEEN STREET	KINSTON	28501	2525221458	11/18/2008
18	347127	CAPE FEAR VALLEY HOMECARE AND HOSPICE	1830 OWEN DRIVE, SUITES 201 & 202	FAYETTEVILLE	28304	9106096740	08/27/2009
19	347136	DUKE HOME HEALTH	4321 MEDICAL PARK DR SUITE 101	DURHAM	27704	9196203853	03/12/2009
20	347170	GENTIVA HEALTH SERVICES/SALISB	297 EAST 22ND STREET	KANNAPOLIS	28083	7049331001	05/13/2009
21	347171	GENTIVA HEALTH SERVICES	CYPRESS BAY PLAZA 5167 US HWY 70 WEST	MOREHEAD CITY	28557	2527269300	03/05/2009
22	347172	LIBERTY HOME CARE	1401 BOGGS DRIVE	MOUNT AIRY	27030	3367197434	09/16/2009
23	347176	REX HOME SERVICES	2709 BLUE RIDGE ROAD SUITE 220	RALEIGH	27607	9197844548	04/23/2009
24	347179	WAKEMED HOME HEALTH	2920 HIGHWOODS BLVD SUITE 200	RALEIGH	27604	9193500100	04/30/2009
25	347185	PIEDMONT HOME CARE	100 EAST 9TH AVENUE	LEXINGTON	27292	3362488212	09/17/2009
26	347196	TOTAL CARE HOME HEALTH	9009-C PERIMETER WOODS DRIVE	CHARLOTTE	28216	7045982716	09/03/2009
27	347210	UNION REGIONAL HOME CARE	101 EAST FRANKLIN STREET	MONROE	28111	7042833381	06/18/2009
28	347217	GENTIVA HEALTH SERVICES	74 WHEATON AVENUE	YOUNGSVILLE	27596	9195542279	05/21/2009
29	347218	UNIVERSITY HEALTH SYSTEMS HOME HEALTH AND HOSPICE	304 GRANVILLE ST.	WINDSOR	27983	2527942622	04/16/2009
30	347222	MARIA PARHAM HOSPITAL	566 RUIN CREEK RD	HENDERSON	27536	2524313708	05/07/2009
31	347226	GENTIVA HEALTH SERVICES	206 S TURNER STREET	PINK HILL	28572	2525686022	05/14/2009
32	347231	HEALTHKEEPERZ	2601 NORTH ELM STREET, SUITE B	LUMBERTON	28358	9105220010	02/25/2009
33	347236	GENTIVA HEALTH SERVICES	249 EAST NC HWY 54 STE 310	DURHAM	27713	9193611921	12/18/2008
34	347238	HOME CARE OF THE CAROLINAS	707 ALBEMARLE ROAD SUITE 2	TROY	27371	9105723800	09/03/2009
35	347239	LIBERTY HOME CARE, LLC A + MJ	3200 SPRING FOREST ROAD SUITE 201	RALEIGH	27616	9108153122	03/19/2009
36	347307	LIBERTY HOME CARE II, LLC	921 E CASWELL STREET	WADESBORO	28170	9108153122	02/05/2009
37	347308	LIBERTY HOME CARE	103 S FLORENCE STREET	MAXTON	28364	9108153122	04/09/2009
38	347319	ALBEMARLE HOME CARE	103 ARPDC STREET	HERTFORD	27944	2523384066	11/30/2007
39	347320	ALBEMARLE HOME HEALTH	2793 CARATOKE HWY, CURRITUCK GOV COMPLEX	CURRITUCK	27929	2523384066	01/26/2007
40	347321	ALBEMARLE HOME CARE	160 US 158 E BUILDING B	CAMDEN	27921	2523384066	03/20/2008
41	347322	ALBEMARLE HOME CARE EDENTON	100 W FREEMASON CIRCLE	EDENTON	27932	2523384066	04/11/2008
42	347326	HOME HEALTH PROFESSIONALS	2550 COURT DRIVE, SUITE 103	GASTONIA	28054	7048641131	08/26/2009
43	347334	LIBERTY HOME CARE, LLC	3414 N DUKE STREET, SUITE 201	DURHAM	27705	9108153122	06/04/2009
44	347335	LIBERTY HOME CARE	1306 W WENDOVER AVENUE SUITE 100	GREENSBORO	27408	9108153122	01/28/2009

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, CMS, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project(0838-0583), Washington, D.C. 20503.

Provider/Supplier Number	Provider/Supplier Name
340028	CAPE FEAR VALLEY MEDICAL CENTER

Type of Survey (select all that apply)

[A] [ ] [ ] [ ] [ ]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

[A] [ ] [ ] [ ] [ ]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID								
1. 22563	01/24/2012	01/26/2012	1.00	0.00	12.50	0.00	5.00	8.00
2. 14819	01/24/2012	01/26/2012	0.50	0.00	12.50	0.00	5.00	5.00
3. 22798	01/24/2012	01/26/2012	0.50	0.00	12.50	0.00	3.00	8.00
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 1.00

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

DEPARTMENT OF HEALTH AND HUMAN SERVICES — CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

ID: PJWF11

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

Facility ID: 943057

1. MEDICARE/MEDICAID PROVIDER NO.
(L1) 340028
2. STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CAPE FEAR VALLEY MEDICAL CENTER
(L4) 1638 OWEN DRIVE P O BOX 2000
(L5) FAYETTEVILLE, NC (L6) 28302

4. TYPE OF ACTION: 6 (L8)
1. Initial 2. Recertification
3. Termination 4. CHOW
5. Validation 6. Complaint
7. On-Site Visit 9. Other
8. Full Survey After Complaint

5. EFFECTIVE DATE CHANGE OF OWNERSHIP
(L9)

6. DATE OF SURVEY 01/06/2012 (L34)

8. ACCREDITATION STATUS: 1 (L10)
0 NOT ACCREDITED 1 JC 3 DNV

7. PROVIDER/SUPPLIER CATEGORY 01 (L7)

01 Hospital	05 HHA	09 ESRD	13 FTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	15 ASC
04 SNF	08 OPT/SP	12 RHC	16 HOSPICE

FISCAL YEAR ENDING DATE: (L35)
09/30

11. LTC PERIOD OF CERTIFICATION
From (a):
To (b):

12. Total Facility Beds 597 (L18)

13. Total Certified Beds 597 (L17)

10. THE FACILITY IS CERTIFIED AS:
A. In Compliance With Program Requirements Compliance Based On:
___1. Acceptable POC

And/Or Approved Waivers Of The Following Requirements:
___2. Technical Personnel
___3. 24 Hour RN
___4. 7-Day RN (Rural SNF)
___5. Life Safety Code
___6. Scope of Services Limit
___7. Medical Director
___8. Patient Room Size
___9. Beds/Room

X B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: B* (L12)

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
	597			
(L37)	(L38)	(L39)	(L42)	(L43)

15. FACILITY MEETS
1861 (e) (1) or 1861 (j) (1): (L15)

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):
An unannounced, onsite complaint investigation was conducted January 04-06, 2012. Two of the four allegations were substantiated with one deficiency related to 482.23 Nursing Services. NC00077584

17. SURVEYOR SIGNATURE Date: 01/16/2012 (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 01/16/2012 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY
___ 1. Facility is Eligible to Participate
___ 2. Facility is not Eligible
(L21)

20. COMPLIANCE WITH CIVIL RIGHTS ACT:

21. 1. Statement of Financial Solvency (HCFA-2572)
2. Ownership/Control Interest Disclosure Stmt (HCFA-1513)
3. Both of the Above:

22. ORIGINAL DATE OF PARTICIPATION (L24)

23. LTC AGREEMENT BEGINNING DATE (L41)

24. LTC AGREEMENT ENDING DATE (L25)

25. LTC EXTENSION DATE: (L27)

27. ALTERNATIVE SANCTIONS
A. Suspension of Admissions: (L44)
B. Rescind Suspension Date: (L45)

26. TERMINATION ACTION: (L30)
VOLUNTARY 00
01-Merger, Closure
02-Dissatisfaction W/ Reimbursement
03-Risk of Involuntary Termination
04-Other Reason for Withdrawal
INVOLUNTARY
05-Fail to Meet Health/Safety
06-Fail to Meet Agreement
OTHER
07-Provider Status Change
00-Active

28. TERMINATION DATE: (L28)

29. INTERMEDIARY/CARRIER NO.
00000 (L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

EXHIBIT
tabbies
K

FORM CMS-1539 (7-84) (Destroy Prior Editions)

020499

Department of Health and Human Services
Medicare/Medicaid/CLIA Complaint Form

Control Number: PJWF11 (NC00077584)

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number
3 4 0 0 2 8

Facility Name and Address
CAPE FEAR VALLEY MEDICAL CENTER
1638 OWEN DRIVE P O BOX 2000
FAYETTEVILLE, NC 28302

3. Date Complaint Received
1 2 2 9 1 1
MM DD YY

4. Receiving Component
1 State Survey Agy.
[1] 2 RO

5. Date Acknowledged
0 1 0 3 1 2
MM DD YY

6A. Source of Complaint
1 [3]
2 [ ]
3 [ ]
1 Resident/Patient Family
2 Ombudsman
3 Facility Employee/Ex-Employ
4 Anonymous
5 Other

6B. Total Number of Complainants
0 1

7. Allegations

	7.A. Category	7.B. Findings (To be completed following investigation)	7.C. Number of Complainants per Allegation
1	1 2	0 1	0 1
2	0 6	0 1	0 1
3			
4			
5			

7.A. Category:
1 Resident Abuse; 2 Resident Neglect; 3 Resident Rights; 4 Patient Dumping; 5 Environment; 6 Care or Services; 7 Dietary; 8 Misuse of Funds/ Property; 9 Certification/Un-authorized Testing; 10 Proficiency Test; 11 Falsification of Records / Reports; 12 Unqualified Personnel; 13 Quality Control; 14 Specimen Handling; 15 Diagnostic Erroneous Test Results; 16 Fraud/False Billing; 17 Fatality/Transfusion Fatality; 18 Other (Specify) _____; 19 Life Safety Code; 20 State Monitoring

7.B. Findings (To be completed following investigation):
01 Substantiated
02 Unsubstantiated/ Unable to Verify

8. Action (if multiple actions, indicate earliest action)
[1]
1 Investigate within 2 working days
2 Investigate within 10 working days
3 Investigate within 45 working days
4 Investigate during next onsite
5 Referral (Specify) _____
6 Other Action (Specify) _____
7 None

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by
[1] 1 State Survey Agency
2 RO
3 Other (Specify) _____

10. Complaint Survey Date
0 1 0 6 1 2
MM DD YY

11. Findings (Under 7B Above)

12. Proposed Actions Taken by SA or RO
1: 0 4
2:
3:

1 Recommend Termination (23-day)
2 Recommend Termination (90-day)
3 Recommend Intermediate Sanction
4 POC (No Sanction)
5 Fine
6 Denial of Payment for New Admissions
7 License Revocation
8 Receivership
9 Provisional License
10 Special Monitor
11 Directed POC
12 Limitation of Certificate
13 Suspension of Certificate
14 Revocation of Certificate
15 Injunction
16 Civil Monetary Penalty
17 TA & Training for Unsuccessful PT
18 State Onsite Monitoring
19 Suspension of Part of Medicare Payments
20 Suspension of All Medicare Payments
21 None
22 Other (Specify) _____
23 Enforcement Action

13. Date of Proposed Action
0 1 0 6 1 2
M MD D Y Y

14. Parties Notified and Dates

Party	Date
1. [1]	0 1 2 0 1 2
2. [2]	0 1 2 3 1 2
3. [ ]	

1 Facility
2 Complainant
3 Representative
4 Other (Specify) _____

M M D D Y Y

15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567)
M MD DY Y

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt
MM D D Y Y

17. CMS RO/MSA Action
[ ]
1 None
2 Termination (23-day)
3 Termination (90-day)
4 Intermediate Sanction
5 Move Routine Survey Date Forward
6 Limitation of Certificate
7 Suspension of Certification
8 Revocation of Certificate
9 Injunction
10 Civil Monetary Penalty
11 TA & Training For Unsuccessful PT
12 Cancellation of Medicare Approval
13 Other (Specify) _____
14 Enforcement Action

18. Date of Final Action Sign-off
MM D D Y Y

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 01/06/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAT	PROVIDER PLAN OF CORRECTION (EACH CORRCTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 398	482.23(b)(6) SUPERVISON OF CONTRACT STAFF Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services. This STANDARD is not met as evidenced by: Based on the hospital's policy review, "Nursing Unit Shift Assessment Sheet" review, non-employed licensed nursing personnel files, and staff interview, the hospital failed to ensure that non-employed licensed nursing staff received a documented unit-specific orientation evaluation before assigned an independent patient care assignment in 1 of 6 sampled non-employed licensed nurses (Agency Nurse #2). Findings include: A review of the hospital's policy "Nursing Agency Personnel" (reviewed 08/17/2010) revealed "D. Orientation to the unit is to be provided prior to independent assignment of patient care. 1. Eight (8) to 24 hours on general units and 12-24 hours on special units is generally sufficient. E. Unit-specific skills and competencies are documented and placed in agency nurse file located in the office of ____ (hospital) Agency Coordinator." A review on 01/05/2012 of the non-employed licensed nursing personnel file for Agency Nurse #2 revealed that the nurse was contracted to work at the hospital on 12/19/2011. The review	A 398	**Corrective action(s) and the systems that have been or will be implemented to correct the deficiency:** The Nursing Agency Personnel policy will be revised to assure that agency nurses work alongside an assigned preceptor until both the preceptor and agency nurse agree (s)he is ready for a full patient care assignment. (We expect the agency nurse and the preceptor to agree on this competency by the conclusion of the second supervised shift.) **Education:** All managers and staff members responsible for nurse assignments will be educated as to this change in process. This education will be reinforced by nursing managers (service line leaders) as they round on each unit on all shifts. **Monitoring:** The agency staffing office will validate compliance with this policy by reviewing each agency nurse's competency document at the beginning of their tenure with the organization. The orientation/competency document has been modified to capture an attestation by the agency nurse and the preceptor that the new nurse is competent and comfortable with a normal patient care assignment (without a preceptor). **Responsibility:** Vice President of Nursing Services	2/21/ 2012

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE — (X6) DATE

Michael Mayock

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 01/06/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CAPE FEAR VALLEY MEDICAL CENTER	1638 OWEN DRIVE P O BOX 2000 FAYETTEVILLE, NC 28302

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAT	PROVIDER PLAN OF CORRECTION (EACH CORRCTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 398	Continued From page 1 revealed that the nurse left the hospital without written notice on 12/26/2011. The review of the nurses file revealed that she was assigned unit specific orientation on the hospital's 3 South Medical-Surgical/Telemetry Unit on 12/22/2011 and 12/23/2011 for a total of 24 hours. A review on 01/5/2012 of the hospital's "Nursing Unit Shift Assessment Sheet" dated 12/23/2011 revealed that the Agency Nurse #2 was independently assigned to a total of six (6) patient's without any other orienting nurse assigned to the same patients. The review revealed that the unit's charge nurse was originally assigned to be the orientation preceptor for Agency Nurse #2. The review further revealed that a shortage of nursing staff on the unit for 12/23/2011 changed the charge nurse's assignment to include taking a total of six (6) patients of her own. No documentation was found in the assignment sheet where Agency Nurse #2 received orientation on 12/23/2011 and did not take an independent patient assignment. A telephone interview on 01/5/2012 at 1030 with Agency Nurse #2 revealed that she felt unsafe and overwhelmed on 12/23/2011 due to her orientation being cut short. The interview further revealed that she was told that she would receive a total of two days of orientation to the unit she was working and felt that she was let down due to the overall shortage of staff. An interview on 01/05/2012 at 1940 with the unit charge nurse assigned to orient Agency Nurse #2 on 12/23/2011 revealed "We had a very busy night and some call outs that made our unit short. I was going to not have any patients so I could			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	340028	A. BUILDING _____ B. WING _____	C 01/06/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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A 398	Continued From page 2 orient the nurse (Agency Nurse #2), but I had to take a full assignment and we all took care of our own patients." An interview on 01/04/2012 at 1410 with Agency Nurse #1 revealed that the hospital provides a total of 2 days on the units. The interview revealed that she received her orientation and had no other concerns with her orientation. An interview on 01/04/2012 at 1430 with Agency Nurse #3 revealed that the hospital provides a total of 2days on the units. The interview revealed that she worked in the hospital's emergency department and completed both days of her orientation in the emergency department. The interview revealed that she received her orientation and had no other concerns with her orientation. An interview on 01/04/2012 at 1510 with the hospital's Agency Coordinator revealed that the agency nursing staff should receive a total of 2 days on the unit that they work. The interview did reveal the hospital's Agency Coordinator did not know if any of the Agency Nurses actually received their individual unit orientation. "I only have a copy of their actual time. I can not tell by the time if they actually are assigned with staff for orientation. Reference NC00077584.			

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Provider/Supplier Number	Provider/Supplier Name
340028	CAPE FEAR VALLEY MEDICAL CENTER

Type of Survey (select all that apply) [A]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply) [D]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
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SURVEY TEAM AND WORKLOAD DATA

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Team Leader ID								
1. 25021	01/04/2012	01/06/2012	1.00	0.00	2.00	2.00	3.00	1.00
2. 14819	01/05/2012	01/06/2012	0.50	0.00	6.50	2.00	3.00	0.50
3. 15546	01/04/2012	01/06/2012	1.00	0.00	20.00	2.00	6.00	5.50
4. 16369	01/04/2012	01/06/2012	1.00	0.00	2.00	2.00	3.00	1.00
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 1.00

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

In 2001, CFVHS began an extensive strategic planning endeavor that involved physicians, board members, and administrative staff. Work sessions included review and revision of the CFVHS mission and vision statements, statistics, financial data, and market comparison. Strategic initiatives are a result of analyzing the data and setting goals. Twelve task forces were formed, with each assigned one initiative. One of the initiatives was focused on assessment of current CFVHS facilities and planning for the future. As a result, the Master Facilities Steering Committee was developed (2002) which resulted in the development of the CFVMC Health Pavilion North and the Valley Pavilion at CFVMC. Physicians, board members, and administrative staff at CFVHS have continued strategic planning efforts as a result of the incredible increase in utilization of existing facilities and resources in Cumberland County.

The proposed new hospital will include the 65 acute care beds identified as needed in the *2011 State Medical Facilities Plan* for Cumberland County and two operating rooms which will be relocated from Highsmith-Rainey Specialty Hospital ("HRSH").

The proposed location in Cumberland County will expand access to the residents of northern Cumberland County while decompressing congestion on the CFVMC campus in Fayetteville. CFVMC has determined that the proposed project provides the most effective alternative for the development of acute care hospital services.

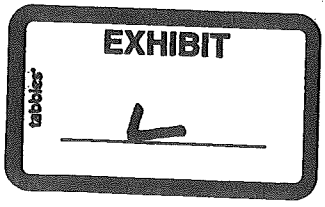
CFV North will be licensed as part of CFVMC. At completion of this project, there will be four licensed acute care hospitals with five campuses under the CFVHS umbrella as reflected in the following table.

Cape Fear Valley Health System
Proposed Acute Care Bed Capacity

Hospital	Proposed Acute Care Bed Capacity
Cape Fear Valley Medical Center	490
Cape Fear Valley Medical Center – CFV North Hospital	65
Hoke Community Medical Center	41
Bladen County Hospital	48
Highsmith-Rainey Specialty Hospital (LTACH)	66
Total System Acute Care Beds including LTACH	710

Source: LRAs; HCMC CON Application

The proposed CFV North Service Area includes parts of zip codes in Cumberland County, southwest and southern Harnett County, and northwest Sampson County, as shown on the following service area map. Additional detailed maps of Cumberland County and the service area are included in Exhibit 34.



The need determination for 65 acute care beds in the Cumberland Service Area in the *2011 SMFP* results from the application of the aforementioned substantive changes to the Acute Care Bed Need Determination Methodology.

Utilization of Inpatient and Outpatient Hospital Services at CFVMC

Development of the proposed 65 new acute care beds at CFV North, in addition to meeting the primary and secondary acute care needs of the defined service area, will allow the shift of patient day volume out of the existing beds at CFVMC relieving the high utilization at CFVMC and relieving congestion on the CFVMC campus.

The following table shows the historical utilization of acute care beds at the one existing acute care hospital in the defined service area as reported on the Cape Fear Valley Medical Center Annual License Renewal Application.

Cape Fear Valley Medical Center
Historical Acute Care Bed Utilization
October 2004 – September 2010

	FFY 2005	FFY 2006	FFY 2007	FFY 2008	FFY 2009	FFY 2010	CAGR 2005 - 2010
Inpatient Days	132,678	134,128	136,755	145,017	149,828	155,926	3.3%
% Change		1.1%	2.0%	6.0%	3.3%	4.1%	
Inpatient Admissions	25,734	26,745	27,128	28,846	29,108	29,189	2.6%
% Change		3.9%	1.4%	6.3%	0.9%	0.3%	
ADC	363.5	367.5	374.7	396.2	410.5	427.2	
Operational Acute Care Beds	407	394	397	490	490	490	
Occupancy Rate	89.3%	93.3%	94.4%	80.9%	83.8%	87.1%	
CON Approved Acute Care Beds	407	394	531	531	531	531	
Occupancy Rate	89.3%	93.3%	70.6%	74.6%	77.3%	80.5%	

Source: LRAs; CON Applications; CFVMC Internal Data

The previous table shows steady growth in acute care inpatient days, inpatient admissions, and ADC as CFVMC's inventory of acute care beds has grown over the last six federal fiscal years and utilization of operational beds has exceeded 80% during the entire timeframe. CFVMC also has CON approval for 41 additional beds which are to be developed at Hoke Community Medical Center in Hoke County. Even including these 41 beds in the acute care bed capacity, utilization of total licensed and approved acute care beds exceeded 80% in FFY 2010. The following graph illustrates the significant increase in patient days at CFVMC over

- **Current medical/surgical services at CFVMC are at capacity.**
- **Physician support for the project is overwhelming.**
- **Community support for the project is overwhelming (please see Exhibits 27 to 29).**
- **Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.**
- **CFVMC's emergency room is experiencing record volumes and is at capacity.**
- **CFV North offers a choice for inpatient and outpatient care closer to home.**
- **The proposed location of CFV North on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.**
- **Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to CFV North.**

Baseline CY 2010 patient days are reflected in the following table.

CFV North
Baseline Acuity Adjusted Patient Days from Zip Code Service Area
January 2010 – December 2010

Zip	County	Estimated CY 2010 Patient Days Closer to CFV-North	70% Percent of CY 2010 Patient Days Shifted to CFV-North	Baseline CY 2010 Patient Days Shifted to CFV-North
Primary Service Area				
28301	Cumberland	6,136		
28303	Cumberland	372		
28311	Cumberland	7,334		
28312	Cumberland	2,046		
28344	Cumberland/Sampson	166		
28356	Cumberland	738		
28390	Cumberland/Harnett	3,085		
28395	Cumberland	695		
Secondary Service Area				
28323	Harnett	130		
28326	Harnett	290		
TOTAL PSA and SSA		**20,992**	**70%**	**14,694**

Source: CFVHS DSS Data System; Exhibit 33, Table 7

As shown in the previous table, CFV North utilized 14,694 acuity adjusted patient days as a baseline for projecting future inpatient utilization for the new community hospital located in northern Cumberland County.

markets in north Cumberland County and southwest and southern Harnett County which are growing as a result of expansion at Fort Bragg and the BRAC.

Upon completion, CFV North will meet the acute care needs of the defined service area. The table below shows the projected patient days and occupancy rates for CFV North in the first three years of operation. Note that CFV North's projected occupancy rate will be greater than the target occupancy rate required by Policy AC-5 – Replacement of Acute Care Capacity in the *2009 State Medical Facilities Plan*, and target utilization rates in the Acute Care Bed Need Methodology and CON Criteria and Standard for New Acute Care Beds. As the defined service area continues to evolve and grow, all future acute health care needs can be met by the development and expansion of CFV North.

CFV North
Average Daily Census, Licensed Beds, and Occupancy
October 2014 through September 2017

	PY 1 Oct 2014 - Sep 2015	PY 2 Oct 2015 - Sep 2016	PY 3 Oct 2016 - Sep 2017
Inpatient Discharges	2,709	3,088	3,655
Days (including ICU)	12,591	14,353	16,986
ALOS	4.65	4.65	4.65
ADC	34.5	39.3	46.5
Proposed Acute Care Bed Capacity	65	65	65
Occupancy	53.1%	60.5%	71.6%

Source: Exhibit 33, Table 1

Projected utilization for CFV North is based upon a shift of volume from CFVMC to CFV North. Historical utilization at CFV North and the population of the defined service area supports the development of the proposed project as reflected in the methodology utilized here. It should be noted however, that CFVMC believes these are conservative estimates. As discussed in this Application, the economic downturn in the last several years has impacted some areas of growth, in particular, elective services, such as outpatient surgery, and preventive services. CFVHS fully anticipates that additional growth will occur, both in the CFV North Service Area and at CFVMC with economic recovery. However, no projections have been included which depend on an improved economy. In additional, as previously discussed, CFV North believes the proposed new community hospital will result in some market opportunities including the opportunity to recapture lost market share in northern Cumberland County and potential growth due to the increasing population in southwest and southern Harnett County.

The development of the 65 new acute care beds and relocation of two operating rooms at CFV North will result in increased access to high quality patient care services from CFVHS inpatient facilities and physicians that the community has depended on for years. The proposed project responds to one of the central purposes of the CON Law: to encourage

HOKE COMMUNITY MEDICAL CENTER

Since 2004, CFVMC has received CON approval to develop 137 additional acute care beds to meet this increasing demand. The following table illustrates the timeframe for approval of these changes in bed capacity, the most recent of which was in 2007.

Cape Fear Valley Medical Center – Changes in Acute Care Bed Capacity

Year	Licensed and Approved Acute Care Bed Capacity	Change in Acute Care Bed Capacity	Explanation	CON Project I.D.
2003	394			
2004	440	46	Transfer 46 beds from HRSH	M-7069-04
2005	484	44	44 new acute care beds from SMFP	M-7093-04 and cost overrun M-7436-05
2006	509	25	25 new acute beds from SMFP	M-7616-06
2007	531	22	22 new acute beds from SMFP	M-7926-07
2008	531			
2009	531	0	41 shifted from CFVMC to CFV West	M-8353-09
Total New Acute Care Beds at CFVMC		137		

Source: Hospital records.

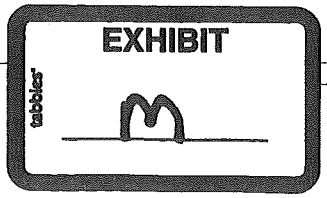
Of the 137 additional acute care beds CON approved for CFVHS reflected in the previous table, 96 have been developed and currently are operational. The remaining 41 acute care beds are the subject of this application.

The following table illustrates the location of the 44 beds as originally planned.

LOCATION	ORIGINAL	REMAINING 41 BEDS
2 East (Observation)	15	15
3 North (Observation)	9	9
3 Floor Nephrology	1	1
CSICU	3	--
4 North (Currently offices)	16	16
	44	41

Source: Hospital records CON Project I.D. # M-7436-05

As shown in the previous table, only 3 beds have been implemented in the CSICU at this time. Further analysis has shown that to implement the remaining beds as planned will require substantial additional capital expenditure. All of the original locations referenced in the above table are in one of the original bed towers at CFVMC. As a result, the older rooms must be brought to current licensure standards. The financial impact of these requirements was not realized at the time of the filing of the CON application for the 44 beds and



subsequently cannot be developed as originally approved. In order to implement the additional 41 beds, CFVHS considered strategic alternatives for the development of these beds in an effort to address changing market demands and population growth.

The need for the proposed HCMC, a new community hospital, is substantiated by these strategic efforts. The proposed location in Hoke County will expand access to the residents of Hoke County and southwest Cumberland County while decompressing congestion on the Owen Drive campus of CFVHS.

HCMC will be licensed as a separate acute care hospital under the umbrella of CFVHS. As a result, at completion of this project, there will be four licensed acute care hospitals under the CFVHS umbrella as reflected in the following table.

Cape Fear Valley Health System
Acute Care Bed Capacity

Current Licensed and CON Approved Bed Capacity			
	Licensed Beds	CON Approved Beds	Licensed and CON Approved Bed Capacity
Cape Fear Valley Medical Center (includes 41 acute care beds approved for Cape Fear Valley West)	490	41	531
Hoke Community Medical Center	0	0	0
Bladen County Hospital	48	0	48
Highsmith-Rainey Specialty Hospital (LTACH)	66	0	66
Total System Acute Care Beds including LTACH	604	41	645
Proposed Bed Capacity			
	Licensed Beds	CON Approved Beds	Licensed and CON Approved Bed Capacity
Cape Fear Valley Medical Center (no longer includes 41 acute care beds approved for Cape Fear Valley West)	490	0	490
Hoke Community Medical Center	41	0	41
Bladen County Hospital	48	0	48
Highsmith-Rainey Specialty Hospital (LTACH)	66	0	66
Total System Acute Care Beds including LTACH	645	0	645

Surgical services will be provided at all four licensed acute care hospitals under the CFVHS umbrella upon completion of the project as reflected in the following table.

III. NEED/DEMAND

1. (a) Describe, in specific terms, the unmet need that necessitated the inclusion of each of the proposed project components (i.e., beds, services, and medical equipment), as set forth in the description of the scope of services in Section II.1.

Overview

Hoke Healthcare, LLC and its parent company, Cape Fear Valley Health System are proposing to construct and operate a new full-service community hospital, called Hoke Community Medical Center ("HCMC") located on U.S. Highway 401 in Hoke County. The proposed facility will include 41 acute care beds, two operating rooms, and emergency and outpatient services for the community.

In November, 2009 CFVHS received CON approval to develop CFV West, CON Project I.D. M-8353-09, a community hospital located on the border of Hoke and Cumberland Counties with 41 acute care beds. This Application and the CFV West Application both propose to build a community hospital using the 41 acute care beds for which Cape Fear Valley Health System ("CFVHS") currently has a CON. Hoke Healthcare and CFVHS are not proposing the construction of two separate community hospitals. Only one community hospital will be constructed. The 41 acute care beds are not new acute care beds. If this Application is approved, CFV West will not be built and the CON issued for CFV West will be surrendered to the CON Section upon issuance of a CON for HCMC located in Hoke County.

The proposed community hospital in Hoke County provides a better alternative to meeting the needs of the residents of Hoke and southwest Cumberland Counties. This alternative was not available to CFVHS when the CFV West CON Application was submitted in July 2009. If this Application is approved, CFV West, Project I.D. M-8353-09, which was approved in December 2009 and currently is under appeal, will not be constructed. Only one community hospital with 41 acute care beds will be constructed.

The new hospital will include 41 CON-approved acute care beds per Project I.D. # M-7093-04 (and cost overrun Project I.D. # M-7436-05) and two operating rooms (including one existing operating room from Highsmith Rainey Specialty Hospital ("HRSH") plus one CON-approved OR per Project I.D. # M-8004-07).[6] As a result, the acute care beds and operating rooms at HCMC will result in the completion of two previously approved CON Applications.

The proposed location in Hoke County will expand access to the residents of Hoke County and southwest Cumberland County while decompressing congestion on the CFVMC campus in Fayetteville. CFVHS has determined that the proposed project provides a more effective

[6] Project I.D. # M-7615-06 to add one shared operating room at CFVMC was approved in late 2006; in 2007 CFVMC submitted a subsequent CON application Project I.D. M-8004-07 to convert space in cardiac surgery suite to a shared operating room, cardiac surgery no longer needs this additional operating room. The approved CFV West CON Application with two operating rooms will not be constructed if this project is approved.

alternative for the development of these two approved CONs copies of which are included in Exhibit 39.

HCMC will be a separately licensed acute care hospital under the umbrella of CFVHS. As a result, at completion of this project, there will be four licensed acute care hospitals under the CFVHS umbrella as reflected in the following table.

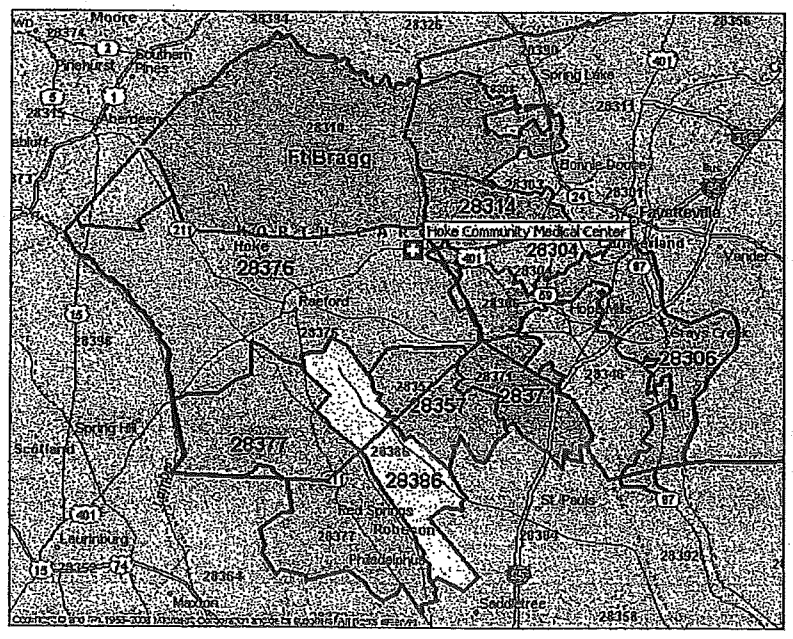
Cape Fear Valley Health System
Proposed Acute Care Bed Capacity

Hospital	Proposed Acute Care Bed Capacity
Cape Fear Valley Medical Center	490
Hoke Community Medical Center	41
Bladen County Hospital	48
Highsmith-Rainey Specialty Hospital (LTACH)	66
Total System Acute Care Beds including LTACH	645

Source: LRAs; HCMC CON Application

The proposed HCMC Service Area includes zip codes in Hoke County, southwest Cumberland County, and northern Robeson County, as shown on the following service area map. Additional maps of Hoke and southwest Cumberland County with additional detail are included in Exhibit 31.

Hoke Community Medical Center
Zip Service Area



HOKE COMMUNITY MEDICAL CENTER

In 1998, CFVHS was invited into Hoke County to begin providing health care services and has since enjoyed a long standing relationship with the community in Hoke County. CFVHS purchased an 8,300 square foot Medical Arts Building in Raeford for Hoke Family Medical Center, a rural health center. This facility is open 6 days per week and provides a wide array of primary care and specialty services. CFVHS has shown its commitment to the residents of Hoke County by continually expanding services provided on-site at Hoke Family Medicine. Current services provided include primary medical care for the entire family, ages birth to death, on-site x-ray, laboratory services, and occupational health. Hoke Family Medical Center also provides weekly specialty clinics for Allergy/Immunology, Cardiology, Hematology, OB/GYN coverage and Nephrology. These physicians have been regularly involved in the planning for HCMC. CFVHS has methodically grown and expanded the provision of health care services in Hoke County to meet the health needs of the community.

To meet the needs of the expanding Hispanic population, many of the providers and staff at Hoke Family Medical Center are bilingual. Much of the patient education materials and health information is translated into Spanish to meet the needs of this practice population. (Please see Exhibit 33).

CFVHS provides after-hours urgent care, radiology services, EKG, pulmonary function, occupational medicine, city employees sick call, all county and city drug testing, Special Olympics participant physicals and a broad array of laboratory services in Hoke County.

Since 2003, CFVHS has anticipated the further development of more comprehensive acute care services in Hoke County in conjunction with the strategic planning process. In 2008, the Cape Fear Valley Board of Trustees approved a strategic plan that included the development of an acute care facility to service residents of Hoke County as the population growth dictated. It is important to note that in FY 2009 CFVHS provided more inpatient days to residents of Hoke County than any other provider and provided more than 77% of all Hoke County OB inpatient cases.

CFVHS's health care commitment to Hoke County has been consistent and has grown in accordance with the community's need. This approach has resulted in the residents of Hoke County aligning themselves with Cumberland County for health care services. CFVHS recognizes the need for a community hospital to serve the residents of Hoke County. The proposed HCMC is the result of this commitment to the residents of Hoke County and the residents of Hoke County's increased utilization and dependence on Cumberland County healthcare providers.

Historical Utilization of Existing Acute Care Health Service Facilities in the Defined Service Area

Cape Fear Valley Medical Center

CFVHS opened 93 new acute care beds starting the end of September 2008 as a result of the new Valley Pavilion at CFVMC. Utilization of the 490 inpatient acute care beds at CFVHS exceeded 83% in FY 2009 and in CY 2009 total acute care inpatient days exceeded

150,000. Utilization of the 490 operational acute care beds was 84.7% in calendar year 2009. Developing the 41 acute care beds at HCMC, in addition to meeting the primary and secondary acute care needs of the defined service area, will allow the shift of patient day volume out of the existing beds at CFVMC thus allowing additional specialty level admissions that currently must leave Cumberland County.

The following table shows the historical utilization of acute care beds at the one existing acute care hospital in the defined service area as reported on the Cape Fear Valley Medical Center annual License Renewal Application.

Cape Fear Valley Medical Center
Historical Acute Care Bed Utilization

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	CAGR 2005-2009
Licensed Acute Care Inpatient Days	132,678	134,128	136,755	145,017	149,828	
Growth		1.1%	2.0%	6.0%	3.3%	3.10%
Licensed Acute Care Inpatient Admissions	25,734	26,475	27,128	28,846	29,108	
Growth		2.9%	2.5%	6.3%	0.9%	3.15%
Average Daily Census (ADC)	363.5	367.5	374.7	396.2	410.5	
Occupancy Rate	89.3%	93.3%	94.4%	80.9%	83.8%	
Licensed and Operational Acute Care Beds	407	394	397	490	490	

Source: SMFP; LRAs; Exhibit 30, Table 72
Note: CFVMC opened 93 additional beds in Sept. 2008.

The previous table shows steady growth in acute care inpatient days, inpatient admissions, and average daily census (ADC) as the number of licensed acute care beds at CFV Medical Center have grown over the last five years. The following graph illustrates the significant increase in patient days at CFVMC over the last five years.

HOKE COMMUNITY MEDICAL CENTER

CFVMC Projected Inpatient Days
FY 2009 – FY 2016

	FFY 2009	FFY 2010	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016
CFVHS Projected Interim and Future less Volume Shifted to HCMC	149,828	152,825	155,881	158,999	162,179	157,959	159,056	160,581
ADC	410.5	418.7	427.1	435.6	444.3	432.8	435.8	439.9
Occupancy Rate	83.8%	85.4%	87.2%	88.9%	90.7%	88.3%	88.9%	89.8%

Source: Exhibit 30, Table 75

The previous table reflects projected utilization of the 490 acute care beds at CFVMC and assumes that the 41 beds at HCMC become operational in October 2013 (FY 2014). The following table combines projected patient days for HCMC and CFVMC to reflect total projected utilization for all 531 licensed and CON approved acute care beds at CFVHS in Cumberland and Hoke Counties.

CFVMC Projected Inpatient Days
FY 2009 – FY 2016

	FFY 2009	FFY 2010	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016
HCMC Projected Patient Days						7,463	9,674	11,524
CFVMC Projected Patient Days	149,828	152,825	155,881	158,999	162,179	157,959	159,056	160,581
Combined HCMC and CFVMC	149,828	152,825	155,881	158,999	162,179	165,422	168,731	172,105
ADC	410.5	418.7	427.1	435.6	444.3	453.2	462.3	471.5
Occupancy Rate	83.8%	85.4%	87.2%	88.9%	90.7%	85.4%	87.1%	88.8%
Licensed Bed Capacity	490	490	490	490	490	531	531	531

Source: Exhibit 30, Tables I, 75

As shown in the previous table, projected utilization for total CFVHS acute care beds is projected to exceed the SMFP planning target of 75.2% for facilities with an average daily census greater than 200 patients per day. The following table shows total beds needed to meet the growing demand for inpatient services at CFVHS acute care facilities, based upon the *SMFP* planning target of 75.2% occupancy.

CFVHS Acute Care Facilities
Projected Acute Care Bed Need
FY 2009 – FY 2016

	FFY 2009	FFY 2010	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016
HCMC Projected Patient Days						7,463	9,674	11,524
CFVMC Projected Patient Days	149,828	152,825	155,881	158,999	162,179	157,959	159,056	160,581
Combined HCMC and CFVMC	149,828	152,825	155,881	158,999	162,179	165,422	168,731	172,105
ADC.	410.5	418.7	427.1	435.6	444.3	453.2	462.3	471.5
Occupancy Rate	83.8%	85.4%	87.2%	88.9%	90.7%	85.4%	87.1%	88.8%
Projected Bed Need @ 75.2%	546	557	568	579	591	603	615	627
Licensed Bed Capacity	490	490	490	490	490	531	531	531
Additional Bed Need	56	67	78	89	101	72	84	96

Source: Exhibit 30, Table 75

As reflected in the previous table, utilization of total licensed and CON approved acute care beds at CFVHS exceeded the 75.2% SMFP planning target in FY 2009. Additional acute care beds are identified as needed in the future. This analysis supports the need for the 41 beds which are the subject of the proposed community hospital. Projected volumes for HCMC will be shifted from CFVMC reducing congestion on the current campus and improving access for the population of southwest Cumberland and Hoke Counties.

2. Projected CFVHS Obstetrical Patient Days and Beds

Obstetrical days at CFVMC have increased substantially during the last several years, increasing at a 7.7%% annual growth rate from FY 2007 to FY 2008. The following table shows historical growth at CFVHS which reflects a 5.7% CAGR from 2006 to 2009.

CFVMC
Zip Code Acuity Adjusted Patient Days
Hoke Community Medical Center Service Area

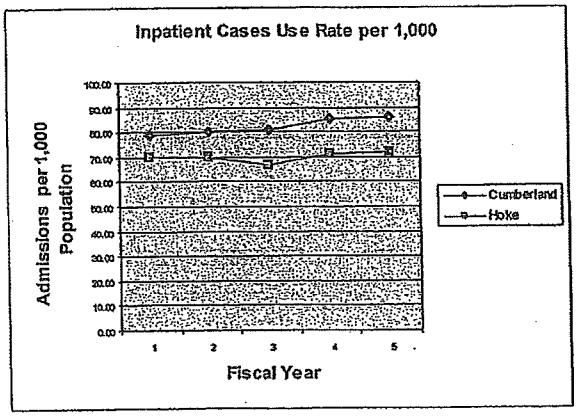
Zip Code	County	FY 2009 Patient Days
28304	Cumberland	8,483
28306	Cumberland	8,591
28314	Cumberland	6,341
28371	Roberson	1,115
28357	Hoke/Robeson	399
28376	Hoke	2,973
28386	Hoke/Robeson	280
28377	Hoke/Robeson	366
Total Days At HCMC		28,548

Source: CFVHS DSS Data System; Claritas; Exhibit 30, Table 6
Medical Surgical Exclusions: Delivery DRGs ,Mental Health and Drug Abuse DRGs, Rehab, Normal Newborns, NICU, Diag Cardiac Cath and all DRGs with FY2009 Relative Weight >=2.0; others as previously discussed.

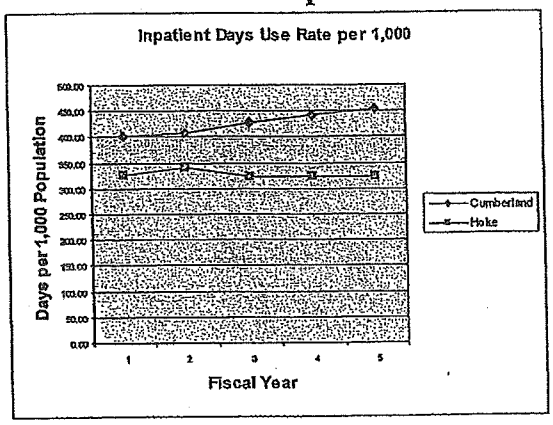
b. Zip Code Specific Population Growth Rates

It is reasonable to assume that utilization will continue to increase by zip code population growth rates and indeed is a conservative growth estimate. Growing by only the population growth rate assumes that there will be no increase in market share as a result of the proposed facility. In addition, using the zip code specific population growth rate assumes that the inpatient admission and inpatient day use rates for the residents in Cumberland and Hoke Counties will remain constant. In fact since 2004, inpatient discharge use rates have increased in both Cumberland and Hoke Counties as reflected in Graph 1. and inpatient day use rates have increased in Cumberland County and remained flat in Hoke County as reflected in Graph 2. below.

Graph 1



Graph 2



Source: Exhibit 30, Table 10

As shown in the previous graphs, both the patient day use rates and inpatient day use rates for both counties have increased or remained flat since 2004. Thus, the use of population growth rates to project future HCMC inpatient volumes is a reasonable and conservative approach.

The following zip code specific population growth rates were used to project future volume for HCMC.

Zip Code Specific Population Growth Rates
Hoke Community Medical Center Service Area

Zip Code	County	City/ Town	CAGR 2009-2016
28304	Cumberland	Fayetteville	0.18%
28306	Cumberland	Fayetteville	1.35%
28314	Cumberland	Fayetteville	0.95%
28371	Roberson	Parkton	1.42%
28357	Hoke/ Roberson	Lumber Bridge	0.65%
28376	Hoke	Raeford	2.91%
28348	Cumberland	Hope Mill	1.62%
28386	Hoke/ Roberson	Shannon	1.14%
28377	Hoke/ Roberson	Red Springs	1.10%
Total			1.34%

Source: Claritas; Exhibit 30, Table 7

c. **Percent CFVHS Volume Shift to Hoke Community Medical Center**

The following assumptions related to the percent market volume shift for medical surgical patient days are used in the projections.

Percent Market Volume Shift
Acuity Adjusted, Non-Obstetric Inpatient Days from
Existing CFVMC to Hoke Community Medical Center

Zip Code	County	PY 1 FY 2014	PY 2 FY 2015	PY 3 FY 2016
28304	Cumberland	10.5%	12.8%	15.0%
28306	Cumberland	10.5%	12.8%	15.0%
28314	Cumberland	10.5%	12.8%	15.0%
28371	Roberson	7.0%	8.5%	10.0%
28357	Hoke/ Robeson	7.0%	8.5%	10.0%
28376	Hoke	56.0%	68.0%	80.0%
28386	Hoke/ Robeson	7.0%	8.5%	10.0%
28377	Hoke/ Robeson	7.0%	8.5%	10.0%

Source: Exhibit 30, Table 6

Zip level volume shifted was based upon current utilization of existing acuity adjusted medical surgical services at CFVMC and the need for additional acute care beds in the market, geographic proximity of the zip population to the proposed

HCMC community hospital, discussion with CFVHS representatives working and living in the proposed service area, congestion at the existing campus of CFVMC on Owen Drive, and mileage and driving time analysis. Market volume shift assumptions were made considering these factors for each zip code.

It is conservatively assumed that only 15% of those patients currently seeking medical surgical services at CFVMC from the three Cumberland County zip codes will shift to the new HCMC, even though over 30% of the population is proximate to HCMC. While 100% of Hoke County residents will be closer to the proposed facility, HCMC was conservative in its estimated market volume shift for this population assuming a market volume shift of only 80% by Project Year 3. HCMC assumes that 10% of market volumes would shift from the three zip codes that overlap Hoke and Robeson County and Parkton, in Robeson County. This is a conservative assumption for the Hoke/Robeson zips as 100% of the Hoke County residents in these zips are geographically closer to the proposed hospital.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from the current CFVMC to the new HCMC hospital.

- Current medical/surgical services at CFVMC are at capacity.
- Physician support for the project is overwhelming.
- Community support for the project is overwhelming (see Exhibits 21 to 24).
- There currently are five CFVHS employed physician practices with 14 physicians in the defined service area: including Hoke Family Medical Center, Hope Mills Family Care, Cape Fear Valley Pediatric Care, Cape Fear Valley OB\GYN Clinic, and Perinatology Clinic.
- Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.
- HCMC offers a choice for inpatient and outpatient care closer to home.
- The proposed location of HCMC on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.
- Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to HCMC.

Step 3. Project Hoke Community Medical Center Acute Care Medical Surgical Inpatient Days and Bed Need

Projected HCMC inpatient days for the first three years of operation were calculated using FY 2009 zip code level acuity adjusted patient days multiplied by the zip code specific population compound annual growth rate and percent volume shift from CFVMC as previously discussed. HCMC assumed the new facility would grow at a reasonable rate, achieving 70% of the market shift in Project Year 1, 85% of the market shift in Project Year 2, and 100% of the proposed market shift by the end of Project Year 3. Projected acute care medical surgical inpatient patient days by zip code are reflected in the following

table. Projected in-migration also is reflected in the following table as is total acute care medical surgical bed need.

Hoke Community Medical Center
Projected Patient Days
FY 2009 – FY 2016

Zip Code	County	FFY09 Cases	FFY09 Patient Days	FFY10	FFY11	FFY12	FFY13	FFY14	Projected Pt Days HCMC PY1 FFY 2014	Percent to HCMC	FFY15	Projected Pt Days HCMC PY 2 FFY 2015	Percent to HCMC	FFY16	Projected Pt Days HCMC PY 3 FFY 2016	Percent to HCMC	Population CAGR 2009-2016
28304	Cumberland	1,810	8,483	8,498	8,513	8,528	8,543	8,558	899	10.5%	8,573	1,093	12.8%	8,588	1,288	15.0%	1.0018
28306	Cumberland	2,015	8,591	8,707	8,825	8,944	9,065	9,187	965	10.5%	9,311	1,187	12.8%	9,437	1,416	15.0%	1.0135
28314	Cumberland	1,461	6,341	6,401	6,462	6,523	6,585	6,648	698	10.5%	6,711	856	12.8%	6,774	1,016	15.0%	1.0095
28371	Roberson	284	1,115	1,131	1,147	1,163	1,180	1,196	84	7.0%	1,213	103	8.5%	1,230	123	10.0%	1.0142
28357	Hoke/Robeson	112	399	402	404	407	409	412	29	7.0%	415	35	8.5%	418	42	10.0%	1.0065
28376	Hoke	692	2,973	3,059	3,148	3,240	3,334	3,431	1,921	56.0%	3,531	2,401	68.0%	3,634	2,907	80.0%	1.0291
28386	Hoke/Robeson	74	280	283	286	290	293	296	21	7.0%	300	25	8.5%	303	30	10.0%	1.0114
28377	Hoke/Robeson	93	366	370	374	378	382	387	27	7.0%	391	33	8.5%	395	40	10.0%	1.0110
Total Days At HCMC			28,548						4,643			5,734			6,861		
Total Cases		6,541															
ALOS		4.36															
Other Zips and Counties		10.00%															
Total Patient Days									5,159			6,371			7,624		
ADC									14.1			17.5			20.9		
Occupancy with 25 Medical Surgical Beds									56.5%			69.8%			83.5%		

Source: Claritas, Table 6; Thomson Zip Level Data
Assumptions: Thomson Inpatient Data Medical Surgical Exclusions: Delivery DRGs (370-375),Mental Health and Drug Abuse DRGs (424-433 and 521-523), Rehab (462), Normal Newborns (391), NICU (385- 390), Diag Cardiac Cath (124,125) and all DRGs with FFY2009 Relative Weight >=2.0
Patient days projected using zip specific CAGR

The following table summarizes the previous projections and reflects the proposed medical surgical bed capacity and projected occupancy levels for medical surgical beds at HCMC for the first three project years.

Hoke Community Medical Center
Projected Acute Care Medical Surgical Inpatient Days
October 2013 – September 2016

Zip Code	Projected Pt Days HCMC PY 1 FFY 2014	Projected Pt Days HCMC PY 2 FFY 2015	Projected Pt Days HCMC PY 3 FFY 2016
Total Patient Days	5,159	6,371	7,624
ADC	14.1	17.5	20.9
Bed Need at 66.7% Occupancy	21.2	26.2	31.3
Medical Surgical Beds	25.0	25.0	25.0
Occupancy with 25 Medical Surgical Beds	56.5%	69.8%	83.5%

Source: Exhibit 30, Table 2

The previous table reflects projected acute care medical surgical bed need based upon the *State Medical Facilities Plan* Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients, which results in a medical surgical acute care bed need at HCMC of 31 medical surgical acute care beds in PY 3. The proposed 25 medical surgical acute care beds at HCMC are projected to achieve an occupancy level of 83.5% in PY 3.

Step 4. Project Acute Care Medical Surgical Discharges

Acuity adjusted FY 2009 CFVMC medical surgical acute care inpatient discharge and inpatient day data specific to the defined zip code service area were analyzed to determine an average length of stay for the proposed HCMC of 4.36 days. Actual data is included in Exhibit 30, Table 6. Annual total acute care medical surgical inpatient days were divided by average length of stay to project acute care medical surgical discharges for each of the three project years.

Hoke Community Medical Center
Projected Acute Care Medical Surgical Discharges
October 2013 – September 2016

Zip Code	Projected Pt Days HCMC PY 1 FFY 2014	Projected Pt Days HCMC PY 2 FFY 2015	Projected Pt Days HCMC PY 3 FFY 2016
Total Patient Days	5,159	6,371	7,624
ALOS	4.4	4.4	4.4
Acute Care Medical Surgical Discharges	1,182	1,460	1,747

Source: Exhibit 30, Table 1

The previous table reflects projected acute care medical surgical discharges for the proposed facility. HCMC is projected to exceed 1,700 medical surgical discharges by the third year of operation.

3. Projected Obstetrical Inpatient Discharges, Days, and Bed Need

Projected obstetrical inpatient discharges, days, and bed need were determined using the following steps.

Step 1. Determine Obstetrical Patient Volume from Hoke Community Medical Center Zip Code Service Area

As previously discussed, the proposed HCMC will be a community hospital which will provide obstetric services. To determine total obstetrical discharges and patient days at HCMC, zip code level obstetrical inpatient cases and days were determined using the Thomson Reuters database.

The following table shows FY 2009 base data from service area zip codes. Zip code 28348 which includes the town of Hope Mills was included in determining future need for obstetrical services at HCMC. Existing obstetrical services at CFVMC are at capacity and in need of expansion. The proposed project will include an emphasis on Women's services, in particular obstetrical services as a result of the needed expansion of the existing program at CFVMC. As a population base in southwest Cumberland County, adjacent to the defined medical surgical service area, which is growing as a result of young families and women of childbearing age, Hope Mills is included in the projections for future OB need at HCMC.

CFVMC
Zip Code Obstetrical Cases
Hoke Community Medical Center Service Area

Zip Code	County	City/Town	FY09
28304	Cumberland	Fayetteville	432
28306	Cumberland	Fayetteville	493
28314	Cumberland	Fayetteville	643
28348	Cumberland	Hope Mills	386
28371	Roberson	Parkton	64
28357	Hoke/Robeson	Lumber Bridge	20
28376	Hoke	Raeford	398
28386	Hoke/Robeson	Shannon	38
28377	Hoke/Robeson	Red Springs	67
Total Cases At HCMC			2,541

Source: Thomson Reuters; Claritas; Exhibit 30, Table 21

Step 2. Project Hoke Community Medical Center Obstetrical Inpatient Days – Methodology and Assumptions

HCMC projected obstetrical inpatient days for the first three years of operation using the following methodology.

Projected Obstetrical Patient Day Utilization = [(Current Obstetrical Patients x Annual Zip Code Specific Population Growth Rates x Percent Volume Shifted) + In-migration] x Obstetrical Average Length of Stay

a. Current Obstetrical Patient Utilization

The following table reflects the total patient day volume by zip code provided at CFVMC to residents of the proposed service area in FY 2008.

CFVMC
Zip Code Obstetrical Cases
Hoke Community Medical Center Service Area

Zip Code	County	City/ Town	FFY09
28304	Cumberland	Fayetteville	432
28306	Cumberland	Fayetteville	493
28314	Cumberland	Fayetteville	643
28348	Cumberland	Hope Mills	386
28371	Roberson	Parkton	64
28357	Hoke/Robeson	Lumber Bridge	20
28376	Hoke	Raeford	398
28386	Hoke/Robeson	Shannon	38
28377	Hoke/Robeson	Red Springs	67
Total Cases At HCMC			2,541

Source: Thomson Reuters; Claritas; Exhibit 30, Table 21

b. Zip Code Specific Population Growth Rates – Women 15 – 44 Years of Age

It is reasonable to assume that utilization will continue to increase by zip code population growth rates for women of childbearing age. Growing by only the population growth rate assumes that there will be no increase in market share as a result of the proposed facility. The following zip code specific population growth rates were use to project future volume for obstetrical services at HCMC.

Hoke Community Medical Center
Zip Code Specific Population Growth Rates
Women 15 – 44 Years of Age

Zip Code	County	City/ Town	CAGR 2009-2016
28304	Cumberland	Fayetteville	-1.2%
28306	Cumberland	Fayetteville	0.3%
28314	Cumberland	Fayetteville	-0.6%
28348	Cumberland	Hope Mills	0.1%
28371	Roberson	Parkton	0.0%
28357	Hoke/ Robeson	Lumber Bridge	0.0%
28376	Hoke	Raeford	1.8%
28386	Hoke/ Robeson	Shannon	1.1%
28377	Hoke/ Robeson	Red Springs	1.1%

Source: Claritas; Exhibit 30, Table 23

c. **Percent CFVMC Volume Shift to Hoke Community Medical Center**

The following assumptions related to the percent market volume shift for obstetrical patient days are used in the projections.

Percent Market Volume Shift
Acuity Adjusted, Non-Obstetric Inpatient Days from
Existing CFVMC to Hoke Community Medical Center

Zip Code	County	City/ Town	PY1 FY 2014	PY1 FY 2014	PY1 FY 2014
28304	Cumberland	Fayetteville	26.8%	38.3%	45.0%
28306	Cumberland	Fayetteville	26.8%	38.3%	45.0%
28314	Cumberland	Fayetteville	26.8%	38.3%	45.0%
28348	Cumberland	Hope Mills	17.9%	25.5%	30.0%
28371	Roberson	Parkton	17.9%	25.5%	30.0%
28357	Hoke/ Robeson	Lumber Bridge	17.9%	25.5%	30.0%
28376	Hoke	Raeford	53.6%	76.5%	90.0%
28386	Hoke/ Robeson	Shannon	17.9%	25.5%	30.0%
28377	Hoke/ Robeson	Red Springs	17.9%	25.5%	30.0%

Source: Exhibit 30, Table 21

Zip level volume shifted was based upon current utilization of existing obstetrical services at CFVMC and the need for additional obstetrical beds in the market, the emphasis on women's services and obstetrical services that will be part of the culture at HCMC, geographic proximity of the zip population to the proposed HCMC community hospital, discussion with CFVHS representatives working and living in the proposed service area, congestion at the existing campus of CFVMC on Owen Road, and mileage and driving time analysis. Market volume shift assumptions were made considering these factors for each zip code.

It is assumed that approximately 45% of those patients currently seeking obstetrical care at CFVMC from three of the four Cumberland County zip codes will shift to

the new HCMC. Since 100% of Hoke County residents will be closer to the proposed facility, HCMC estimated market volume shift for this population assuming a market volume shift of only 90% by Project Year 3. HCMC assumes that 30% of market volumes would shift from the three zip codes that overlap Hoke and Robeson counties, which is a conservative estimate since 100% of the Hoke County residents in these zips are geographically closer to the proposed hospital. Finally, assumptions for residents of Hope Mills (zip 28348) and Parkton (28371) in Robeson County also assume a 30% market shift.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from the current CFVMC to the new HCMC hospital.

- **Current obstetrical services at CFVMC are at capacity.**
- **Physician support for the project is overwhelming.**
- **Community support for the project is overwhelming.**
- **There currently are 5 CFVHS employed physician practices with 14 physicians in the defined service area: including Hoke Family Medical Center, Hope Mills Family Care, Cape Fear Valley Pediatric Care, Cape Fear Valley OB\GYN Clinic, and Perinatology Clinic.**
- **Congestion and traffic on Owen Road, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.**
- **HCMC offers a choice for inpatient and outpatient care closer to home.**
- **The proposed location of HCMC on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.**
- **Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to HCMC.**

Step 3. Project Hoke Community Medical Center Obstetrical Patients, Inpatient Days and Bed Need

Projected HCMC obstetrical cases for the first three years of operation were calculated using FY 2009 zip code level acuity adjusted cases multiplied by the zip code specific population compound annual growth rate and percent volume shift from CFVMC. HCMC assumed the new facility would grow at a reasonable rate and projected obstetrical patients by zip code as previously discussed and reflected in the following table. Projected in-migration also is reflected in the following table.

Hoke Community Medical Center
Projected Obstetrical Patients
FY 2009 – FY 2016

Zip Code	County	FFY09	FFY10	FFY11	FFY12	FFY13	FFY14	Projected OB Cases HCMC PY 1 FFY 2014	Percent to HCMC	FFY15	Projected OB Cases HCMC PY 2 FFY 2015	Percent to HCMC	FFY16	Projected OB Cases HCMC PY 3 FFY 2016	Percent to HCMC	Zip Population Women 15-44 CAGR 2009-2016
28304	Cumberland	432	427	422	417	412	407	109	26.8%	402	154	38.3%	398	179	45.0%	0.9882
28306	Cumberland	493	494	496	497	498	500	134	26.8%	501	192	38.3%	502	226	45.0%	1.0027
28314	Cumberland	643	639	635	631	628	624	167	26.8%	620	237	38.3%	616	277	45.0%	0.9940
28348	Cumberland	386	386	387	387	388	388	69	17.9%	389	99	25.5%	389	117	30.0%	1.0012
28371	Roberson	64	64	64	64	64	64	11	17.9%	64	16	25.5%	64	19	30.0%	0.9998
28357	Hoke/Robeson	20	20	20	20	20	20	4	17.9%	20	5	25.5%	20	6	30.0%	1.0003
28376	Hoke	398	405	413	420	428	436	233	53.6%	444	339	76.5%	452	407	90.0%	1.0183
28386	Hoke/Robeson	38	38	39	39	40	40	7	17.9%	40	10	25.5%	41	12	30.0%	1.0105
28377	Hoke/Robeson	67	68	68	69	70	71	13	17.9%	71	18	25.5%	72	22	30.0%	1.0106
Total Cases At HCMC		2,541						747			1,071	0.0%		1,265	0.0%	
Total Days		7,052														
Other Zips and Countles		10%						83			119	0.0%		141	0.0%	
Total OB Cases								830			1,190	0.0%		1,406	0.0%	

Source: Claritas, Table 23; Thomson, Table 28
Assumptions: Cases projected using zip specific CAGR

Average length of stay was determined based upon a review of actual ALOS for the defined service area for obstetric services in FY 2009. The following table summarizes the previous projections and reflects the proposed obstetrical bed capacity and projected occupancy levels for obstetrical beds for the first three project years.

Hoke Community Medical Center
Projected Obstetrical Inpatient Days
October 2013 – September 2016

	PY1 FY 2014	PY1 FY 2014	PY1 FY 2014
Total Obstetrical Cases	830	1,190	1,405
Average Length of Stay	2.78	2.78	2.78
Projected OB Patient Days	2,304	3,303	3,900
Projected OB ADC	6.3	9.1	10.7
HCMC Acute Care Beds Needed at 66.7%	9.5	13.6	16.0
HCMC Proposed OB Bed Capacity	16	16	16
HCMC Projected Utilization of 16 beds	39.5%	56.6%	66.8%

Source: Exhibit 30, Tables 21, 25

The previous table reflects projected obstetric bed need based upon the *State Medical Facilities Plan* Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients, which results in a obstetrical bed need at HCMC of 16 obstetrical beds in PY 3. The proposed 16 obstetrical beds at HCMC are projected to achieve an occupancy level of 66.8% in PY 3.

4. Projected Births and C-Section Volume

For purposes of these projections, HCMC assumed that total births equal total OB cases. While in fact there are cases of multiple births, assuming one to one, obstetrical cases to births results in a reasonable projection. To project C-Section volume, actual data obstetrical data from the defined zip codes service area was used as reflected in Exhibit 30, Tables 24-26 and in the following table.

Hoke Community Medical Center
Projected Births and C-Section
October 2013 – September 2016

	PY1 FY 2014	PY1 FY 2014	PY1 FY 2014
Total OB Patients/Births	830	1,190	1,405
CFVMC C-section Rate for Zip Service Area	29.6%	29.6%	29.6%
C-section Volume	246	352	416
Csection Room Need	0.62	0.89	1.06
Proposed C-section Rooms	1	1	1

Source: Exhibit 30, Tables 24, 25, 26
**C-section rate is for residents of defined zip service area*

As shown in the previous table, HCMC will have sufficient C-Section volume to justify one C-Section room initially at the proposed new community hospital.

5. Projected ICU Days and Bed Need

Projected ICU beds were determined using total projected inpatient days at HCMC and FY 2008 ICU utilization data from North Carolina hospitals. HCMC reviewed historical ICU utilization for all hospitals in North Carolina reporting ICU utilization. That data is included in Exhibit 30, Table 15. ICU patient days as a percent of Total Acute Inpatient Patient Days (less neonatal days) for all North Carolina hospitals reporting ICU data had a mean value of 12.2% in FY 2008. The range for ICU days as a percent of total days for all North Carolina hospitals was 36.3% at the high end and 3.6% at the low end. The same data reflect a median value for ICU patient day utilization as a percent of Total Patient Days (less neonatal days) of 10.9%.

For community hospitals with total patient days in a range similar to the projected patient days for HCMC, the percent of total days that were ICU days in FY 2008 was 13.3%. Based upon the total North Carolina ICU database, HCMC ICU days were projected assuming that 8.5% of total acute inpatient days would be ICU days. That percent represents the average ICU days as a percent of total days for North Carolina hospitals in the lower 50% ranking of ICU days as a percent of total days as reflected in Exhibit 30, Table 15.

Therefore, HCMC projected ICU days reflects a conservative estimate of total days. HCMC elected to be conservative as the proposed hospital is projected to offer a full-service suburban community hospital level of care (based on DRG acuity weights of less than 2.0) for residents of the HCMC Service Area. The following table shows projected ICU patient days and the resulting ICU bed need for HCMC.

Hoke Community Medical Center
Projected ICU Patient Days and Bed Need
October 1, 2013 – September 30, 2016

	PY 1 FFY 2014	PY 2 FFY 2015	PY 3 FFY 2016
Total Patient Days	7,463	9,674	11,524
ICU Percent of Total Days	8.5%	8.5%	8.5%
ICU Days	637	825	983
ICU ADC	1.7	2.3	2.7
ICU Bed Need @ 60%	2.91	3.77	4.49
CFVWest ICU Bed Capacity	4.0	4.0	4.0
Occupancy	43.6%	56.5%	67.3%

Source: Exhibit 30, Table 3

The previous table reflects projected ICU patient days and ICU bed need based upon and the ICU CON Criteria and Standards planning occupancy target of 60% for small ICUs, which results in a need at HCMC for 4 ICU beds in PY 3 (FY 2016). The proposed 4 bed ICU unit is projected to achieve an occupancy level of 67.3% in PY 3.

6. Projected Observation Patient Days and Bed Need

Projected observation patient days were determined based upon observation data specific to the proposed zip code service area at CFVMC in FY 2009. Historical data is included in Exhibit 30, Table 17. The average ratio was one observation bed for every 5.6 inpatient days. The following table shows projected observation patient days and the resulting observation bed need for HCMC.

Hoke Community Medical Center
Projected Observation Patient Days and Bed Need
October 1, 2013 – September 30, 2016

	PY 1 FFY 2014	PY 2 FFY 2015	PY 3 FFY 2016
Total Days	7,463	9,674	11,524
Ratio Obs:Total Days	1:5.6	1:5.6	1:5.6
Obs Cases/Days	1,342	1,739	2,072
Obs ADC	3.7	4.8	5.7
Obs Bed Need @ 66.7%	9	9	9

Source: Exhibit 30, Table 4
Note: Observation Bed Need calculation = 5.7 ADC/66.7% target occ rate = 9 beds needed

The previous table reflects projected observation patient days and bed need based upon the *State Medical Facilities Plan* Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients, which results in a need for 9 observation beds at HCMC in PY 3, seven of which will be located in the general medical surgical unit and two of which will be located within the obstetrical labor and delivery area of HCMC.

7. Projected Surgical Cases and Shared Operating Room Need

Projected inpatient and outpatient surgical volume and shared operating room need were determined using the following steps.

Step 1. Project Hoke Community Medical Center Acute Care Inpatient and Outpatient Surgery – Methodology and Assumptions

HCMC projected inpatient and outpatient surgical volume for the first three years of operation using the following methodology.

Projected Inpatient Surgery = (Current Inpatient Surgical Utilization x Annual Zip Code Specific Population Growth Rates x Percent Volume Shifted) + In-migration

Projected Outpatient Surgery = (Current Outpatient Surgical Utilization x Annual Zip Code Specific Population Growth Rates x Percent Volume Shifted) + In-migration

a. Current Surgical Utilization

The following table reflects the total surgical volume by zip code provided at existing CFVHS surgical facilities, CFVMC and HRSH, to residents of the proposed service area in FY 2009.

CFVHS
Zip Code Inpatient and Outpatient Surgical Volume
Hoke Community Medical Center Service Area

Zip Code	County	Town	Inpatient	Outpatient
28304	Cumberland	Fayetteville	324	889
28306	Cumberland	Fayetteville	347	850
28314	Cumberland	Fayetteville	269	824
28371	Roberson	Parkton	52	165
28357	Hoke/Robeson	Lumber Bridge	12	49
28376	Hoke	Raeford	139	378
28386	Hoke/Robeson	Shannon	20	60
28377	Hoke/Robeson	Red Springs	32	73
Total			1,195	3,288

Source: Exhibit 30, Tables 35, 36
Note: Inpatient excludes c-section volumes

b. Zip Code Specific Population Growth Rates

It is reasonable to assume that utilization will continue to increase by a population growth rate which indeed is a conservative growth estimate. Growing by only the population growth rate assumes that there will be no increase in market share as a result of the proposed facility. A review of surgical use rates for Cumberland and Hoke counties reflects use rates that have increased and decreased from 2006 through 2009 as indicated in Exhibit 30, Table 41. The decrease in outpatient utilization from 2008 to 2009 may be a

result of the economic downturn and subsequent decrease in elective surgical procedures. Recent economic indicators support a reverse of the downward economic trend.

Therefore HCMC use of the zip code specific population growth rate results in a reasonable projection of need for operating rooms at the proposed HCMC. In addition, the annual *SMFP* planning methodology for operating rooms utilizes a population based growth rate to project future surgical volume. The following zip code specific population growth rates were use to project future volume for HCMC.

Zip Code Specific Population Growth Rates
Hoke Community Medical Center Service Area

Zip Code	County	City/Town	CAGR 2009-2016
28304	Cumberland	Fayetteville	0.18%
28306	Cumberland	Fayetteville	1.35%
28314	Cumberland	Fayetteville	0.95%
28371	Roberson	Parkton	1.42%
28357	Hoke/Roberson	Lumber Bridge	0.65%
28376	Hoke	Raeford	2.91%
28348	Cumberland	Hope Mill	1.62%
28386	Hoke/Roberson	Shannon	1.14%
28377	Hoke/Roberson	Red Springs	1.10%
Total			1.34%

Source: Claritas; Exhibit 30, Table 34

c. **Percent CFVHS Volume Shift to Hoke Community Medical Center**

The following assumptions relate to the percent market volume shift are used in the projections.

Percent Market Volume Shift
Inpatient and Outpatient Surgery from
Existing CFVHS to Hoke Community Medical Center

Zip Code	County	PY 1 FY 2014	PY 2 FY 2015	PY 3 FY 2016
Inpatient				
28304	Cumberland	10.5%	12.8%	15.0%
28306	Cumberland	10.5%	12.8%	15.0%
28314	Cumberland	10.5%	12.8%	15.0%
28371	Roberson	7.0%	8.5%	10.0%
28357	Hoke/Robeson	7.0%	8.5%	10.0%
28376	Hoke	56.0%	68.0%	80.0%
28386	Hoke/Robeson	7.0%	8.5%	10.0%
28377	Hoke/Robeson	7.0%	8.5%	10.0%
Outpatient				
28304	Cumberland	17.5%	21.3%	25.0%
28306	Cumberland	17.5%	21.3%	25.0%
28314	Cumberland	17.5%	21.3%	25.0%
28371	Roberson	10.5%	12.8%	15.0%
28357	Hoke/Robeson	10.5%	12.8%	15.0%
28376	Hoke	56.0%	68.0%	80.0%
28386	Hoke/Robeson	10.5%	12.8%	15.0%
28377	Hoke/Robeson	10.5%	12.8%	15.0%

Source: Exhibit 30, Table 33

Surgery market volume shift for years one and two were projected slightly less (at 70% and 85% of the project year three shift) as the facility will be new and time is allowed for the volume to grow. The following factors were considered important to the determination of the percent of market volume projected to shift from the zip code service area.

Zip level volume shifted was based upon geographic proximity of the zip population to the proposed HCMC community hospital, discussion with CFVHS representatives working and living in the proposed service area, congestion at the existing campus of CFVMC on Owen Drive, and mileage and driving time analysis.

Separate assumptions were assumed by zip code. Inpatient assumptions are consistent with those made for inpatient medical surgical days. Assumptions for inpatient market volume shift are lower than outpatient market shift to allow for inpatient surgeries not initially provided at HCMC.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from the current CFVMC to the new HCMC hospital.

- **Physician support for the project is overwhelming.**
- **Community support for the project is overwhelming.**
- **There currently are 5 CFVHS employed physician practices with 14 physicians in the defined service area: including Hoke Family Medical Center, Hope Mills**

Family Care, Cape Fear Valley Pediatric Care, Cape Fear Valley OB\GYN Clinic, and Perinatology Clinic.

- Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.
- HCMC offers a choice for inpatient and outpatient care closer to home.
- The proposed location of HCMC on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.
- Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to HCMC.

Step 2. Project Surgical Cases in Defined Service Area

HCMC projected surgical cases by zip code are reflected in the following table. Projected in-migration and total surgical cases also are included.

Surgical Projections for Hoke Community Medical Center
October 2013 through September 2016

Zip Code	Town	FFY09	FFY10	FFY11	FFY12	FFY13	FFY14	Projected Surgery HCMC PY1 FFY 2014	Percent to HCMC	FFY15	Projected Surgery HCMC PY2 FFY 2015	Percent to HCMC	FFY16	Projected Surgery HCMC PY3 FFY 2016	Percent to HCMC
Inpatient															
28304	Fayetteville	324	325	325	326	326	327	34	10.5%	327	42	12.8%	328	49	15.0%
28306	Fayetteville	347	352	356	361	366	371	39	10.5%	376	48	12.8%	381	57	15.0%
28314	Fayetteville	269	272	274	277	279	282	30	10.5%	285	36	12.8%	287	43	15.0%
28371	Parkton	52	53	53	54	55	56	4	7.0%	57	5	8.5%	57	6	10.0%
28357	Lumber Bridge	12	12	12	12	12	12	1	7.0%	12	1	8.5%	13	1	10.0%
28376	Raeford	139	143	147	151	156	160	90	56.0%	165	112	68.0%	170	136	80.0%
28386	Shannon	20	20	20	21	21	21	1	7.0%	21	2	8.5%	22	2	10.0%
28377	Red Springs	32	32	33	33	33	34	2	7.0%	34	3	8.5%	35	3	10.0%
SubTotal Inpatient Surgery At HCMC		1,195						201			249			298	
Other Zips and Counties		10%						22			28			33	
Total Inpatient Surgery At HCMC								224			277			331	
Outpatient															
28304	Fayetteville	889	891	892	894	895	897	157	17.5%	898	191	21.3%	900	225	25.0%
28306	Fayetteville	850	861	873	885	897	909	159	17.5%	921	196	21.3%	934	233	25.0%
28314	Fayetteville	824	832	840	848	856	864	151	17.5%	872	185	21.3%	880	220	25.0%
28371	Parkton	165	167	170	172	175	177	19	10.5%	180	23	12.8%	182	27	15.0%
28357	Lumber Bridge	49	49	50	50	50	51	5	10.5%	51	6	12.8%	51	8	15.0%
28376	Raeford	378	389	400	412	424	436	244	56.0%	449	305	68.0%	462	370	80.0%
28386	Shannon	60	61	61	62	63	63	7	10.5%	64	8	12.8%	65	10	15.0%
28377	Red Springs	73	74	75	75	76	77	8	10.5%	78	10	12.8%	79	12	15.0%
SubTotal Outpatient Surgery At HCMC		3,288						750			925			1,105	
Other Zips and Counties		10%						83			103			123	
Total Outpatient Surgery At HCMC								834			1,028			1,227	
Weighted Inpatient OR Hours								671			830			993	
Weighted Outpatient OR Hours								1,250			1,541			1,841	
Total Weighted OR Hours								1921			2371			2834	
Shared ORs Need at 1872 Hours Per Room								1.0			1.3			1.514	
Total Shared ORs								2			2			2	

Source: Exhibit 30, Table 33

Total projected surgical cases reflected in the previous table for October 2013 through September 2016 were used to project shared operating rooms need for HCMC, also reflected in the previous table. C-Section volume was subtracted from FY 2009 inpatient surgical volumes prior to calculating surgical operating rooms needed.

Step 3. Project Shared Operating Room Need in the Defined Service Area

Projected inpatient and outpatient surgical cases were used to project shared operating rooms needed at HCMC using the case weighting and operating room capacity assumptions used in the *State Medical Facilities Plan* Operating Room need methodology. The following table reflects the operating rooms needed at HCMC.

Hoke Community Medical Center
Projected Shared Inpatient/Ambulatory Operating Room Need
October 2013 – September 2016

Zip Code	PY 1 FFY 2014	PY 2 FFY 2015	PY 3 FFY 2016
Total Inpatient Surgery At HCMC	224	277	331
Total Outpatient Surgery At HCMC	834	1,028	1,227
Weighted Inpatient OR Hours	671	830	993
Weighted Outpatient OR Hours	1,250	1,541	1,841
Total Weighted OR Hours	1,921	2,371	2,834
Shared ORs Need at 1872 Hours Per Room	1.03	1.27	1.51
Total Shared ORs	2	2	2

Source: Exhibit 30, Table 33

The previous table shows projected inpatient and outpatient surgical cases and the resulting shared operating rooms needed based upon the *State Medical Facilities Plan* Operating Room Need Methodology, inpatient surgical case weighting of 3.0 hours per case, outpatient surgical case weighting of 1.5 hours per case, and a planning target of 1,872 operating hours per year which results in a need at HCMC for two shared surgical operating rooms in Project Year 3. The previous table shows projected surgery volume sufficient to support 1.51 operating rooms or a need for two shared operating rooms[51] at HCMC during the third year of operation.

8. Projected Hospital-Based Outpatient Visits

Projected hospital outpatient visits were determined using the following steps.

[51] The 1.51 OR deficit is rounded up to 2.0 ORs in accordance with the operating room need methodology included in the *2009SMFP*. In Step 5 of the methodology, page 63 of the *2010 SMFP*, a projected deficit of 0.5 or greater is rounded to the next whole number in Service Areas with more than 10 operating rooms.

Step 1. Determine Outpatient Visits from Hoke Community Medical Center Zip Code Service Area

The proposed HCMC will be a community hospital which will provide outpatient services. To determine total outpatient cases at HCMC, zip code level data was analyzed. The following table shows FY 2009 base data from service area zip codes.

CFVHS Historical Outpatient Volume

Zip Code	City/ Town	County	2009
28304	Fayetteville	Cumberland	18,963
28306	Fayetteville	Cumberland	19,791
28314	Fayetteville	Cumberland	17,733
28371	Parkton	Hoke/ Robeson	2,638
28357	Lumber Bridge	Hoke/ Robeson	847
28376	Raeford	Hoke	5,981
28386	Shannon	Hoke/ Robeson	530
28377	Red Springs	Robeson	807
Total			67,290

Source: Exhibit 30, Table 68

Step 2. Project Hoke Community Medical Center Acute Care Medical Surgical Inpatient Days –Methodology and Assumptions

HCMC projected outpatient cases for the first three years of operation using the following methodology.

Projected Outpatient Cases = (Current Outpatient Cases x Annual Zip Code Specific Population Growth Rates x Percent Volume Shifted) + In-migration

a. Current Outpatient Case Volume

The following table reflects the total outpatient cases by zip code provided at CFVMC to residents of the proposed service area in FY 2009.

CFVHS Historical Outpatient Volume

Zip Code	City/ Town	County	2009
28304	Fayetteville	Cumberland	18,963
28306	Fayetteville	Cumberland	19,791
28314	Fayetteville	Cumberland	17,733
28371	Parkton	Hoke/ Robeson	2,638
28357	Lumber Bridge	Hoke/ Robeson	847
28376	Raeford	Hoke	5,981
28386	Shannon	Hoke/ Robeson	530
28377	Red Springs	Robeson	807
Total			67,290

Source: Exhibit 30, Table 68
Note: Volumes do not include outpatient surgery or emergency visits

b. **Zip Code Specific Population Growth Rates**

It is reasonable to assume that utilization will continue to increase by zip code population growth rates and indeed is a conservative growth estimate. Actual outpatient visit growth for the zip code service area was 6.2% from FY 2008 to FY 2009 as reflected in Exhibit 30, Table 68. Growing by only the population growth rate assumes that there will be no increase in market share as a result of the proposed facility.

The following zip code specific population growth rates were use to project future volume for HCMC.

Zip Code Specific Population Growth Rates
Hoke Community Medical Center Service Area

Zip Code	County	City/ Town	CAGR 2009-2016
28304	Cumberland	Fayetteville	0.18%
28306	Cumberland	Fayetteville	1.35%
28314	Cumberland	Fayetteville	0.95%
28371	Roberson	Parkton	1.42%
28357	Hoke/Roberson	Lumber Bridge	0.65%
28376	Hoke	Raeford	2.91%
28348	Cumberland	Hope Mill	1.62%
28386	Hoke/Roberson	Shannon	1.14%
28377	Hoke/Roberson	Red Springs	1.10%
Total			1.34%

Source: Claritas; Exhibit 30, Table 66

c. **Percent CFVMC Volume Shift to Hoke Community Medical Center**

The following assumptions related to the percent market volume shift for outpatient cases are used in the projections.

Percent Market Volume Shift
Outpatient Cases
Existing CFVMC to Hoke Community Medical Center

Zip Code	2014	2015	2016
28304	17.5%	21.3%	25.0%
28306	17.5%	21.3%	25.0%
28314	17.5%	21.3%	25.0%
28371	10.5%	12.8%	15.0%
28357	10.5%	12.8%	15.0%
28376	56.0%	68.0%	80.0%
28386	10.5%	12.8%	15.0%
28377	10.5%	12.8%	15.0%

Source: Exhibit 30, Table 67

Zip level volume shifted was based upon geographic proximity of the zip population to the proposed HCMC community hospital, discussion with CFVHS representatives working and living in the proposed service area, congestion at the existing campus of CFVMC on Owen Road, and mileage and driving time analysis. The projected outpatient visit market volume shifts are consistent with the outpatient surgical shift projections previously utilized.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from the current CFVMC to the new HCMC hospital.

- **Physician support for the project is overwhelming.**
- **Community support for the project is overwhelming.**
- **There currently are 5 CFVHS employed physician practices with 14 physicians in the defined service area: including Hoke Family Medical Center, Hope Mills Family Care, Cape Fear Valley Pediatric Care, Cape Fear Valley OB\GYN Clinic, and Perinatology Clinic.**
- **Congestion and traffic on Owen Drive, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.**
- **HCMC offers a choice for inpatient and outpatient care closer to home.**
- **The proposed location of HCMC on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.**
- **Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to HCMC.**

Step 3. Project Hoke Community Medical Center Acute Care Outpatient Cases

Projected HCMC outpatient cases for the first three years of operation were calculated using FY 2009 zip code level outpatient cases multiplied by the zip code specific population compound annual growth rate and percent volume shift from CFVMC. HCMC assumed the new facility would grow at a reasonable rate and projected acute care medical surgical inpatient patient days by zip code as previously discussed and reflected in the following table. Projected in-migration also is reflected in the following table.

Hoke Community Medical Center
Projected Outpatient Cases Defined Service Area
2009 – 2016

Zip Code	Town	2009	2010	2011	2012	2013	2014	2015	2016
28304	Fayetteville	18,963	18,996	19,030	19,063	19,097	19,130	19,164	19,198
Projected Volume Shift							17.5%	21.3%	25.0%
HCMC Projected Visits							3,348	4,072	4,799
28306	Fayetteville	19,791	20,058	20,329	20,604	20,882	21,165	21,451	21,740
Projected Volume Shift							17.5%	21.3%	25.0%
HCMC Projected Visits							3,704	4,558	5,435
28314	Fayetteville	17,733	17,901	18,071	18,242	18,415	18,590	18,767	18,945
Projected Volume Shift							17.5%	21.3%	25.0%
HCMC Projected Visits							3,253	3,988	4,736
28371	Parkton	2,638	2,675	2,713	2,752	2,791	2,830	2,870	2,911
Projected Volume Shift							10.5%	12.8%	15.0%
HCMC Projected Visits							297	366	437
28357	Lumber Bridge	847	853	858	864	869	875	881	886
Projected Volume Shift							10.5%	12.8%	15.0%
HCMC Projected Visits							92	112	133
28376	Raeford	5,981	6,155	6,334	6,518	6,708	6,903	7,104	7,310
Projected Volume Shift							56.0%	68.0%	80.0%
HCMC Projected Visits							3,866	4,830	5,848
28386	Shannon	530	536	542	548	555	561	567	574
Projected Volume Shift							10.5%	12.8%	15.0%
HCMC Projected Visits							59	72	86
28377	Red Springs	807	816	825	834	843	852	862	871
Projected Volume Shift							10.5%	12.8%	15.0%
HCMC Projected Visits							89	110	131
HCMC Zip Code ED Visits							14,708	18,109	21,605
Total HCMC ED including Inmigration			10%				**16,342**	**20,121**	**24,006**

Source: Exhibit 30, Table 67
Note: Does not include inpatient surgery or emergency visits.

The previous table reflects projected outpatient cases for HCMC based upon historical volumes and population growth.

9. Projected Emergency Department Visits and Emergency Treatment Rooms

Step 1. Determine Emergency Visits from Hoke Community Medical Center Zip Code Service Area

The proposed HCMC will be a community hospital which will provide emergency services. To determine total emergency visits at HCMC, zip code level data was analyzed. The following table shows 2009 base data from service area zip codes.

CFVMC
Historical Emergency Visits

City	County	Zip Code	CY 2009
Fayetteville	Cumberland	28304	11,859
Fayetteville	Cumberland	28306	13,773
Fayetteville	Cumberland	28314	12,427
Parkton	Hoke	28371	2,166
Lumber Bridge	Hoke/Robeson	28357	724
Raeford	Hoke/Robeson	28376	6,104
Shannon	Hoke/Robeson	28386	491
Red Springs	Robeson	28377	750
Total Zip ED Visits			48,294

Source: Exhibit 30, Table 52

Step 2. Project Hoke Community Medical Center Emergency Visits – Methodology and Assumptions

HCMC projected emergency visits for the first three years of operation using the following methodology.

Projected Emergency Visits = (Current Emergency Visits x Annual Zip Code Specific Population Growth Rates x Percent Volume Shifted) + In-migration

a. Current Emergency Visits

The following table reflects historical emergency visits by zip code provided at CFVMC to residents of the proposed service area in 2009.

CFVMC
Historical Emergency Visits

City	County	Zip Code	CY 2009
Fayetteville	Cumberland	28304	11,859
Fayetteville	Cumberland	28306	13,773
Fayetteville	Cumberland	28314	12,427
Parkton	Hoke	28371	2,166
Lumber Bridge	Hoke/Robeson	28357	724
Raeford	Hoke/Robeson	28376	6,104
Shannon	Hoke/Robeson	28386	491
Red Springs	Robeson	28377	750
Total Zip ED Visits			48,294

Source: Exhibit 30, Table 52

b. Zip Code Specific Population Growth Rates

It is reasonable to assume that utilization will continue to increase by zip code population growth rates and indeed is a conservative growth estimate. Growing by only the population growth rate assumes that there will be no increase in market share as a result of the proposed facility. In addition, emergency volume at CFVMC

has increased significantly over the last two years as previously discussed. North Carolina emergency visit use rates also are included in Exhibit 30, Table 65 and reflect significant increases in emergency room use. Therefore, population growth is a conservative growth estimate for future emergency volume at HCMC.

The following zip code specific population growth rates were use to project future volume for HCMC.

Zip Code Specific Population Growth Rates
Hoke Community Medical Center Service Area

Zip Code	County	City/Town	CAGR 2009-2016
28304	Cumberland	Fayetteville	0.18%
28306	Cumberland	Fayetteville	1.35%
28314	Cumberland	Fayetteville	0.95%
28371	Roberson	Parkton	1.42%
28357	Hoke/Roberson	Lumber Bridge	0.65%
28376	Hoke	Raeford	2.91%
28348	Cumberland	Hope Mill	1.62%
28386	Hoke/Roberson	Shannon	1.14%
28377	Hoke/Roberson	Red Springs	1.10%
Total			1.34%

Source: Claritas; Exhibit 30, Table 50

c. Percent CFVMC Volume Shift to Hoke Community Medical Center

The following assumptions related to the percent market volume shift for outpatient cases are used in the projections.

Percent Market Volume Shift
Emergency Visit Projections
Existing CFVMC to Hoke Community Medical Center
October 2013 – September 2016

Zip Code	City	County	2014	2015	2016
28304	Fayetteville	Cumberland	21.0%	25.5%	30.0%
28306	Fayetteville	Cumberland	21.0%	25.5%	30.0%
28314	Fayetteville	Cumberland	21.0%	25.5%	30.0%
28371	Parkton	Hoke	14.0%	17.0%	20.0%
28357	Lumber Bridge	Hoke/Robeson	14.0%	17.0%	20.0%
28376	Raeford	Hoke/Robeson	63.0%	76.5%	90.0%
28386	Shannon	Hoke/Robeson	14.0%	17.0%	20.0%
28377	Red Springs	Robeson	14.0%	17.0%	20.0%

Source: Exhibit 30, Table 51

Zip level volume shifted was based upon geographic proximity of the zip population to the proposed HCMC community hospital, discussion with CFVHS representatives working and living in the proposed service area, congestion at the

existing campus of CFVMC on Owen Road, and mileage and driving time analysis. In addition, emergency volume shifts are slightly higher as it is assumed more of the population geographically closer will seek emergency care at the location closest to home. Separate assumptions were assumed by zip code.

The following factors were considered important to the determination of the percent of existing market volume projected to shift from the current CFVMC to the new HCMC.

- Physician support for the project is overwhelming.
- Community support for the project is overwhelming.
- There currently are 5 CFVHS employed physician practices with 14 physicians in the defined service area: including Hoke Family Medical Center, Hope Mills Family Care, Cape Fear Valley Pediatric Care, Cape Fear Valley OB\GYN Clinic, and Perinatology Clinic.
- Congestion and traffic on Owen Road, where CFVMC is located, will continue to grow with the expected population growth in the defined service area.
- HCMC offers a choice for inpatient and outpatient care closer to home.
- The proposed location of HCMC on Hwy 401 will result in ease of access to the existing population in the defined zip code service area.
- Some patients will continue to seek care at other CFVHS hospitals, therefore 100% of the demand for inpatient services in the service area will not shift to HCMC.

Step 3. Project Hoke Community Medical Center Acute Care Emergency Visits

Projected HCMC emergency visits for the first three years of operation were calculated using FY 2009 zip code level emergency visits multiplied by the zip code specific population compound annual growth rate and percent volume shift from CFVMC. HCMC assumed the new facility would grow at a reasonable rate and projected acute care medical surgical inpatient patient days by zip code as previously discussed and reflected in the following table. Projected in-migration also is reflected in the following table.

Hoke Community Medical Center
Projected Emergency Visits Defined Service Area
2009 – 2016

Zip Code	Town	Actual	Projected						
		CY 2009	2010	2011	2012	2013	2014	2015	2016
28304	Fayetteville	11,859	11,880	11,901	11,922	11,943	11,964	11,985	12,006
Projected Volume Shift						21.0%	21.0%	25.5%	30.0%
HCMC Projected Visits						2,508	2,512	3,056	3,602
28306	Fayetteville	13,773	13,959	14,148	14,339	14,533	14,729	14,928	15,130
Projected Volume Shift						21.0%	21.0%	25.5%	30.0%
HCMC Projected Visits						3,052	3,093	3,807	4,539
28314	Fayetteville	12,427	12,545	12,664	12,784	12,905	13,028	13,151	13,276
Projected Volume Shift						21.0%	21.0%	25.5%	30.0%
HCMC Projected Visits						2,710	2,736	3,354	3,983
28371	Parkton	2,166	2,197	2,228	2,259	2,291	2,324	2,357	2,390
Projected Volume Shift						14.0%	14.0%	17.0%	20.0%
HCMC Projected Visits						321	325	401	478
28357	Lumber Bridge	724	729	733	738	743	748	753	758
Projected Volume Shift						14.0%	14.0%	17.0%	20.0%
HCMC Projected Visits						104	105	128	152
28376	Raeford	6,104	6,282	6,464	6,652	6,846	7,045	7,250	7,460
Projected Volume Shift						63.0%	63.0%	76.5%	90.0%
HCMC Projected Visits						4,313	4,438	5,546	6,714
28386	Shannon	491	497	502	508	514	520	526	532
Projected Volume Shift						14.0%	14.0%	17.0%	20.0%
HCMC Projected Visits						72	73	89	106
28377	Red Springs	750	758	767	775	783	792	801	810
Projected Volume Shift						14.0%	14.0%	17.0%	20.0%
HCMC Projected Visits						110	111	136	162
HCMC Zip Code ED Visits						13,189	13,393	16,516	19,736
Total HCMC ED Including In-migration						14,655	14,881	18,352	21,928
Convert to FYs							FFY2014	FFY2015	FFY2016
Total HCMC ED Volume including In-migration							**14,825**	**17,484**	**21,034**
Total Service Area ED Treatment Spaces Needed			1,333				11	13	16

Source: Exhibit 30, Table 51

The previous table reflects projected emergency visits projected for HCMC based upon historical volumes and population growth.

Hoke Community Medical Center
Projected Emergency Department Visits and Treatment Areas
October 2013 – September 2016

	PY1 FFY 2014	PY2 FFY 2015	PY3 FFY 2016
Total HCMC ED Volume	14,825	17,484	21,034
Total Service Area ED Treatment Spaces Needed	11	13	16

Source: Exhibit 30, Table 51

The previous table reflects total emergency department visits, and emergency department treatment rooms needed based upon American College of Emergency Physicians emergency planning capacity of 1,333 Emergency Visit per Treatment Room for Emergency Departments with 20,000 Visits, included in Exhibit 30, Table 58, which results in a need at HCMC for 16 emergency treatment rooms in the third year of operation.

10. Projected Ancillary Services Utilization

As previously discussed, HCMC will be a community hospital with a full range of inpatient and outpatient services. Equipment planning for the proposed HCMC was completed by CFVHS's internal management staff with assistance from BBH Design.

HCMC will have a comprehensive array of diagnostic equipment including:

- A full-service laboratory;
- A full-service pharmacy;
- A new 16-slice CT scanner (replacement of an existing CT scanner which will be relocated); and,
- A contract with vendor for mobile MRI scanner service.

Other imaging equipment at HCMC will include:

- One digital routine x-ray unit/room;
- One digital combination x-ray/fluoro unit/room;
- One nuclear medicine camera (no coincidence circuitry);
- One digital ultrasound unit;
- Two portable, digital x-ray units for use on the patient floors, ED, and ORs;
- One Mini C-Arm unit—for use in the ED for Post-Reduction studies (x-ray after the fracture is reduced);
- Two multi-purpose C-Arm units for use in the ORs; and,
- PACS system connecting HCMC to CFVHS.

A complete list of diagnostic imaging equipment valued at more than $10,000 is included in Exhibit 29.

In addition, a substantial amount of laboratory and pharmacy equipment will be needed at HCMC. A complete list of laboratory equipment valued at more than $10,000 is included in Exhibit 29.

Additional equipment itemized in Exhibit 29 includes equipment needed for physical therapy, speech therapy, and respiratory therapy services available for inpatients and outpatients.

Ancillary utilization projections were calculated based upon actual ancillary utilization patterns for the defined service area. Acuity adjusted admission, outpatient visits, and emergency visits at CFVHS hospitals were analyzed to determine the actual volume of ancillary services utilized. HCMC assumes that projected ancillary utilization at HCMC will imitate current ancillary utilization patterns determined for the acuity adjusted zip code volume at CFVHS.

Relevant data was acquired from CFVHS internal hospital systems for FY 2007 through FY 2009 and a three-year average was determined. Inpatient ancillary volumes for HCMC were projected using the three-year average percent of total inpatient discharges. Outpatient ancillary volumes were projected using the three-year average percent of total outpatient and ED visits as shown in the following table. Historical data and relevant percentages used to project future ancillary volume are included in Exhibit 30, Table 71. Data was analyzed to determine the relationship between ancillary volumes and inpatient, outpatient, and ED volumes.

Hoke Community Medical Center
Projected Ancillary Service Utilization
October 2013 – September 2016

	PY1 FFY 2014	PY2 FFY 2015	PY3 FFY 2016
MRI (mobile)	630	768	919
CT	3,003	3,655	4,374
Ultrasound	1,631	1,983	2,374
Other Radiology	7,730	9,402	11,253
Pharmacy Units	244,752	303,243	362,385
Lab Units	70,610	86,904	103,907
Speech Therapy	714	872	1,043
Respiratory Therapy	6,346	8,118	9,677
Physical Therapy	9,338	11,353	13,588

Source: Exhibit 30, Table 70

The previous table reflects projected ancillary services utilization at HCMC in the defined service area for the first three years of the proposed project.

Conclusion

The reasonableness of locating a new community hospital in Hoke County near the Cumberland County border to serve residents of Hoke and southwest Cumberland Counties has been substantiated by the projected need for services due to significant population growth experienced over the past years and volumes which are projected to continue in the foreseeable future.

Upon completion, HCMC can begin to meet the growing acute care needs in the defined service area. The table below shows the projected patient days and occupancy rates for HCMC in the first three years of operation. Note that HCMC's projected occupancy rate will be greater than the target occupancy rate required by Policy AC-5 – Replacement of Acute Care Capacity in the *2009 State Medical Facilities Plan*. As the defined service area continues to grow, its future acute health care needs can be met by the development and expansion of HCMC.

Hoke Community Medical Center
Average Daily Census, Licensed Beds, and Occupancy
October 2013 through September 2016

	PY1 - FFY 2014	PY2 - FFY 2015	PY3 - FFY 2016
Total Pt Days	7,463	9,674	11,524
Total Cases	2,012	2,650	3,152
ADC	20.4	26.5	31.6
Projected Acute Care Capacity	41	41	41
Occupancy	49.9%	64.6%	77.0%

Source: Exhibit 30, Table 1

The development of the 41 CON-approved CFVHS acute care beds, two operating rooms (one of which is the CON approved operating room not yet developed at CFVMC/CFV West), and a new C-section room at HCMC will result in increased access to high quality patient care services in a local community that has depended for years on CFVHS inpatient facilities and physicians. The proposed project responds to one of the central purposes of the CON Law: to encourage efficient, cost-effective solutions which maximize existing resources rather than unnecessarily duplicate existing services.

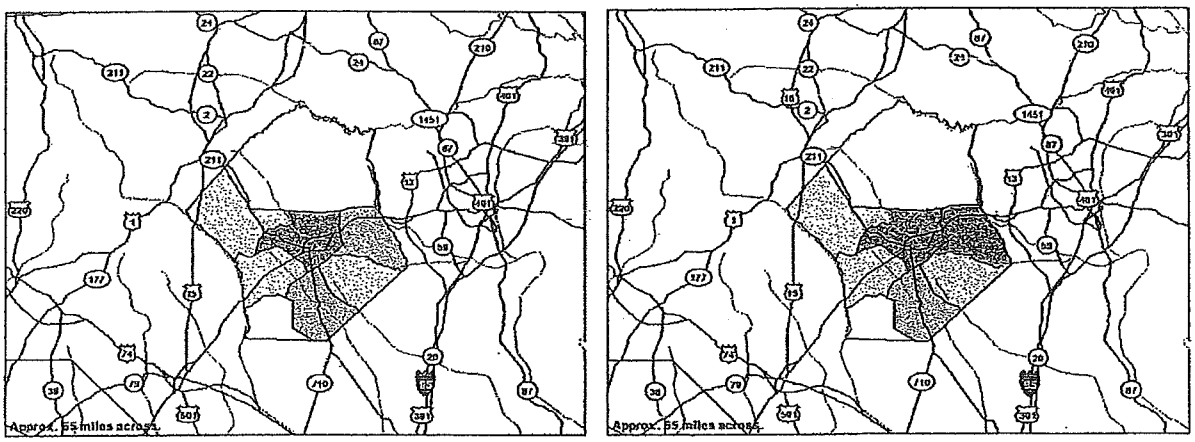
(c) Document that the facility is needed at the proposed site as opposed to another area of the service area.

HCMC will be located in Hoke County on U.S. Highway 401 in Cumberland County, approximately two to three miles from the Cumberland County border as previously discussed. The proposed site represents the most reasonable location in the two county area as opposed to another location in the zip service area or the combined two county geographic area. U.S. Highway 401 is the main thoroughfare through Hoke County and all roads in Hoke County lead to US Hwy 401. The location will be easily accessible from areas within the defined zip service area. Furthermore, the population base in eastern Hoke County and

southwestern Cumberland County is the fastest growing geographic area in the market as illustrated in the following maps and discussion.

Hoke County Population Density per Square Mile

1990 **2000**



Source: US Census

As shown in the previous maps, between 1990 and 2000 the population growth in Hoke County was on the eastern side of the County. An analysis of census tract population for Hoke County also illustrates that the population growth is projected to continue in the eastern part of the county as shown in the following table.

Hoke County Census Tract Population Data

	Total		Women 15-44		65+		Under 18	
Census Tract	2009	2014	2009	2014	2009	2014	2009	2014
9701	23,531	28,266	5,945	6,647	1,022	1,648	7,959	9,298
9702	9,292	10,243	1,800	1,929	728	1,103	2,468	2,668
9703	4,988	5,133	950	949	854	960	1,175	1,200
9704	6,814	7,351	1,498	1,620	490	799	2,108	2,238
Total	44,625	50,993	10,193	11,145	3,094	4,510	13,710	15,404
				Percent of Total				
9701	52.7%	55.4%	25.3%	23.5%	4.3%	5.8%	33.8%	32.9%
9702	20.8%	20.1%	19.4%	18.8%	7.8%	10.8%	26.6%	26.0%
9703	11.2%	10.1%	19.0%	18.5%	17.1%	18.7%	23.6%	23.4%
9704	15.3%	14.4%	22.0%	22.0%	7.2%	10.9%	30.9%	30.4%

Source: Claritas

As shown in the previous table, the largest and fastest growing population base in Hoke County is census tract 9701. This census tract includes the population in eastern Hoke County and the active base for Fort Bragg.

CFVHS Patient Origin – Inpatient Surgery

County	Percent
Cumberland	75.2%
Robeson	7.2%
Hoke	4.3%
Sampson	4.3%
Harnett	2.6%
Bladen	2.4%
All Others	3.9%
Total	100.0%

Source: CFVHS Internal Data

CFVHS Patient Origin – Outpatient Surgery

County	Percent
Cumberland	74.4%
Robeson	9.0%
Hoke	4.5%
Sampson	3.7%
Harnett	2.7%
Bladen	2.0%
All Others	3.7%
Total	100.0%

Source: CFVHS Internal Data

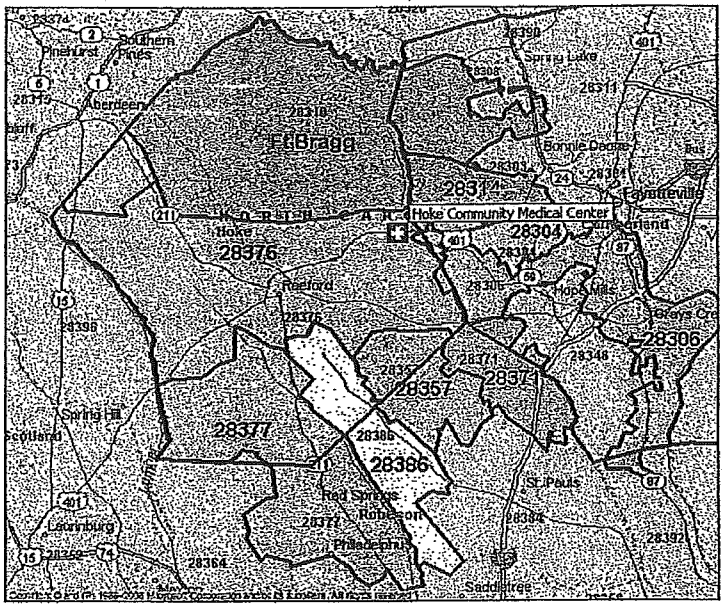
5. (a) Describe the geographic boundaries of the proposed service area (i.e. area in which patients to be served reside) for the facility or services under review and explain the rationale for the service area boundaries proposed.

The proposed HCMC Service Area includes Hoke County, zip codes in southwest Cumberland County, and zips in northern Robeson County, as shown on the following service area map.

The proposed service area includes three zip codes in southwest Cumberland, all of Hoke County and one zip in the northern corner of Robeson County. As reflected in Exhibit 30, Table 13 approximately 30% of the total population in zip codes 28314, 28306 and 28304 are geographically closer to the proposed HCMC. Exhibit 30, Table 14 also shows that over 30% of the population of the three zips which straddle the Hoke-Robeson County line are geographically closer to the proposed site for HCMC.

(b) Provide a map indicating the geographical relationship of the proposed service area to your facility or services under review.

Hoke Community Medical Center
Zip Service Area



(c) Project patient origin (by percentage) by county of residence for the proposed project for the first two years of operation following completion of the project. (See example format below)

HCMC Patient Origin – Inpatient Patient Days

County	PY1	PY2
Cumberland	59.6%	59.5%
Hoke	36.3%	36.5%
Robeson	4.0%	4.0%
Total	100.0%	100.0%

Source: Exhibit 30, Table 9
Note: 10% Other In-migration allocated to Cumberland and Hoke County as previously discussed in responses to CON Criteria and Standards.
Numbers may not foot due to rounding.

HCMC Patient Origin – Outpatient Visits

County	PY 1	PY2
Cumberland	70.6%	70.2%
Hoke	25.1%	25.5%
Robeson	4.3%	4.3%
Total	100.0%	100.0%

Source: Exhibit 30, Table 21
Note: 10% Other In-migration allocated to Cumberland and Hoke County as previously discussed in responses to CON Criteria and Standards.
Numbers may not foot due to rounding.

HCMC Patient Origin – Emergency Visits

County	PY 1	PY2
Cumberland	63.6%	63.2%
Hoke	31.8%	32.1%
Robeson	4.7%	4.7%
Total	100.0%	100.0%

Source: Exhibit 30, Table 53
Note: 10% Other In-migration allocated to Cumberland and Hoke County as previously discussed in responses to CON Criteria and Standards.
Numbers may not foot due to rounding.

HCMC Patient Origin –Surgery Cases

County	PY 1	PY2
Cumberland	61.4%	61.0%
Hoke	34.0%	34.4%
Robeson	4.6%	4.6%
Total	100.0%	100.0%

Source: Exhibit 30, Table 37
Note: 10% Other In-migration allocated to Cumberland and Hoke County as previously discussed in responses to CON Criteria and Standards.
Numbers may not foot due to rounding.

(d) Explain all assumptions and the specific methodology used to project patient origin, particularly if the projected patient origin is different from the facility's historical patient origin.

Please see the response in III.5. which describes the service area. Patient origin was projected based upon population projections and projected volume shifted from CFVHS as reflected in III.1.b. and Exhibit 30.

6. (a) Identify all providers of each service component included in the proposed project located in the service area and provide the utilization at each of these providers during the last full fiscal year prior to submission of this application.

Acute Care and Surgical Service Providers in the Defined Service Area

The proposed HCMC Service Area includes zip codes in southwest Cumberland County, eastern Hoke County with a few of those Hoke County zip codes straddling Robeson County. CFVHS is the only inpatient service provider in the defined service area. Historical utilization is reflected in the following table.

Cape Fear Valley Medical Center
Acute Care Bed Utilization – FY 2009

Acute Care Hospital	Zip Code	Licensed and Operational Acute Care Beds	Licensed Acute Care Patient Days	Licensed Acute Care Inpatient Admissions	Average Daily Census (ADC)	Occupancy Rate
Cape Fear Valley Medical Center	28304	490	149,828	29,108	410.5	83.8%

Source: 2010 Annual License Renewal Application

There are three providers of surgical services in the defined service area. The following table shows utilization data of existing providers in the last full fiscal year prior to the submission of this Application.

Fayetteville Ambulatory Surgery Center Utilization – FY 2009

Surgical Services Provider	Zip Code	Licensed and Operational Surgical Operating Rooms	Inpatient Cases	Ambulatory Cases
Cape Fear Valley Medical Center	28304	13	6,239	5, 804
Highsmith Rainey Specialty Hospital	28301	4	72	2,511
Fayetteville Ambulatory Surgery Center	28304	11	0	14,210
Total		24	6,311	22,525

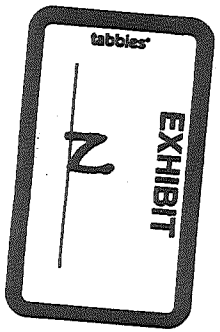
Source: 2010 Annual License Renewal Applications
** Excludes open heart and C-Section rooms and volumes at CFVMC*

(b) Explain and provide specific documentation of the inadequacy or inability of the existing providers to meet the identified need.

Projected utilization for HCMC is based upon a shift in the service area inpatient volume from the existing CFVMC to a community facility which is more accessible to the local population. This Application is a the next logical step in CFVHS's commitment to provide health care services to residents of Hoke and southwest Cumberland County as those populations grow to a level that support inpatient and outpatient services in a community-based facility. By locating inpatient, outpatient,

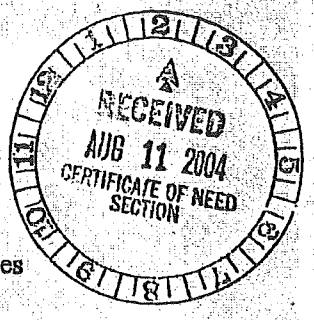
Cape Fear Valley Health System
Facility Utilization
FY2011 - FY2018, data from page 50 of the CON Application.

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
CFVHS	170,061	172,494	174,963	177,466	180,005	182,581	185,194	187,844
HCMC				3,110	8,384	10,445	11,524	11,524
CFV-North					6,296	13,472	15,670	16,986
CFVMC	170,061	172,494	174,963	174,357	165,326	158,664	158,000	159,334
CFVHS								
490-bed Utilization	95.1%	96.2%	97.8%					
531-bed Utilization				91.6%				
596-bed Utilization					82.7%	83.7%	85.1%	86.3%
HCMC								
41-bed Utilization				20.8%	56.0%	69.6%	77.0%	77.0%
CFV-North								
65-bed Utilization					26.5%	56.6%	66.0%	71.6%
CFVMC								
490-bed Utilization	95.1%	96.2%	97.8%	97.5%	92.4%	88.5%	88.3%	89.1%



CAPE FEAR VALLEY MEDICAL CENTER – NEW ACUTE CARE BEDS

Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT PROJECT
State of North Carolina, Department of Health and Human Services



OFFICE USE ONLY
Project I. D. Number: M-7093-04
Proposal Type: _____

Batch Category:
Beginning of Review:

I. IDENTIFICATION

1. Legal Name of the Applicant: The applicant is the existing legal entity (i. e., person or organization) that will own the facility. If the facility will be leased, complete two copies of Section VIII for the project; one with the lessor as the applicant and the other with the lessee as the applicant.

Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System
(Name of Applicant)

1638 Owen Drive, Post Office Box 2000
(Street & Number)

Fayetteville	**NC**	**28302-2000**	**Cumberland**
(City)	(State)	(Zip)	(County)

2. Name of Parent Company (if applicable):

N/A

(Street & Number)

(City) (State) (Zip)

3. Person to whom all correspondence and questions regarding this application should be directed:

Lawrence C. Miller	**Director of Reimbursement**
(Name)	(Title)

1638 Owen Drive, Post Office Box 2000
(Street & Number)

Fayetteville	**NC**	**28302-2000**	**(910)609-6440**
(City)	(State)	(Zip)	(Area Code & Phone Number)

EXHIBIT
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CAPE FEAR VALLEY MEDICAL CENTER – NEW ACUTE CARE BEDS

I. IDENTIFICATION

4. Name of Lessor (If applicable):

County of Cumberland
(Street & Number)

117 Dick Street, Suite 512

Fayetteville	**NC**	**28302-1829**
(City)	(State)	(Zip)

5. Name of Lessee: (If applicable) (Attach copy of lease agreement)

Cumberland County Hospital System, Inc.

1638 Owen Drive
(Street & Number)

Fayetteville	**NC**	**28304**
(City)	(State)	(Zip)

6. Name of Management Company: (If applicable) (Attach copy of management contract) **(See Exhibit 1)**

Cumberland County Hospital System, Inc.

1638 Owen Drive
(Street & Number)

Fayetteville	**NC**	**28304**
(City)	(State)	(Zip)

7. Name of existing/proposed facility as it will appear on a certificate of need. (i.e. Jones Health Care d/b/a Jones of Smithburg):

Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System
(Name of Facility)

Cumberland
(County)

1638 Owen Drive, Post Office Box 2000	**Fayetteville**	**NC**	**28302-2000**
(Street & Number)	(City)	(State)	(Zip)

CAPE FEAR VALLEY MEDICAL CENTER – NEW ACUTE CARE BEDS

I. IDENTIFICATION

8. Provide a brief project description to identify the basic components of the project including the bed complement and proposed levels of care. This should be a one-sentence description for identification purposes only.

The addition of 44 acute care beds.

II. SCOPE OF SERVICES/QUALITY OF CARE

1. Describe all components of the proposed project. Include a discussion of the proposed beds, equipment to be purchased, and services.

Historical high inpatient utilization at Cape Fear Valley Medical Center over the past 9 quarters has severely challenged our ability to ensure access to services in a timely manner.

Multiple resources are consumed daily by the Health System to improve patient throughput and reduce length of stay in order for us to accommodate patients awaiting admission through our Emergency Department, direct admissions from physicians' offices, and patients waiting at home or at other hospitals for transfer.

Cape Fear Valley Health System requests permission to add the forty-four (44) acute beds determined to be needed in Cumberland County, according to the 2004 State Medical Facilities Plan, to its licensed inventory of beds. Forty-one (41) of the beds are proposed to be used as general acute medical-surgical beds and the remaining three (3) are proposed to be classified as intensive care beds.

These beds can be accommodated in existing space within the Medical Center, some of which has been previously licensed bed space converted to office, waiting, and support areas. The remaining available space is within areas we utilize for short-term/observational patient care yet meets state code requirements for licensed bed space. The forty-four (44) beds will increase Cape Fear Valley Medical Center's acute licensed capacity to 438 beds.

The up-fitting time and expense for Cape Fear Valley Medical Center will be minimal. Twenty-eight (28) of the additional forty-four (44) acute care beds available can be operational within 90 days of the CON Section's approval. The remaining sixteen (16) can be operational within twelve (12) months of the Section's approval.

The following presents the logistics of the bed locations and are identified on floor line drawings in Exhibit 9:

- **One (1) bed will become operational on 3-North and added to the twenty-four (24) bed Nephrology Unit.**
- **Three (3) beds will become operational in the Cardiac Surgery Intensive Care Unit and added to its current eight (8) bed capacity.**
- **Nine (9) beds will become operational within the 3-North Observation Unit and utilized for medical-surgical patients.**
- **Fifteen (15) beds will become operational within the 2-East Observation Unit and utilized for medical-surgical patients.**

II. SCOPE OF SERVICES/QUALITY OF CARE

1. (Continued)

- **Sixteen (16) beds will become operational on 4-North, an area utilized in the past as a nursing unit. This area is currently utilized as office and support space and will require minimal modernization to convert for clinical purposes.**

Basic furniture and room/unit equipment exists for twenty-eight (28) of the forty-four (44) proposed beds.

The remaining sixteen (16) beds, previously licensed, require modernization with reconstruction of a Nurses' station and should be completed within twelve (12) months.

Sixteen (16) Hill-Rom Versa Care Beds, along with over-bed tables, bedside tables, recliners, and side chairs will be purchased for these rooms. Total moveable equipment is estimated at $292,495.

II. SCOPE OF SERVICES/QUALITY OF CARE

2. Describe any changes or innovations in existing services, either outpatient and/or inpatient, that will be associated with this project. Explain how this project will differ from any existing services currently being provided in the service area.

There are no planned changes to existing services. The decision to reclaim space on 4-North at the Medical Center to accommodate the 16 beds will require relocation of some current offices but will have no effect upon the provision of clinical services.

The beds within the two Observation units, which are proposed to be licensed as part of this application, will be utilized for adult medical-surgical patients. This is a continuation of the scope of service and patient type currently being experienced in these units. Medical-surgical patients are assigned to Observation units for the purpose of determining the need to admit or to observe post-procedurally until discharge criteria are met. However, approximately 15 patients per day in our Observation Unit beds have orders to be admitted but cannot be placed in duly licensed beds because of the high census levels throughout the Medical Center.

II. SCOPE OF SERVICES/QUALITY OF CARE

3. Explain how the administrative and clinical departments will be organized to accommodate the provision of the additional services or equipment proposed in this application.

Included in Exhibit 22 is a copy of the organizational chart for Cape Fear Valley Health System. The addition of the requested beds will not effect any changes in the current organizational structure. The beds will be incorporated into existing areas where nursing care is provided or will be provided, and responsibility for the care of patients occupying those beds will remain with the current nursing leadership.

II. SCOPE OF SERVICES/QUALITY OF CARE

4. (a) Describe any additional services to be offered or other potential components of this project that are being planned for future development. Provide the time frame in which these components/services would be made available.

There are no additional services to be offered in relation to this project. The addition of 44 beds will allow us to improve current service to our patients who frequently lie on stretchers in our Emergency department or at home waiting for an available bed.

The administrative staff, physician leadership and Board of Trustees, along with HDR, a Nationally recognized leader in consultation regarding strategic facility planning, jointly developed a strategic master facility plan for the health care system over the past twenty-four (24) months. That plan (Exhibit 28) addresses bed and service needs for the next ten (10) years.

In concert with the strategic master facility plan and planning process, an application was filed by the Health System in June 2004 addressing future plans for growth and service improvement. Included within that application is a request to transfer 46 beds currently underutilized at Highsmith-Rainey Memorial Hospital to the Medical Center campus.

Review of the projections which follow demonstrates that approval to transfer the 46 beds from Highsmith-Rainey Memorial Hospital and approval to operate the 44 beds represented in this application would still yield an occupancy rate of 80.8% for total acute care beds the Medical Center campus:

FY 2009

The Pavilion Application – 46 acute beds added from Highsmith

Acute Care Beds	% Occupancy	ICU Beds	% Occupancy	Total Acute Care Beds	% Occupancy
390	88.4%	50	92.5%	440	88.9%

CAPE FEAR VALLEY MEDICAL CENTER – NEW ACUTE CARE BEDS

II. SCOPE OF SERVICES/QUALITY OF CARE

4. (a) (Continued)

FY 2009

44 New Acute Care Beds

Acute Care Beds	% Occupancy	ICU Beds	% Occupancy	Total Acute Care Beds	% Occupancy
397	86.8%	41	112.8%	438	89.3%

Aggregation of Applications

FY 2009

Combined

Acute Care Beds	% Occupancy	ICU Beds	% Occupancy	Total Acute Care Beds	% Occupancy
431	80.0%	53	87.3%	484	80.8%

II. SCOPE OF SERVICES/QUALITY OF CARE

4. (Continued)

(b) Submit a copy of the planning document for the project if one exists.

See Exhibit 28.

(c) Submit an itemized copy of the applicant's three-year capital expenditure budget. How does the proposed project impact this budget?

See Exhibit 7. This project is included in the 2005 Capital Budget.

II. SCOPE OF SERVICES/QUALITY OF CARE

5. Discuss alternative solutions, including the implications of maintaining the status quo and/or modifying existing resources.

Maintaining Status Quo

Sustained occupancy rates of 90% or greater for medical-surgical beds over a period of 9 quarters has contributed to significant capacity management issues for the Medical Center. Likewise, intensive care beds have operated for 6 quarters with occupancy rates greater then 90%.

In addition to 15-20 patients per day who have admission orders and are housed, out of necessity in observation beds, patients with admission orders for an ICU bed and/or medical-surgical bed frequently have to be held in the Emergency Department due to non-availability of beds.

Efforts by the Health System to improve discharge planning/execution and patient throughput have been substantial but insufficient to meet the incoming volume of patients. The Medical Center, specifically, has struggled with capacity issues to the point that failure to do more than the status quo would be impractical at best. This is especially true in light of our ability to put the proposed beds into operation almost immediately and at minimal cost.

Renovation

Careful attention has been given to evaluation of space within the Medical Center and its suitability for conversion to inpatient bed space. The only such space available and appropriate for said purpose is the space being proposed as part of the scope of this application.

New Construction

An alternative would be to consider the construction of another wing on the campus or an additional unit above the fourth floor of the current Patient Services Tower.

New construction would be more costly than the proposed method estimated at $1,851,245 for minimum renovation and equipment as presented in Section VIII.1. Capital Costs and Financing.

Aside from the obvious difference in the cost of new construction versus renovation, the addition of a new wing would likely affect existing structures on campus such as the heliport or access perimeter roads, which would escalate the overall project cost even further.

New construction to gain only 44 beds is unnecessary since those beds can be integrated into space, which is currently available.

II. SCOPE OF SERVICES/QUALITY OF CARE

6. Identify all relevant facility, programmatic, and service specific licensure, certification, and accreditation standards associated with the proposed project. How will the project be consistent with these standards?

- **Cape Fear Valley Health System is licensed by the NC Department of Health and Human Services (NCDHHS).**
- **Cape Fear Valley Health System has provider approval from the US Department of Health and Human Services (USDHHS).**
- **Cape Fear Valley Health System has approval under the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).**
- **Radiology and Nuclear Medicine are accredited by the American College of Radiology (ACR).**
- **Our Cancer Center is approved by the American College of Surgeons Commission on Cancer as a Community Hospital Comprehensive Cancer Program.**
- **The Laboratory Services are accredited under College of American Pathologists (CAP).**
- **Our Rehabilitation Center is accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF).**
- **The Radiology Department has a license from the NC Division of Radiation, Department of Environment, Health and Natural Resources (NCDEHR).**
- **Cape Fear Valley Health System clinical services adhere to various practice parameters and standards to include: American Academy of Sleep Medicine (AASM), recommendations and practices of AORN, ANA, NLN, ASPAN, AACN, OSHA regulations, CLIA, and Standards of Practice for Physical Therapy.**

Each of these standards and accreditations is further indication of the quality standards within which the component services of the project will operate.

II. SCOPE OF SERVICES/QUALITY OF CARE

8. (Continued)

10A NCAC 14C .1203 PERFORMANCE STANDARDS

(a) The applicant shall demonstrate that the proposed project is capable of meeting the following standards:

(1) the overall average annual occupancy rate of all intensive care beds in the facility, excluding neonatal and pediatric intensive care beds, over the 12 months immediately preceding the submittal of the proposal, shall have been at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds; and

For the 12 months ended June 30, 2004, CFVMC experienced an occupancy rate of 98.0% in our 38 adult ICU beds.

(2) the projected occupancy rate for all intensive care bed in the applicant's facility, exclusive of neonatal and pediatric intensive care beds, shall be at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds, in the third operating year following the completion of the proposed project.

The projected occupancy for the third year after project completion for the 41 ICU beds is 112.9 percent.

(b) All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided.

1. **Intensive care occupancy levels have exceeded 90% since January 2003 and physicians clamor for greater capacity. Forecasting done, in conjunction with HDR planning staff, has not produced any findings that would imply a reduction in the utilization of intensive care beds.**
2. **Recruitment of physicians has resulted in the addition of 60 physicians to the community over the past year and active recruitment continues in the specialties of neurosurgery, vascular surgery, and orthopedics, all of whom require intensive care bed access.**
3. **Cape Fear Valley Health System's positioning along the I-95 corridor will continue to serve as a conduit for trauma cases, a significant number of whom will require intensive care services.**
4. **The Medical Center is turning down an average of eleven (11) patient referrals per month from other facilities during calendar year 2004.**
5. **The percentage of emergency department visits requiring intensive care services will follow historical patterns and proportions.**

III. NEED/DEMAND

1. (a) Describe, in specific terms, the unmet need that necessitated the inclusion of each of the proposed project components (i.e., beds, services, and medical equipment), as set forth in the description of the scope of services in Section II.1.

- **The growing demand for medical patient admissions has created significant challenges regarding placement at appropriate levels of care, infection control, staff skill mix and patient/physician/staff dissatisfaction.**
- **The "mushrooming" medical population has forced us to place medical patients on surgical units, the gynecological unit and step-down units in order to reduce long stays in the Emergency Department or to accommodate them as direct admissions. This practice evolved out of necessity but has frequently negatively impacted our ability to accommodate elective surgical cases, a situation which, in addition to challenges previously mentioned, significantly affects revenue.**
- **In order to simply accommodate the volume of patients over the past several quarters, additional space has been renovated to house observation-status patients. Efforts have been underway for two- to-three years to make provision for these observation and "day" patients such that we could avoid having these occupy our licensed in-patient beds. In spite of creating an additional 28-bed observation unit, a post-cardiac catheterization recovery unit and increasing our telemetry capability for observation beds by 15, we continue to experience several days per week where patients with admission orders occupy observation beds because acute care beds are not available.**
- **The average time for an Emergency Department patient awaiting admission to a bed is 13 hours and 30 minutes.**
- **Patient throughput and bed management is a daily priority for the Medical Center, and significant resources are expended to facilitate admissions, discharges, surgical schedules and clinical procedures.**
- **Daily bed meetings occur at 7:30 A.M. and 4:00 P.M. to assess bed needs and strategize for enhancement of throughput. Frequently, additional meetings are convened during very high census or service-specific crisis periods such as having more ICU patients than beds available.**
- **Staff from Nursing Administration, Bed Control, Care Coordination, Housekeeping and Patient Transportation, at a minimum, are involved in problem solving to keep patients moving throughout the system and minimize the impact on Emergency Department and Post Anesthesia Care Unit operations.**
- **We have sustained occupancy levels averaging 96% over 5 quarters in our existing intensive care units restricting our ability to accommodate needs within the Health System and to accept outside referrals.**

III. NEED/DEMAND

1. (a) (Continued)

- **"Overnighting" critical post-operative patients in the Post Anesthesia Care Unit (PACU) occurs 2-3 times per month due to non-availability of ICU beds.**
- **Critical patients frequently remain in the Emergency Department for more than 8 hours due to non-availability of ICU beds.**
- **The need has driven the Medical Center to the necessary practice of utilizing observation beds for licensed bed purposes for some time, and the strategic analysis and projections provide no indication that this pattern will reverse. This dilemma further validates the State's allocation of an additional 44 beds to Cumberland County in the 2004 State Medical Facilities Plan.**
- **The only other alternative we know to use to reduce the influx of patients is to cancel elective surgical cases. This has actually occurred on a few occasions, but eliminating the opportunity to generate revenue to help cover indigent care and complex medical cases which are poorly reimbursed is not fiscally prudent.**

III. NEED/DEMAND

1. (b) Provide statistical data that substantiates the existence of an unmet need for each project component and proposed services identified in Section II.1.

As referenced in Section II, in the spring of 2002, the Health System, in cooperation with HDR, undertook the development of a strategic master facilities plan to meet the needs of the community over the next 10 years.

The planning process was broad in scope and progressed over a period of 1½ years. As would be expected, significant emphasis was given the methodology for determining bed need over the course of those 10 years.

HDR uses an advanced computer-based modeling method to account for all the factors that affect inpatient bed need projections. Key functions of the system used in this project include:

- Population based with age and sex use rates calculated in terms of age and sex cohorts at the 5-year increments for male and female.
- Clinically based by defining for CFVHS the DRGs and principal procedure codes that represent 80% of admissions, or in this case 122 procedure codes, summarized into 32 service lines and further summarized into 9 centers of excellence.
- Service line specific projections with year-by-year volume calculations for 10 years to form the basis of service line strategies.
- Crosswalk translations to convert clinically based data to DRG based data for financial planning.
- Conversion of service line patient days into projected patient care unit patient days through a matrix process to allow for accurate bed need planning by service line under a revised care delivery model.

The full HDR Master Facility Planning documents are included in this application as Exhibit 28 for more specific, detailed review of the analysis. In summary, however, the demand calculations plus the introduction of utilization rate changes, forecasted the need to operationalize 100 additional beds by 2012. The overwhelming majority of those beds were determined to be needed for adult medical-surgical patients and intensive care patients.

Although methodologies of bed need determination vary, the analysis referenced herein and the analysis depicted in the 2004 State Medical Facilities Plan both validate the need for expanding bed capacity for Cumberland County.

III. NEED/DEMAND

1. (b) (Continued)

The literature supports, as does the Health Care Advisory Board in its publication regarding hospital capacity management, that an 85% occupancy level is the most efficient level and that efforts should be directed toward that achievement.

In referencing Section IV. 1 (a), Utilization, historical medical-surgical occupancy rates at Cape Fear Valley Medical Center have been 90% or greater for the past 9 quarters, and intensive care bed occupancy has exceeded 92% for 6 of those same 9 quarters.

By year end, FY 2004, surgical volumes at the Medical Center (excluding endoscopy, obstetrics, and cardiac) will have increased more than 9% over the past 3 years. This calculation includes actual volumes for 2001-2003 and 2004 annualized from year-to-date performance.

In spite of a growth rate of over 50% in our medical staff over the past six years, access to care remains problematic since occupancy has remained very high and the number of beds has not increased for several years.

Two new orthopedic surgeons are being actively recruited to the Medical Center for practices which have pent up demand requiring evaluation and elective surgery. The current orthopedic surgeons have as many as 25 patients waiting to be scheduled for surgery at the time, and the Health System opened an orthopedic clinic this past year in order to meet the need for timely follow up of orthopedic patients following Emergency Department visits because it was frequently impossible for them to be effectively "worked in" to crowded orthopedic office practices.

Growth opportunities exist in secondary markets but continually high occupancy rate severely restricts our ability to accommodate them, and several years of rejecting those opportunities result in driving that demand elsewhere.

Projections for growth remain minimal with less than one additional admission per day due largely to capacity saturation.

Assuming flat growth in volume over the next 3 years with a slight reduction in length of stay as a result of successful best practice initiatives, the only way to reduce the occupancy toward the target level is to increase the number of available beds.

III. NEED/DEMAND

1. (b) (Continued)

Although records were not maintained prior to January 2004, since that time, 15%-26% of the post anesthesia patients at the Medical Center per month have been held in the PACU from 1-12 hours after meeting recovery criteria due to non-availability of beds.

From April 2002 through April 2004, the Medical Center turned away 112 patient referrals from area hospitals due to non-availability of beds.

Of the 41 patients transferred into our cardiac intensive care units during the past 12 months, 14 were from Sampson Regional Medical Center and were the result of outreach in that market by a group of our cardiologists. These same cardiologists are strengthening their potential to capture additional market share by providing an office practice in that community and are following suit in Robeson County where professional relationships with referring physicians are strong as well.

Twenty-five percent (25%) of the patients transferred from other facilities to our non-cardiac intensive care units were transferred from Southeastern Regional Medical Center with conditions associated with the neurosurgical service. The Health System has 4 neurosurgeons on staff who have a backlog of patients requiring wait times for elective patients of 3-4 months. The physician recruitment office staff is working with these physicians to aggressively search for additional neurosurgeons in order to improve access.

An average of 10 patients per day with orders for admission are held in our Emergency Department due to the lack of adequate adult medical-surgical and intensive care beds.

III. NEED/DEMAND

7. Explain and provide specific documentation of the inadequacy or inability of existing providers to meet the identified need.

As discussed in Section III, Cape Fear Valley Medical Center operates at near maximum capacity as an acute care facility and, on multiple days per month, exceeds capacity.

Cape Fear Valley Medical Center has averaged greater than 85% occupancy for the past 5 years, and projections indicate no reversal in that pattern. Neighboring Southeastern Regional Medical Center is also experiencing increasing census levels.

The tertiary nature of Cape Fear Valley Medical Center attracts referrals for comprehensive care to Fayetteville, particularly with the large, diverse complement of medical specialists on staff. With the exception of cardiologists and thoracic surgeons at Southeastern Regional Medical Center, none of the other acute providers in our 6-county service area offer the sub-specialists in medicine and surgery to support the need for more acute care beds, comprehensive heart and vascular services, sleep disorders, high-tech cancer treatment and imaging (PET, 3.OT MRI, four IMRT capable linear accelerators), extensive cardiac and intensive care services.

Even in the event that another provider could assist with meeting the need in respect to patient volume, physician referral patterns are highly unlikely to change sufficiently to positively impact the problem.

Additionally, there are no known providers who are positioned to operationalize the available 44 beds as quickly and efficiently or as cost effectively as Cape Fear Valley Medical Center.

CAPE FEAR VALLEY MEDICAL CENTER – NEW ACUTE CARE BEDS

XII. ACTUAL PROPOSED SCHEDULE

Project the specific dates (i.e., month, day, and year) for each of the following milestones. If a milestone is not applicable, please enter NA and explain why it is not applicable on a separate page.

Note that the schedule which you propose is extremely important. The timetable you provide determines (1) the period of time during which the project must be developed, and (2) the time(s) at which the Agency shall request a progress report(s). Therefore, this schedule should reflect the actual dates each milestone is anticipated to be completed. If the CON decision is made on a later date than the one identified in 1.(a) in the timetable below, the schedule will be adjusted accordingly by the Certificate of Need Section.

1. Certificate of Need		
(a) Anticipated Date of Decision (90 to 150 days from beginning date of review period)		11/29/04
(b) Date of Issuance of the Certificate of Need (Date may not be less than 31 days following the decision date)		12/30/04
2. Financing		
(a) Obtaining construction financing		Available
(b) Obtaining permanent financing		Available
(c) Obtaining funds necessary to undertake project		Available
3. Design	28 Beds	16 Beds
(a) Completion of preliminary drawings	09/15/04	01/15/05
(b) Completion of final drawings and specifications	10/15/04	03/15/05
(c) Approval of final drawings and specifications by the Construction Section, Division of Facility Services	12/15/04	05/15/05
4. Construction		
(a) Approval of Site by Construction Section, DFS	12/15/04	05/15/05
(b) Contract award (Notice to Proceed)	01/04/05	06/01/05
(c) 25% completion of construction (25% of the dollar value of the contract in place	02/01/05	09/11/05
(d) 50% completion of construction	02/20/05	11/15/05
(e) 75% completion of construction	03/10/05	02/15/06
(f) Completion of construction	04/01/05	04/01/06
(g) Occupancy /offering of service(s)	04/15/05	04/15/06
5. Acquisition of Medical Equipment (Repeat as needed for each major project component)		
(a) Ordering equipment	N/A	01/15/06
(b) Arrival equipment	N/A	03/31/06
(c) Operation of equipment	N/A	04/15/06
6. Other Milestones		
(a) Licensure of Facility		
(b) Certification of beds		
(c) Other (Specify)		