May 31, 2011 Comments from Novant Health, Inc.
Regarding Rex Healthcare, Inc.
Acute Care Bed Certificate of Need Application for
a New 40-Bed Hospital in Wakefield (J-8670-11)
Submitted April 15, 2011 for May 1, 2011 Review

In accordance with N.C.G.S. Section 131E-185(a1)(1), Novant Health, Inc. submits the following comments regarding the CON Application of Rex Healthcare, Inc. to construct a separately licensed hospital in Wakefield (J-8670-11).

I. Introduction

The following applications were submitted in response to the need determination identified in the *2011 State Medical Facilities Plan* (*2011 SMFP*) for 101 acute care beds in Wake County:

- J-8660-11: WakeMed to spend $57.5 million to add 79 beds at its main Raleigh campus,
- J-8661-11: WakeMed Cary to spend $2.1 million to add 22 beds
- J-8667-11: Rex Healthcare to spend $278.8 million to add 11 beds, replace 115 acute care beds, and change in scope for Project ID J-8532-10 (cardiovascular renovation expansion project)
- J-8669-11: Rex Healthcare to spend $136.6 million to build a separately licensed 50-bed hospital in Holly Springs
- J-8670-11: Rex Healthcare to spend $102.2 million on a separately licensed 40-bed hospital in Wakefield
- J-8673-11: Holly Springs Hospital II, LLC to build a 50-bed $77.7 million hospital in Holly Springs

Rex Healthcare (Rex) proposes to develop a new, separately licensed 5-story acute care hospital with a 31-bed medical/surgical unit, 3-bed ICU, 6-bed LDRP unit, five unlicensed observation beds, one dedicated C-Section OR, one shared operating room (relocated from Rex Hospital), a CT scanner (relocated from the Rex Healthcare of Wakefield imaging center), and other hospital services. The fifth story of the proposed hospital is a "mechanical penthouse."

The address for the Rex Wakefield Hospital is 1200 Governor Manly Way, Raleigh, NC 27614. The new hospital will be located at the campus of Rex's existing outpatient surgery with 3 dedicated outpatient ORs and diagnostic imaging center, Rex Healthcare of Wakefield, at the corner of Capital Boulevard and New Falls of the Neuse Road in northern Wake County, zip code 27614. As stated at pages 114 and 154-55 of the Rex Wakefield CON Application the services offered today at Rex Healthcare of Wakefield include:

- Urgent Care
- Wellness Center
- Surgery Center with 3 ORs
- Imaging center with MRI, CT, ultrasound, general radiography, digital mammography, and bone density screening

- Laboratory Services
- Sleep Studies
- Satellite Cancer Center
- Medical Office Building

II. CON Review Criteria

N.C.G.S. 131E-183 (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.

A. Methodology is Flawed and Results in Overstated Volume Projections

1. Overstated and Undefined Inmigration Factor

Rex utilizes a unusually high 25% inmigration factor throughout its Application[1], first in projecting acute care discharges and days and then in projecting surgical utilization. Rex identifies four hospitals which it considers comparable to the proposed Rex Wakefield Hospital. While these hospitals are comparable to Rex Wakefield Hospital in some ways, there is one substantial difference which precludes the use of the "Comparison Group" inmigration factor in northern Wake County. All four of the comparison group hospitals are adjacent to major interstate thoroughfares or controlled access US Highways. Presbyterian Hospital Huntersville is less than one mile from Interstate 77. Presbyterian Hospital Matthews is less than one mile from Interstate 485, which is the major circumferential beltway around Charlotte. CMC-University is less than one mile from both Interstate 85 and Interstate 485. WakeMed Cary is approximately six miles from Interstate 40 but is located the intersection of US Highways 1 and 64, both of which are controlled access US Highways. All of these thoroughfares provide easy access to these hospitals for patients outside each Comparative Group Hospital service area, as defined by Rex in the Rex Wakefield Hospital CON Application. See Rex Wakefield CON Application at pages 160-169.

The proposed Wakefield location is six miles north of Interstate 540, the circumferential beltway around north Raleigh. However, those six miles reflect stop and go traffic and red lights. Rex Wakefield Hospital is not located near any Interstate or US highways or main thoroughfare. Therefore, the proposed 25% inmigration factor for the proposed Rex Wakefield Hospital is unreasonable and overstated.

[1]For discussion of the Rex Wakefield Hospital 25% in-migration factor, see CON Application page 162 ("25% of the med/surg discharges will originate from areas outside the service area.").

Rex also states that the 25% inmigration factor is "consistent with the definition required by federal rules and regulations for tax-exempt hospitals to demonstrate the need for using their funds to incentivize recruited physicians as noted above, and is therefore an unbiased standard for defining a service area." However, this is a specific federal standard focused on the processes by which tax-exempt hospitals recruit physicians rather than a standard for planning hospital-based health care services. The applicant did not explain why this was a useful standard for setting an inmigration percentages when planning for a new community hospital in North Carolina. This standard does not necessarily represent an appropriate inmigration standard for health planning and definition of a service area.

Furthermore, in 2006, in the review of the CON application (Project I.D. G-6404-06) for Forsyth Medical Center's Kernersville Medical Center (a new 50-bed community hospital), located just off Interstate 40 in Kernersville, the CON Section in its findings took issue with the use of a 20% inmigration factor as being too high. The proposed FMC-Kernersville service area was based upon a defined zip code service area (similar to the methodology used by Rex Wakefield Hospital) and historical utilization of Presbyterian Hospital Huntersville. However, the CON Section reviewed historical inmigration rates at WakeMed Cary in the Triangle market which were less than 15% (12.86%) and took issue with the use of 20% inmigration for KMC and initially denied FMC-Kernersville as a result. In addition, the Agency, in reviewing the FMC-Kernersville application, also noted that there were existing hospitals in Forsyth and Guilford Counties[2] that made it less likely that the patients in the FMC-Kernersville 20% inmigration group would drive past these hospitals to go to a hospital in Kernersville. It is worth noting that there are also two tertiary hospital facilities in Wake County, WakeMed and Rex Hospital, as well as UNC Hospitals and Duke University Medical Center in counties proximate to Wake County. Depending on where the patients constituting the 25% inmigration reside, they would actually have to drive past these existing facilities in order to reach the small, 40-bed hospital proposed by Rex in a somewhat out of the way location in Wake County. It is unreasonable to expect this to happen, and Rex's 25% inmigration must be viewed with extreme skepticism. Rex cites no facts that would cause the Agency to believe that a 25% inmigration level is reasonable in this case. Relevant sections of the FMC-Kernersville Medical Center decision are included in Attachment 1.

It is also remarkable to note that almost six years later, that using WakeMed Cary's FFY 2010 Inpatient Services Patient Origin reported on page 19 of the WMC 2011 Hospital Licensure Renewal Application that inmigration remains remarkably stable at less than 15% (14%).

Agency findings approving the Presbyterian Hospital Mint Hill ("PHMH") CON Application (Project I.D. F-76-4806) for a new 50-bed community hospital, which also was based upon a defined zip code service area in Mecklenburg County, support a 10% in-migration assumption in a county that also includes nearby tertiary hospitals such as CMC and Presbyterian Hospital. See pages 19-20 & 23 of the Agency Findings for Presbyterian Hospital Mint Hill included in Attachment 1. In addition, the Agency Findings approving the FMC-Clemmons Medical Center ("CLMC") CON Application (Project I.D. #G-8165-08), for a new 50-bed community hospital, again based upon a zip code service area in Forsyth County, support a 10% inmigration

[2]The hospitals are Forsyth Medical Center, North Carolina Baptist Hospital, Medical Park Hospital, Moses Cone Hospital, Wesley Long Hospital, High Point Regional Medical Center.

assumption, in a county that also includes nearby tertiary hospitals, such as NCBH and Forsyth Medical Center. See pages 24-25 of the Agency Findings for Clemmons Medical Center included in Attachment 1.

Based on the Agency Findings for the 50-bed Kernersville Medical Center in the Triad, the recent Agency findings for PHMH and CLMC, and stable inmigration percentages at WakeMed Cary, Rex Wakefield Hospital has significantly overstated the inmigration at 25% for Rex Wakefield Hospital, 40-bed community hospital. This results in overstated utilization and financial projections. The 25% inmigration assumption used for the Rex Wakefield Hospital application is inconsistent with recent CON Agency findings on inmigration for new community hospitals located in North Carolina's urban counties and therefore should be denied.

Furthermore, it is the applicant's responsibility to define what geography (zip code, census tract, county, state) is included in the inmigration areas that are outside the defined primary and secondary service areas for Rex Wakefield Hospital. See the CON Agency findings at pages 113-114 and 24 for Clemmons Medical Center. The Rex Wakefield Hospital application fails to provide any definitional information as to the locations from which 25% of its inmigration patients will originate. For example, of the 12,078 med/surg patient days of care projected for Year 3 at Rex Wakefield Hospital, the patient origin for 3,020 of those patient days[3] is unknown and undefined. Furthermore, the applicant's 25% inmigration assumption also does not permit the Agency to determine the level of impact of the proposed Rex Wakefield Hospital on existing providers that are located in the Rex Wakefield service area, such as WakeMed North and Franklin Regional Medical Center.

2. Overstated Surgical Volumes

As discussed above, the unreasonable 25% inmigration assumption also adversely impacts Rex's surgical projections. In addition, there are other reasons why Rex's surgical volumes are unreasonable.

Rex proposes one shared inpatient/outpatient surgical operating room at the new hospital and assumes all outpatient volume will continue to be served at the Rex Wakefield Ambulatory Surgery Center and its three ambulatory ORs. Having only one inpatient operating room will substantially limit the inpatient surgical cases that can be provided. Rex Wakefield Hospital is projected to perform 813 inpatient surgical cases in Year 3[4]. This represents 2,439 inpatient surgical hours (813 X 3 hours/inpatient surgical case). The 2,439 surgical hours represents over 81% of the 3,000 annual operating room hours available in one OR (12 hours per day X 250 days/year at 3 hours per inpatient surgical case.[5] Rex Wakefield Hospital will have a full service emergency room, and emergency patients in need of surgery will take precedence over scheduled inpatient cases, resulting in bumping scheduled inpatient cases. Rex does not provide any discussion of how much surgery will be emergency cases. However, 80% utilization of projected capacity reflects practical utilization of the one operating room with no room for unscheduled procedures. Even if only 10% of the available operating room capacity is subject to unscheduled

[3] Calculation: (12,078 X 25%)= 3,020

[4]See page 196 of the application.

[5]See this capacity calculation in Chapter 6 of the 2011 SMFP.

emergency surgical procedures, that will result in scheduled inpatient surgical procedures being bumped or delayed once every three days. Few surgeons would continue practicing at Rex Wakefield after being bumped and told to wait an hour to three or more hours to perform elective inpatient surgery. As a result, Rex projected inpatient surgical cases again are overstated.

On pages 195-196, Rex Wakefield Hospital projects inpatient surgical cases for FFY 2015 to 2017 by multiplying the percentage of Wakefield Service Area discharges that are surgical (35%) by Rex Wakefield Hospital's projected total med/surg discharges. However, its med/surg discharges are overstated as a result of the 25% inmigration factor utilized in the projections, which results in overstated inpatient surgical projections.

Rex does not project outpatient surgical utilization for the Rex Wakefield Ambulatory Surgery Center but continues to utilize projections included in the original 2006 CON Application for the surgery center. On page 554/CON Application Exhibit #32, Rex states that utilization of *"Wakefield in FFY 2011 will equal the project year two utilization projected in the approved CON application."* Utilization for the Rex Wakefield Ambulatory Surgery Center during Project Year 1 was significantly less than that projected in the CON application. Rex provides no documentation or support in its current Rex Wakefield Hospital application to show that utilization at Rex Wakefield Ambulatory Surgery Center has improved for the first six months of FFY 2011. It appears that Rex's assumption that the Wakefield ASC will perform as projected in the original Wakefield ASC CON Application is unsupported and unreasonable. Therefore, the applicant has overstated outpatient surgical utilization for Rex Wakefield Ambulatory Surgery Center.

In addition, Rex grows total outpatient surgical volumes in CON Application Exhibit 32 (pages 544-545) by a factor of 2.3% annually. That rate of growth is inconsistent with recent historical utilization at Rex Hospital, as shown in the following table.

Rex Hospital Surgical Services Utilization
October 2008 - September 2010

Oct - Sept	2009	2010
IP Cases (non-C-Section)	6,867	6,464
% Change		-5.9%
OP Cases	14,678	13,557
% Change		**-7.6%**
Total	21,545	20,021
% Change		-7.1%
Licensed ORs	24	24
ORs Needed at 1,872 Hrs/Yr	22.8	21.2
Surplus (+)/Deficit (-)	1.2	2.8

Source: LRAs

As shown in the above table, outpatient surgery volume declined by 7.6% in the last fiscal year. Rex attributes 7.6% decrease in the growth of Rex's outpatient surgical cases during the two

most recent data years (FFY 09-FFY 10) to the economy[6] and chooses to calculate an average 2.3% growth rate by blending the 3.37% FFY 2007-2009 CAGR for Rex outpatient surgical case growth and 1.24% FFY 2007-2010 CAGR. The applicant does not provide further information or explanation as to why a blended average outpatient surgery growth rate of 2.3% is reasonable or supported. However, as shown in the following table, Exhibit 5, Table 57 of the Novant Holly Spring Hospital CON Application, outpatient surgical use rates for Wake County residents have increased annually since 2007.

Wake County Outpatient Surgical Use Rates

October - September	2007	2008	2009	2010
Total Outpatient Surgeries Performed on Wake County Residents	48,668	52,733	54,348	56,138
Population-Wake County	831,537	866,438	892,409	919,938
Use Rate per 1,000	58.53	60.86	60.90	61.02

Source: Novant Holly Spring Hospital CON App, Exhibit 5, Table 57

As reflected in the previous table, Wake County residents are seeking outpatient surgical services at an increasing rate. However, Rex's share of the Wake County outpatient surgical cases is decreasing.

As shown in the following table the number of Wake County residents seeking surgical care at Rex decreased during the period 2008 to 2010, the timeframe when actual surgical cases performed on residents of Wake County residents has increased as reflected in the use rate table above. Notably, case volume fell by more than 1,000 cases between 2009 and 2010.

Rex Hospital Outpatient Surgical Patient Origin

	2006	2007	2008	2009	2010
Total Outpatient Surgery at Rex Hospital	18,222	17,767	23,672	24,567	24,174
Wake County Residents Receiving Outpatient Surgery at Rex Hospital	14,185	13,704	18,029	18,717	17,700
Non-Wake County Residents Receiving Outpatient Surgery at Rex Hospital	4,037	4,063	5,643	5,850	6,474
Percent Inmigration	22.2%	22.9%	23.8%	23.8%	26.8%

Source: Annual Hospital Licensure Renewal Applications

From the above table, it appears that the decline in surgical volume experienced at Rex is not due solely to the economy as stated by Rex, but due to a shift in surgical market share of Wake County residents to other surgical providers. This shift is reflected in the following table.

[6]See page 172 of the Rex Wakefield Hospital Application.

Rex Hospital Outpatient Surgery Market Share

	2007	2008	2009	2010
Rex Hospital Wake County Residents Outpatient Surgical Volume	13,704	18,029	18,717	17,700
Total Wake County Outpatient Surgery	48,668	52,733	54,348	56,138
Rex Outpt Surgery Mkt Share	28.2%	34.2%	34.4%	31.5%

Source: Annual Hospital Licensure Renewal Applications

As a result, Rex's use of an unreasonably high annual growth rate to project future outpatient surgery volume is an unsupported assumption and leads to an outpatient surgical methodology that overstates its outpatient surgical projections.

3. Imaging and Ancillary Services – Inpatient

On pages 199 through 202, Rex projects imaging and ancillary services for the proposed 40-bed Rex Wakefield Hospital. Rex assumed that the ratio of inpatient imaging and ancillary procedures to inpatient discharges at the proposed new 40-bed community hospital would equal that of Rex Hospital, as a tertiary provider. For outpatient imaging and ancillary services, Rex also assumed that the Rex Wakefield Hospital ratio of outpatient procedures to inpatient procedures would be the same as that of Rex Hospital, except ultrasound, x-ray, and laboratory, which are currently provided on the Wakefield campus.

There is a difference, however, between the proposed new 40-bed community hospital and Rex Hospital – namely, the proposed new hospital will have a fewer service lines than Rex Hospital and will treat lower acuity patients than Rex Hospital. As noted in the Rex Wakefield Hospital Application, "*over 86% of the service lines from the Rex Wakefield Hospital Service Area have an acuity weight less than 2.0.*" See CON Application page 175. Rex states that *"Rex does not propose to provide every acute care service line and will limit its offerings to the following service lines: Medical Cardiology, General Medicine, General Surgery, Gynecology, Neurology, Obstetrics, Ophthalmology, Orthopedics, Spine, and Urology."* See CON Application page 175. In other words, services such as open heart surgery and neurosurgery offered at Rex Hospital in Raleigh are not offered at Rex Wakefield Hospital. Therefore, the proposed new 40-bed community hospital would not be expected to have the same ratio of inpatient imaging and ancillary procedure to inpatient discharges as Rex Hospital. This assumption is unexplained, unreasonable and unsupported as presented in the Rex Wakefield Hospital application. To the extent that the Rex Wakefield Hospital inpatient imaging and ancillary procedures are based on Rex Hospital's ratio, the projected inpatient and outpatient imaging and ancillary procedures are unreliable.

In addition, Rex did not compare its Rex Wakefield Hospital imaging and ancillary service ratios by zip code service area. These ratios can also differ based upon demographics within zip codes in the defined Rex Wakefield Hospital service area. Rex estimated specific male and female medical surgical zip code use rates in its methodology on pages 176-177 and page 182, and could have provided the same level of detail by zip code to determine a ratio of inpatient imaging

and ancillary procedures to inpatient discharges for the proposed population in the Rex Wakefield Service Area.

4. Observation Beds

On pages 203-204, Rex projects observation patients and observation bed need based on the application of 10% to projected total acute care days at the proposed hospital; Rex assumes that observation patients were, on average, 10 percent of total patient days. As discussed in more detail above, Rex's med/surg utilization projections are unreliable because Rex overstated inpatient discharges for Rex Wakefield Hospital. As a result, Rex's projection of observation patients as a percent of total projected acute care days is unreasonable and unreliable.

B. Service Area for Proposed New Hospital-Rex Wakefield Hospital

Rex defines the hospital service area by zip codes as shown in the following table.

Rex Hospital Wakefield Proposed Service Area

Zip Code	Town	County
27571	Rolesville	Wake
27587	Wake Forest	Wake
27596	Youngsville	Franklin
27614*	Raleigh	Wake
27615	Raleigh	Wake
27616	Raleigh	Wake

Source: CON Application J-8670-11, page 167

Please note that the proposed Rex Wakefield Hospital service area includes zip code 27614, which is the same zip code in which WakeMed North is located. WakeMed North is about 5 miles away from the proposed Rex Wakefield site. WakeMed North expects to break ground on the 61-bed women's hospital this fall and open it in late 2013. Though the hospital initially will focus on delivering babies and offering other medical care for women, WakeMed will consider adding a broader range of services in the future.[7] WakeMed North Healthplex's existing Emergency Department and outpatient services, including surgical services are available to men and women. Rex Wakefield did not discuss the impact of the WakeMed North women's hospital on the Rex Wakefield projections. This casts serious doubt on the reasonableness of Rex's projections.

On page 224, Rex identifies the zip code service area as having the county composition shown in following table.

[7] http://www.newsobserver.com/2011/04/14/1128386/wakemed-revives-north-raleigh.html

Rex Hospital Wakefield Service Area
Composition by County

County	Percent of 2015 Population
Wake	91.5%
Franklin	7.4%
Granville	**1.2%**
Total	100.0%

Source: CON Application J-8670-11, page 224

Projected patient origin shown in the previous table is applicable to med/surg discharges (including ICU), obstetric discharges, ED visits, shared operating room, C-Section room, Level I bassinets, CT scans, MRI scans, ultrasound, X-ray/Fluoro, nuclear medicine, lab, respiratory therapy, EKG/Stress, EEG, inpatient PT/OT, pharmacy, and observation patients.

The only explanation Rex provides for converting its projected Zip Code Service Area to a County Service Area is on pages 223-224 where Rex states that

> *"according to Claritas, the Rex Wakefield Hospital Service Area by ZIP code for all services has the following composition by county:*

Rex Wakefield Hospital Service Area
Composition by County

County	Percent of 2015 Population
Wake	91.5%
Franklin	7.4%
Granville	**1.2%**
Total	100.0%

Source: CON Application J-8670-11, page 224

> *Rex based the projected patient origin for Rex Wakefield Hospital services on the composition by county of its services area as shown above.* ***Rex assumes that projected inmigration from outside of the service area will be in direct proportion to the composition by county of the service area.*** *" [emphasis added]*

Based upon this assumption, Rex is projecting that 22.9% of total patient days at Rex Wakefield Hospital will result from Wake County residents who will travel from areas of Wake County south of Wakefield, inside the I-540 beltline, past Wake Med North for inpatient care. Rex projects that nearly 23% of total patient days would come from other zip codes within Wake County as shown in the following table.

Rex Holly Spring Hospital
Projected Inmigration from Other Wake County Zip Codes

Total Rex Wakefield Hospital Projected Patient Days	12,078
Projected Inmigration - 25% of Total Patient Days	3,020
Percent of Inmigration from Wake County	91.5%
Projected Wake County Patient Days from Other Wake County Zip Codes	2,763
Percent of Total Days from Other Wake County Zip Codes	22.9%

Source: CON Application J-8669-11, page 224

The proposed Rex Wakefield Hospital will be a small community hospital with limited services. It is unreasonable to assume that 22.9% of patient days will be from residents of Wake County that must travel past Interstate 540 and through traffic and past other facilities to reach the proposed facility. Therefore, Rex Wakefield has utilized an unreasonable inmigration factor and should be denied.

In contrast, Novant's Holly Springs Hospital utilized a 10% inmigration factor from outside the service area and utilized a smaller Zip Code Service Area. The resulting inmigration for Novant's Holly Spring Hospital is less than 1,300 patient days in comparison.

C. Rex Hospital has and will Continue to have Surplus Operating Rooms

As shown in the following table, Rex Hospital has a growing surplus in its existing inventory of operating rooms.

Rex Hospital Operating Room Utilization
October 2008 – September 2011

Oct – Sept: FFY	2009	2010
IP Cases (non-C-Section)	6,867	6,464
% Change		-5.9%
OP Cases	14,678	13,557
% Change		-7.6%
Total	21,545	20,021
% Change		-7.1%
Licensed ORs	24	24
ORs Needed at 1,872 Hrs/Yr	22.8	21.2
Surplus (+)/Deficit (-)	**1.2**	**2.8**

Source: CON Application

As shown in the previous table, Rex's inpatient, outpatient, and total surgical cases have declined significantly in the most recent fiscal year. Rex proposes to relocate one of its operating rooms to the proposed new hospital in Wakefield, and for that operating room to be licensed as a shared operating room in which inpatient surgical cases are performed. A separate dedicated C-Section operating room has been proposed for C-Section volume.

In a concurrently filed April 15, 2011 CON Application (J-8667-11-Rex Healthcare to spend $278.8 million to add 11 beds, replace 115 acute care beds, and change in scope for Project ID J-8532-10, cardiovascular renovation expansion project), Rex projects surgical volume as shown in the following table.

Rex Hospital Projected Operating Room Utilization
October 2010 – September 2017

Oct – Sept: FFY	2011	2012	2013	2014	2015	2016	2017
IP Cases (non-C-Section)	6,827	6,866	6,905	6,945	6,281	5,936	5,568
% Change	5.6%	0.6%	0.6%	0.6%	-9.6%	-5.5%	-6.2%
OP Cases	12,918	11,100	6,311	4,767	4,303	4,225	4,174
% Change	-4.7%	-14.1%	-43.1%	-24.5%	-9.7%	-1.8%	-1.2%
Total	19,745	17,966	13,216	11,712	10,584	10,161	9,742
% Change	-1.4%	-9.0%	-26.4%	-11.4%	-9.6%	-4.0%	-4.1%
Licensed ORs	24	24	20	20	16	16	16
ORs Needed at 1,872 Hrs/Yr	21.3	19.9	16.1	14.9	13.5	12.9	12.3
Surplus (+)/Deficit (-)	**2.7**	**4.1**	**3.9**	**5.1**	**2.5**	**3.1**	**3.7**

Source: LRAs

The previous table shows that Rex's inventory of operating rooms will decline from 24 to 16 by FY 2017. Rex will shift four operating rooms to Macon Pond Road Outpatient Surgery Center as part of Project ID # J-8053-08. That project scheduled to be operational on January 1, 2013. Rex also proposes to relocate four operating rooms, one to the proposed Rex Wakefield Hospital and three to proposed Rex Holly Springs Hospital.

Declining operating room inventory is accompanied by projected declining operating room utilization at Rex, as shown in the previous table. In each of the seven fiscal years shown in the previous table, Rex has a surplus of operating room inventory. In the third project year of all three concurrently filed CON Applications (FFY 2017), Rex has a surplus of 3.7 operating rooms – circumstances that are not disclosed in any of the three CON Applications.

D. Rex Healthcare of Wakefield has Surplus Operating Rooms

On April 27, 2009, three ambulatory surgical operating rooms at Rex Healthcare of Wakefield became operational. The following table shows utilization of the three dedicated outpatient operating rooms at Rex Healthcare of Wakefield.

Rex Healthcare of Wakefield Operating Room Utilization
October 2009 – September 2010

Oct-Sept	FFY 2010
OP Cases	1,121
ORs Needed at 1,872 Hrs/Yr	0.9
Licensed ORs	3
Surplus (+)/Deficit (-)	**2.1**

Source: CON Application

As shown in the previous table, Rex Healthcare of Wakefield has utilization to support only one of the three dedicated outpatient operating rooms. The three dedicated outpatient operating rooms at Rex Healthcare of Wakefield will be unaffected by this project. Rex Healthcare of Wakefield will continue to operate three dedicated outpatient operating rooms. The inpatient volume for the proposed new hospital is projected to be performed solely in the one shared inpatient/outpatient operating room to be relocated from Rex Hospital.

N.C.G.S. 131E-183 (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.

Each applicant has a burden of presenting, evaluating, and demonstrating that the least costly or most effective alternative has been proposed. Since this application shows the project is not needed under Criterion 3, it is not the least costly or most effective alternative under Criterion 4.

In addition, Rex has at least two alternative methods of meeting the needs of patients, which methods are less costly and more effective than the proposed new 40-bed hospital with one operating room for inpatients, which operating room will be relocated from Rex Hospital in Raleigh. One alternative is to use one of the existing, underutilized operating rooms at Rex Healthcare of Wakefield. Another alternative is not to build the proposed new 40-bed hospital because it duplicates existing and approved health care facilities and capabilities at WakeMed North and WakeMed North Healthplex, in zip code 27614.

For the reasons discussed, the Rex Application does not conform to Criterion (4).

N.C.G.S. 131E-183 (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.

As discussed above, Rex fails to satisfy Criterion 3 because its projections are unreasonable and unsupported. Since the volume projections are integral to the financial projections, Rex's unreasonable volumes cause the project to be financially infeasible, and therefore non-conforming with Criterion 5.

In addition, based on the information provided in the Rex Wakefield Hospital CON ProForma financial projections, the Rex Wakefield Hospital ("RWH") will have negative Net Income in two of the first three years of operation:

Year 1 (10/1/2014-9/30/2015) Net Income: -($12,772,556)
Year 2 (10/1/2015-9/30/2016) Net Income: -($ 4,609,565)
Year 3 (10/1/2016-9/30/2017) Net Income: $ 1,249,688

Thus, over the first three years of operation the applicant projects that Rex Hospital Wakefield will have a cumulative Net Loss of $16,133,121. It does not appear to be a financially feasible or sustainable proposition for Rex to invest $102 Million in a hospital that will lose $16 Million over the first three years of its operation.

For the reasons discussed, the Rex Application does not conform to Criterion (5).

N.C.G.S. 131E-183 (6)

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

As discussed in the context of Criterion (3) above, Rex's methodology for projecting med/surg utilization, ICU utilization, and total acute care utilization are overstated. Rex's methodology is flawed and unreliable and its projections unreasonable.

Furthermore, the proposed hospital is duplicative of the acute care services that have been approved to be provided by WakeMed North and the emergency and outpatient services currently provided by WakeMed North Healthplex. Both which facilities are in the same zip code (27614) as the proposed hospital.

For the reasons discussed, the Rex Application does not conform to Criterion (6).

N.C.G.S. 131E-183 (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.

The proposed Rex Wakefield project is not needed, is not the least costly or most effective alternative, is not financially feasible and unnecessarily duplicates existing services. Based on these multiple failures, the Rex Wakefield project is non-conforming with Criterion 18a.

The proposed Novant Holly Springs Hospital is the only project which will introduce a new health care competitor into the Wake County market. Novant Health, the parent organization of Holly Springs Hospital has a long history of providing accessible care, cost efficient operations and high quality care.

The enhanced competition offered by the Novant Holly Springs Hospital brings a new approach in community hospital design that will be less costly to construct initially, less expensive to operate and maintain, and less costly to expand or renovate, and less disruptive to the ongoing

provision of hospital-based services during expansion or renovation. The design incorporates the state of the art AIA recommendations for infection control (includes biohazard control, hand washing, infection control risk assessments, construction materials), electronic medical records, therapeutic environments (environment of care, green design and sustainability), IT/Healthcare technology and communications (includes patient documentation, imaging), safety and security, dimensional consideration (includes space planning), energy and cost-effectiveness.

In addition, Novant's continued commitment to increasing efficiencies has made Novant a leader in the field. Novant will bring this experience and disciplined approach to the operation of the proposed Holly Springs Hospital to provide a competitive alternative which will have a positive impact upon the cost effectiveness, quality, and access to the services proposed.

In addition, Novant Medical Group has a long successful history of providing high quality, cost effective services to residents of Triad, Coastal, and Triangle Regions of North Carolina, the Greater Charlotte Region (including North & South Carolina), and in northern Virginia . This experience and dedication to accessible community-based patient care is critical to expanding choice in the Wake County market.

IV. CON Criteria and Standards for Acute Care Beds – 10A NCAC 14C .3800

10A NCAC 14C .3802(b)(5)-Projected Inpatient Days By County of Residence

As discussed in the context of Criterion (3) above, Rex's methodology for projecting acute care utilization results in overstated volumes. Therefore, the response to this Rule includes unreasonable and unsupported acute care projected utilization.

10A NCAC 14C .3803(a)-Projected ADC at Target Occupancy Rates

As discussed in the context of Criterion (3) above, Rex's methodology for projecting acute care utilization results in overstated volumes. Therefore, the response to this Rule includes unreliable and unreasonable projected acute care utilization.

Furthermore, Rex overstates total patient discharges and patient day growth and utilization for the combined Rex inpatient facilities through 2017. Historical growth at Rex is reflected in the following table.

Rex Hospital Historical Growth of Inpatient Discharges and Inpatient Days

Oct-Sept	2005	2006	2007	2008	2009	2010
Days of Care	90,852	97,101	99,431	105,270	107,765	101,382
% Change		6.9%	2.4%	5.9%	2.4%	-5.9%
Discharges	23,135	27,526	27,685	27,519	27,212	26,805
% Change		19.0%	0.6%	-0.6%	-1.1%	-1.5%
Licensed Beds	388	388	388	425	425	431
ALOS	3.93	3.53	3.59	3.83	3.96	3.78
ADC	248.9	266.0	272.4	288.4	295.2	277.8
Occupancy	64.2%	68.6%	70.2%	67.9%	69.5%	64.4%

Source: LRA; SMFP

As shown above, discharges at Rex have decreased steadily over the last four years from 27,685 discharges in FFY 2007 to 26,805 discharges in FFY 2010. And inpatient days dropped precipitously (rather than "slightly" as stated on page 171 of the Rex Wakefield Hospital CON Application) from 107,765 inpatient days in FFY 2009 to 101,382 inpatient days in FFY 2010. Based upon projections included in Exhibit 19 Rex projects annual growth in discharges and patient days of 6.5% to 7.7% annually between 2011 and 2015 when the new Rex Wakefield Hospital is proposed to open. This is shown in the following table.

Rex Hospital Projected Growth: Inpatient Days & Discharges

Oct-Sept	2011	2012	2013	2014
Days of Care	107,383	115,691	124,307	132,365
% Change		7.7%	7.4%	6.5%
Discharges	28,392	30,588	32,866	34,997
% Change		7.7%	7.4%	6.5%

Source: Rex Wakefield Hospital CON Application, page 415, Exhibit 16

In comparison, total inpatient discharges and days have never increased for a four-year timeframe for any hospital facility in Wake County at the level projected above by Rex, as shown in the following table.

Historical Wake County Inpatient Admissions and Patient Days

Facility	2005		2006		2007		2008		2009		2010	
	Dischg	Patient Days	Dischg	Patient Days	Dischg	Patient Days	Dischg	Patient Days	Dischg	Patient Days	Dischg	Patient Days
Duke	6,896	28,724	5,493	22,268	4,978	23,185	5,304	25,269	6,263	28,622	7,025	30,629
AGR Adm			-20.35%		-9.38%		6.55%		18.08%		12.17%	
AGR Pt Days				-22.48%		4.12%		8.99%		13.27%		7.01%
Rex	23,135	94,427	27,526	100,098	27,685	101,520	27,519	106,947	27,212	110,325	26,805	101,382
AGR Adm			18.98%		0.58%		-0.60%		-1.12%		-1.50%	
AGR Pt Days				6.01%		1.42%		5.35%		3.16%		-8.11%
WakeMed	31,173	158,980	32,098	166,249	35,082	175,351	35,883	177,318	37,133	175,814	35,542	167,614
AGR Adm			2.97%		9.30%		2.28%		3.48%		-4.28%	
AGR Pt Days				4.57%		5.47%		1.12%		-0.85%		-4.66%
WakeMed Cary Hospital	8,376	35,013	8,939	35,260	9,114	36,625	9,678	38,588	10,002	41,103	10,410	44,469
AGR Adm			6.72%		1.96%		6.19%		3.35%		4.08%	
AGR Pt Days				0.71%		3.87%		5.36%		6.52%		8.19%
Total	69,580	317,144	74,056	323,875	76,859	336,681	78,384	348,122	80,610	355,864	79,782	344,094
AGR Adm			6.43%		3.78%		1.98%		2.84%		-1.03%	
AGR Pt Days				2.12%		3.95%		3.40%		2.22%		-3.31%

Source: Discharges, LRA; Pt Days, SMFP AGR = Annual Growth Rate

As shown in the previous table, the only facility that has accomplished this level of growth in both discharges and days is Duke Raleigh in the four year time frame from FFY 2007 to FFY 2010. However, inpatient utilization has yet to achieve previous levels of utilization experienced in FFY 2005. WakeMed Cary has sustained greater than a 6% growth in patient days for the last three years, some of which growth may have been from WakeMed, which experienced a decrease in inpatient days over the same period. However, WakeMed Cary did not grow in admissions at the same rate, which reflects an increased average length of stay at WakeMed Cary. Furthermore, the growth rate experienced at both Duke Raleigh and WakeMed Cary is on base data which is about a third of the base volume at Rex, i.e., 30,629 inpatient days at Duke Raleigh Hospital compared to 101,382 inpatient days at Rex Hospital in FFY 2010.

Finally the projected inpatient growth rate for inpatient days at Rex is **twice any historical inpatient day growth rates ever experienced in Wake County** as a whole. As a result, the projected interim growth rates for inpatient days at Rex Hospital are unreasonable and result in unsupported and unreliable patient day projections for Rex Healthcare as a whole.

The combined impact of unreasonable inmigration assumptions and unreasonable interim growth rates is a fatal flaw in the projected utilization for inpatient days for total Rex facilities. This rule requires all 540 proposed beds to be utilized at 75.2% utilization in the third project year. Rex fails to achieve this, if reasonable assumptions are utilized.

V. CON Criteria and Standards for Intensive Care Services – 10A NCAC 14C .1200

10A NCAC 14C .1202(b)(3)—Projected Patients & Days of Care by County of Residence

As discussed in the context of Criterion (3) above, Rex's methodology for projecting acute care utilization results in overstated volumes. Therefore, the response to this ICU Rule includes unreasonable acute care projected utilization. As stated on pages 186-187 of the Rex Wakefield Hospital ("RWH") CON Application, the applicant projected RWH ICU Days as a percent of total projected RWH med/surg acute care days. This negatively impacts RWH ICU projections, which are then unreliable and unreasonable.

10A NCAC 14C .1203(a)(2)-Projected Occupancy Rate Target for Proposed ICU Beds

As discussed in the context of Criterion (3) above, Rex's methodology for projecting acute care utilization is overstated. As stated on pages 186-187 of the Rex Wakefield Hospital ("RWH") CON Application, the applicant projected RWH ICU Days as a percent of total projected RWH med/surg acute care days. As a result the projected ICU volume is overstated. Therefore, the response to this Rule includes ICU utilization that is unreasonable and unsupported.

VI. CON Criteria and Standards for Surgical Services – 10A NCAC 14C .2100

10A NCAC 14C .2102(c)(3)-Number of Inpatient & Outpatient Surgical Cases for the Most Recent 12-Month Period

As discussed in detail in the context of Criterion (3) above, Rex Hospital has underutilized operating room inventory.

10A NCAC 14C .2102(c)(4)- Number of Inpatient & Outpatient Surgical Cases Projected to be Performed For Each of the First Three Operating Years In Each Facility

As discussed in the context of Criterion (3) above, Rex's methodology for projecting surgical utilization results in overstated volumes.

Also as discussed in the context of Criterion (3) above, Rex's use of an unreasonably high annual growth rate to project outpatient surgery volume renders its outpatient surgical methodology flawed and unreliable and its surgical projections are thus unreasonable.

Therefore, the response to this Rule includes unsupported and unreasonable projected surgical utilization.

10A NCAC 14C .2103(b)(2)(C)-Number of ORs Needed

As discussed in the context of Criterion (3) above, Rex's methodology for projecting surgical utilization results in overstated volumes.

Also as discussed in the context of Criterion (3) above, Rex's use of an unreasonably high annual growth rate to project outpatient surgery volume renders its outpatient surgical methodology flawed and unreliable and its surgical projections are thus unreasonable.

Therefore, the response to this Rule includes unsupported and unreasonable projected surgical utilization.

VII. Comparative Factors

The Agency Findings in the competitive review in 2007 for Medical Park Hospital-Clemmons and NCBH Davie County Hospital Replacement facility provide comparative factors that should be considered in the review of the Rex Wakefield Hospital, the Rex Holly Springs Hospital, and the Novant Holly Springs Hospital CON Applications all filed on April 15, 2011 in response to a need determination in the 2011 SMFP for 101 New Acute Beds in Wake County. These factors include: Geographic Access, Facility Design, Scope of Services, Staffing, Charges/Revenues, Operating Costs, Access by Underserved Groups, Coordination with Existing Healthcare System, and Community Support. In addition, the Agency Findings for the eight competing CON Applications filed on August 15, 2008 to seek approval for the 41 new acute beds and the 4 new ORs identified in the 2008 SMFP for Wake County. That application included one set of comparative factors for the operating rooms and a separate set of comparative factors for the new acute beds. The Agency used the following comparative factors for the new Wake County ORs: Geographic Accessibility, Demonstration of Need, Financial Feasibility, Coordination with Existing Health Care System, Access by Underserved Groups, Revenue, Operating Expenses, and Documentation of Physician Support. The comparative factors used by the Agency for the new Wake County acute beds were the same eight factors used by the Agency for the operating room comparison in 2008.

GEOGRAPHIC ACCESS

Rex Wakefield Hospital proposes a primary service area (excluding inmigration) that includes six zip codes that encompass northern Wake County, Franklin County, and Granville County. See RWH CON Application at pages 143-144 and 224. That service area currently includes both ORs and acute beds that are operational and accessible at WakeMed North, Granville Health System, Franklin Regional Medical Center, as well as the Rex Healthcare of Wakefield 3OR surgery center.

In contrast, the Novant Holly Springs Hospital CON Application, proposes to locate new acute beds and ORs to a southern Wake County service area that has no local access to acute care beds or operating rooms within the HSH service area. And 12% of the population of Wake County

resides in the HSH area, where 0% of the Wake County ORs and acute beds are currently located.

Thus, the Novant Holly Springs Hospital is comparatively superior to the Rex Wakefield Hospital proposal in terms of improving geographic access for the populations to be served.

DEMONSTRATION OF NEED

As discussed above in these comments the Rex Wakefield Hospital acute bed and OR projected utilization is unreasonable and unreliable under Criterion (3). Thus, RWH did not adequately demonstrate the need for the additional ORs and new acute beds in northern Wake County.

The Novant Holly Springs Hospital has adequately demonstrated that the patient days and surgical cases projected to be performed at Novant's HSH are reasonable and has adequately demonstrated that the population it proposes to serve has the need for the 50 new acute beds and 3 ORs in southern Wake County in the HSH service area. Thus, Novant's HSH is comparatively superior in terms of demonstration of need.

FINANCIAL FEASIBLITY

At the end of the first three project years, Rex Wakefield Hospital projects a cumulative, 3-year net loss of over $16 Million, with negative net income in two of the first three operating years. It is unclear whether this RWH's net income would support the ability to pay the debt service on the tax-exempt bonds with which Rex proposes to finance the RWH project. See the Rex Wakefield Hospital Application at page 285 and Exhibit 55. Thus, the financial feasibility of the Rex Wakefield Hospital project is questionable.

By comparison, the Novant Holly Springs Hospital projects a cumulative, 3-year net income of $4.7 Million and shows positive net income in the two of the first three project years. As demonstrated in the Novant Holly Springs Hospital Projected Statement of Revenues and Expenses, Holly Springs Hospital is financially feasible.

In addition, the capital cost for Novant's Holly Springs Hospital, which has 10 more acute beds proposed, than the 40-bed Rex Wakefield Hospital, has a total capital cost of $77.7 Million, which is $24.5 Million less than the capital cost of $102,282,666 for only 40 new acute beds at RWH. Also, RWH's total capital cost per bed is $2.33 Million and Novant HSH's total capital cost per bed is $1.55 Million, a capital cost difference $783,000 per bed to bring the new acute beds on line in Wake County. And the Novant HSH total capital cost per square foot is $548/SF compared to $615/SF for RWH. This is a difference in construction cost of $67/SF, making RWH's Capital Cost/SF 12% more expensive than that of Novant HSH. Novant's Holly Springs Hospital has the more cost-efficient and cost-effective method of bringing the new acute beds into operation in Wake County. And the lower capital cost, also means that Novant HSH will have a lower annual debt service expense (principal and interest) than the debt service expense that Rex Wakefield Hospital will incur. These additional features, also demonstrate the comparatively superior financial feasibility of Novant HSH compared to Rex Wakefield Hospital.

ACCESS BY UNDERSERVED GROUPS

The Project Year 2 percentages of each applicant's projected percentage of entire hospital services to be provided to Medicare and Medicaid recipients, as stated in the applicants' responses to Question VI.14 are set forth in the table below.

Applicant	Projected % of Hospital Services to Medicare Recipients in Year 2	Projected % of Hospital Services to Medicaid Recipients in Year 2
Rex Wakefield Hospital	50.0%	4.4%
Novant Holly Springs Hospital	31.15%	11.61%

With regard to Medicaid recipients, Novant HSH projects the highest percentage of hospital services to be provided to Medicaid recipients. With respect to Medicare recipients, Rex Wakefield Hospital, projects a higher percentage of hospital services to be provided to Medicare recipients. Novant HSH is comparatively superior on access for Medicaid recipients.

GROSS REVENUE

Below is a comparison of Year 3 Inpatient Gross Revenue Per Inpatient Day using the information provided by the applicants' responses to Question X.3:

- Rex Wakefield Hospital's Inpatient Gross Revenue Per Inpatient Day is $7,619 in Year 3
- Novant HSH's Inpatient Gross Revenue Per Inpatient Day is $6,516 in Year 3

Novant HSH projects the lowest Year 3 Inpatient Gross Revenue per Inpatient Day compared to RWH and the other four applicants in the third year of operation.

NET REVENUE

Below is a comparison of Year 3 Net Revenue per adjusted patient day using the information provided by the applicants' responses to Question X.3:

- Rex Wakefield Hospital's net revenue per adjusted patient day is $2,611 in Year 3
- Novant HSH's net revenue per adjusted patient day is $2,728 in Year 3

RWH's net revenue per adjusted patient day is less than that of Novant Holly Springs Hospital. It should be noted that Rex Wakefield Hospital also has a negative cumulative net income of over $16 Million, with negative net income in two of the first three operating years. Thus, RWH's net income is insufficient to cover its operating expenses for RWH Project Years 1 and 2.

OPERATING EXPENSES

Below is a comparison of Year 3 operating costs per adjusted patient day using the information provided by the applicants' responses to Question X.3:

- Rex Wakefield Hospital's operating costs per adjusted patient day are $2,550 in Year 3
- Novant Holly Springs Hospital's operating costs per adjusted patient day are $2,464 in Year 3

Novant's HSH projects a lower operating expense per adjusted patient day than RWH. Novant HSH's operating expense per adjusted patient day is less than that of RWH by $86 or 3.4%. Thus, the lower Novant operating expenses per adjusted patient day are relatively superior to those projected for RWH.

COMMUNITY SUPPORT

At the time the Rex Wakefield Hospital CON Application was filed on April 15, 2011, there appear to be about 200 community letters of support included in Exhibit 62. See RWH Application starting at page 1314, Exhibit 62. These letters appear to include largely expressions of support from Rex employees and current and former patients. There is also one letter of support for the Rex Holly Springs Hospital proposal. There do not appear to be any letters of support from business, community, government officials in the Wakefield area.

At the time the Novant Holly Springs Hospital CON Application was filed on April 15, 2011, there were about 375 letters of support from Novant Medical Group-Triangle patients and residents of southern Wake County and surrounding communities including Holly Springs, Fuquay-Varina, Apex, Cary, New Hill, Garner, Willow Springs, Lillington (Harnett County), and Angier (Harnett County). In addition, Novant HSH Exhibit 16 includes letters and resolutions of support from the Mayor of Holly Springs (page 1781), the Town Council of Holly Springs (page 1603), the Fuquay-Varina Board of Commissioners (page 1604), and Senator Richard Y. Stevens of the North Carolina General Assembly (page 1606). Also, during the comment period two thousand additional community letters of support for the Novant Holly Springs Hospital were submitted to the CON Agency. It is clear that the Novant Holly Springs Hospital proposal has significant support from the residents and leadership of the Holly Springs area.

DOCUMENTATION OF PHYSICIAN SUPPORT

Based on the physician letters of support in the Rex Wakefield CON Application at Exhibit 62, it appears there are about 276 letters of support from primary care, medical specialist, and surgical physicians. There are letters of support from physicians practicing in Wake, Orange, Durham, Franklin, Granville, Harnett, Johnston, Nash, Person, Sampson, Vance, and Wayne counties, based on data provided on the web sites for the physician practices listed on pages 1014-1022, Exhibit 62 of the Rex Wakefield Hospital CON Application. It should also be noted that the physician letters of support for the Rex Wakefield 40-bed hospital and the physician letters of support for the Rex Holly Springs 50-bed hospital are identical. In other words, the exact same physician letters are used to support both of the new community hospitals, with one located in the southern most part of Wake County, and the other located in the northern most part of Wake

County. The Rex Wakefield Hospital and the Rex Hospital Holly Springs are 36 miles and 43 minutes driving time from each other, although both are located in Wake County. The two new proposed Rex community hospitals at Wakefield and Holly Springs have a combined total of 90 acute inpatient beds, 5 operating rooms, and 26 ED treatment rooms. Presumably it is not practical or expected that all 276 physicians will practice at both the northern Wake County proposed community hospital in Wakefield and the southern Wake County proposed community hospital in Holly Springs. The Rex Wakefield Hospital CON Application is not specific about which or how many of these 276 physicians are most likely to seek privileges at, practice at or refer to Rex Wakefield Hospital. In addition, the 19 letters of support from the surgeons of Wake Heart and Vascular Associates[8] seem to focus their support on the Rex (Main) Hospital Heart & Vascular Center CON Application ("scope change") and do not specify in their letters whether they intend to practice at the proposed Rex Wakefield Hospital. The Agency may not be able to determine if there is sufficient physician support that is specific to the proposed Rex Wakefield Hospital.

The Novant Holly Springs Hospital CON Application includes a HSH Chief of the Medical Staff letter, Medical Director/physician letters of support for services at HSH including Normal Newborn Nursery/Neonatal Level I, GI Endoscopy, Radiology, CT Scans, Emergency Medicine, Anesthesiology, Surgical Services, Inpatient Care Specialists/Hospitalists, Intensive Care Unit, Pathology, and Obstetrics, as well as physician support letters from primary care, medical specialist, and surgical physicians. Of the eleven Medical Director/Chief of Service letters for HSH, seven are from physicians practicing in the Triangle area today (Neonatal, GI Endoscopy, Radiology, Pathology, Anesthesia, Surgery, and CT Scans). These are found in Exhibit 14 of the Novant HSH CON Application. This exhibit also includes physician letters of support representing 42 individual primary care physicians (family practice, internal medicine, pediatrics) practicing in Wake, Durham, and Franklin counties, including three physician practices with offices in Holly Springs today. Novant HSH Exhibit #14 also includes physician letters of support representing 15 individual medical specialists including cardiology, gastroenterology, hepatology, medical oncology, neurology, pathology, pulmonology, and radiology. These physicians or their groups have offices in Wake, Durham, Franklin, Harnett, Moore, Orange, and Alamance Counties, including four practices with offices in Cary, NC. Finally, Exhibit 14 in the Novant HSH CON Application includes surgeon letters of support representing 32 individual surgeons, including ENT, general surgery, orthopedics, obstetrics and gynecology, and vascular surgery. These surgeons have offices in Wake, Durham, Franklin, and Orange counties, including three practices with offices in Apex or Cary.

Together these Novant HSH physician and medical director letters of support represent 100 individual physicians, the majority of whom practice in the Triangle area today, including Wake County. Each of their signed letters express a plan to seek medical staff privileges at Novant HSH, a commitment to admit patients to Novant HSH, an intent to refer appropriate patients to the Novant HSH, an intent to perform surgery a Novant HSH, a commitment to refer appropriate patients to other physicians and specialists on the Novant HSH medical staff for imaging studies, surgery, or emergency department care, or to perform the duties of medical director/chief of service for certain clinical service lines at HSH. See pages 1454- 1594 in Exhibit 14 of the Novant HSH CON. These Novant HSH signed physician letters address their support for only

[8]Rex Wakefield Hospital CON Application pages 1015 and 1029-1067 in Exhibit 62.

one hospital, the Novant Holly Springs Hospital, rather than two or more hospitals[9], which appears to be the format for many of the letters in the Rex Wakefield and Rex Holly Springs CON Application. The Novant HSH physician support letters demonstrate sufficient and necessary support for the proposed 50-bed community hospital.

The Agency should also take notice of the greater breadth, depth, and variety of local and regional physician support letters for this Novant 2011 Holly Springs Hospital CON Application compared to the Novant Holly Springs Hospital Application filed just about two and one-half years ago (in August 2008). During that period, the base of physician support letters for Novant's Holly Springs Hospital has grown by 270%.[10]

File: CommentsNovantOnRexWakefieldFINAL.05.29.11.doc

[9]Note that one practice, Triangle Orthopaedic Associates, through its CEO, signed a letter of support for each of the following CON Applications filed on April 15, 2011: the Rex Wakefield Hospital CON Application (see page 1267), the Rex Holly Springs Hospital Application (see page 1353), and the Novant Holly Springs Hospital CON Application (see page 1570) . TOA includes 23 orthopedic surgeons and 6 physical medicine/rehabilitation physicians.

[10]Calculation: ((100-27)/27 physician support letters)= 270%

ATTACHMENT #1

Immigration 2090 Too High
Pages 20-21
24

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: October 26, 2006

PROJECT ANALYST: Martha J. Frisone
CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBER: G-7604-06/ Novant Health, Inc. (lessor) and Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center (lessee)/ Develop 39 new acute care beds and relocate 11 existing acute care beds from Winston-Salem to establish a new facility in Kernersville for provision of acute inpatient services/ Forsyth 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.

C

The applicants, Novant Health, Inc. (lessor) (**Novant**) and Forsyth Memorial Hospital, Inc. (lessee), own and operate Forsyth Medical Center (**FMC**), a hospital located in Winston-Salem in Forsyth County, which is currently licensed for 637 acute care, 68 rehabilitation, 80 psychiatric and 20 nursing facility beds. Novant also owns Medical Park Hospital (**MPH**), which is located across the street from FMC. MPH is currently licensed for 136 acute care beds. Pursuant to the certificate of need issued for Project I.D. #G-7011-04, Novant is authorized to relocate 114 existing acute care beds from MPH to FMC. Thus, upon completion of Project I.D. #G-7011-04, FMC would be licensed for 751 acute care beds and

MPH would be licensed for 22 acute care beds [637 + 114 = 751; 136 – 114 = 22].

In this application, Novant and FMC propose to develop 39 new acute care beds and relocate 11 existing acute care beds from FMC to establish a new site for the provision of acute inpatient services in Kernersville in Forsyth County. Upon completion of this project and Project I.D. #G-7011-04, FMC would be licensed for a total of 790 acute care [637 + 114 + 39 = 790], 68 rehabilitation, 80 psychiatric and 20 nursing facility beds. See Criterion (3) for a detailed description of all the services the applicants propose to provide in Kernersville.

Need Determination - The 2006 State Medical Facilities Plan (2006 SMFP) includes a methodology for determining the need for additional acute care beds in North Carolina by service area. Application of the need methodology in the 2006 SMFP identified a need for 90 additional acute care beds in Forsyth County. The 2006 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 it 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 2006 SFMP]."

The applicants propose to develop 39 of the 90 new acute care beds available in the 2006 SMFP.[1] The facility in Kernersville will not be a separately licensed hospital, but will be operated under FMC's license, and thus, it will be an additional campus of an existing

[1] North Carolina Baptist Hospital submitted an application proposing to develop the other 51 acute care beds [90 – 39 = 51]. See Project I.D. #G-7600-06. The applications are not competitive.

licensed hospital. The applicants do not propose to develop more acute care beds than are determined to be needed in Forsyth County.

FMC and Novant propose to develop a 24 hour emergency services department at Forsyth Medical Center – Kernersville (**FMC-K**). In Exhibit 5, page 6, the applicants provide the projected number of inpatient discharges and patient days of care by major diagnostic category (MDC) to be provided at FMC-K during the first three operating years. The applicants project to provide services at FMC-K in 22 of the 25 MDCs listed in the 2006 SMFP. Therefore, the applicants propose to provide medical and surgical services in at least five MDCs recognized by CMS. The applicants adequately demonstrate that FMC-K will provide inpatient medical services to both surgical and non-surgical patients. Thus, Novant and FMC are qualified applicants and the proposal is consistent with the need determination in the 2006 SMFP for additional acute care beds in Forsyth County.

There are no other need determinations in the 2006 SMFP that are applicable to this review.

Policies – Because the applicants propose to construct new space to replace 11 existing acute care beds to be relocated from Winston-Salem to Kernersville[2], Policy AC-5 is applicable to this review. POLICY AC-5: REPLACEMENT OF ACUTE CARE BED CAPACITY states

> *"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to the utilization targets found below. In determining utilization of acute care beds, only acute care bed 'days of care' shall be counted. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application.*

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[2] Hereinafter, the existing Winston-Salem campus will be referred to as "FMC-WS" and the Kernersville campus as "FMC-K." "FMC" will be used to refer to the entire hospital, including both campuses.

Facility Average Daily Census	*Target Occupancy of Licensed Acute Care Beds (Percent)*
1 – 99	*66.7%*
100 – 200	*71.4%*
Greater than 200	*75.2%*

According to its 2006 Hospital License Renewal Application, during Fiscal Year (FY) 2005, the average daily census (ADC) for the 637 licensed acute care beds at FMC was 564.6 [206,071 / 365 = 564.6]. Thus, based on the above table, the target occupancy for FMC is 75.2% of the capacity of the licensed acute care beds. Based on current utilization, FMC is already operating at 88.2% of licensed acute care capacity. In Exhibit 5, page 4, the applicants provide projected utilization for the total number of acute care beds at FMC during the first three operating years of the proposed project, as illustrated in the following table.

PROJECTED UTILIZATION OF TOTAL # OF ACUTE CARE BEDS

	TOTAL # OF PROJECTED ACUTE CARE PATIENT DAYS		
	YEAR ONE (7/1/09-6/30/10)	YEAR TWO (7/1/10-6/30/11)	YEAR THREE (7/1/11-6/30/12)
FMC-WS (740 acute care beds)	213,810	215,902	218,017
FMC-K (50 acute care beds)	10,613	13,296	16,147
FMC (790 acute care beds)	224,423	229,198	234,164
Average Daily Census (ADC) [1]	614.9	627.9	641.5
% Occupancy [2]	77.8%	79.5%	81.2%

Source: Exhibit 5, page 4.
(1) ADC was calculated by dividing projected acute patient days by 365.
(2) Occupancy was calculated by dividing ADC by 790.

As shown in the above table, in the third operating year, the applicants project an occupancy rate of 81.2% for the entire hospital, which is greater than the target occupancy of 75.2%. The applicants state that they used FMC's actual utilization in FY 2005 as the base year and assumed that utilization would increase at the same rate the population of the service area is projected to increase. See Exhibit 20, Figure 43, for the applicants' assumptions and methodology used to project utilization for the hospital as a whole. The applicants adequately demonstrate the need to maintain FMC's total acute care bed capacity proposed in the application. Therefore, the application is conforming to Policy AC-5. See Criterion (3) for discussion of the applicants' demonstration of need for the acute care beds at FMC-K.

There are no other policies in the 2006 SMFP that are applicable to this review.

In summary, the application is consistent with the need determination in the 2006 SMFP for additional acute care beds in Forsyth County and Policy AC-5. Therefore, the application is conforming to this criterion.

(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.

NC

Novant and FMC propose to develop 39 new acute care beds and relocate 11 existing acute care beds from FMC-WS to establish a an additional campus of FMC in Kernersville (**FMC-K**). Based on the applicants' representations in Section II.1, pages II-1 through II-4, the design schematics in Exhibit 16, and the list of equipment to be acquired provided in Exhibit 18, the applicants propose to offer the following services at FMC-K:

- 46 general medical-surgical (med/surg) acute care beds (39 new and 7 existing to be relocated from FMC-WS)
- 4 intensive care unit (ICU) beds (4 existing to be relocated from FMC-WS)
- 10 unlicensed observation beds
- 4 shared operating rooms (ORs) (3 existing shared ORs to be relocated from FMC-WS[3] and 1 existing shared OR to be relocated from MPH)
- a 24 hour Emergency Room (ER), with 14 treatment rooms
- laboratory (lab) services, including phlebotomy, blood bank, pathology, chemistry, hematology coagulation, micro urinalysis and accessioning
- pharmacy

[3] In Project I.D. #G-7311-05, the applicants were authorized to relocate three existing shared ORs to Kernersville where they would be operated under FMC's license as dedicated outpatient ORs.

- 1 cardiac catheterization (cath) unit (to be relocated from FMC-WS[4])
- 1 new CT scanner
- 1 new x-ray unit
- 1 new x-ray/fluoroscopy unit
- 3 mobile C-arms
- 2 mobile x-ray units
- 1 new nuclear medicine camera (without coincidence circuitry)
- 1 new mammography unit
- 1 new *"Cardiac"* ultrasound (US) unit
- 1 new *"Imaging, Handheld"* US unit
- 2 new *"Therapeutic, Genera"* [sic] US units
- 2 stress testing systems with treadmill
- echocardiography equipment (quantity not provided)
- 1 electroencephalograph (EEG) unit
- 3 electrocardiograph (ECG) units
- 1 pulmonary function testing system

The applicants do not propose to offer obstetric or neonatal services at FMC-K, and do not propose to develop any non-surgical procedure rooms on the new campus.

POPULATION TO BE SERVED

The following table illustrates the historical patient origin for FMC, as reported by the applicants in Section III.4(a), page III-19.

COUNTY	PERCENTAGE OF TOTAL DISCHARGES
Forsyth	60.41%
Stokes	7.20%
Surry	6.27%
Davie	5.58%
Yadkin	5.45%
Davidson	4.97%
Wilkes	2.13%
Other NC Counties	5.68%
Other States	2.33%
Total [(1)]	100.02%

[(1)] Does not equal 100% due to rounding.

[4] The applicants propose to relocate the cardiac cath unit authorized in Project I.D. #G-7266-05 which was approved to be located at FMC-WS. This unit is not yet operational.

The following table illustrates the projected patient origin for FMC-K campus in the third operating year, as reported by the applicants in Exhibit 20, page 8 and Figure 1.

ZIP CODE	COUNTY	CITY	PROJECTED NUMBER OF DISCHARGES YEAR THREE (7/1/11 – 6/30/12)	PERCENTAGE OF TOTAL DISCHARGES
27284 / 27285 [1]	Forsyth	Kernersville	2,011	59.8%
27051	Forsyth	Walkertown	255	7.6%
27009	Forsyth	Belews Creek	65	1.9%
27265	Guilford	High Point	280	8.3%
27235	Guilford	Colfax	46	1.4%
27310	Guilford	Oak Ridge	35	1.0%
Other			673	20.0%
Total			3,365	100.0%

[1] In a footnote to Figure 1 in Exhibit 20, the applicants state that the 27285 zip code is a *"P.O. Box located within the zip code boundary of 27284."*

In Section III.5(a), page III-20, the applicants state

"The service area for FMC-Kernersville consists of zip codes 27284 (including point zip code 27285), 27051, 27009, 27265, 27235, and 27310. The service area for the proposed FMC-Kernersville hospital was developed based on the following analysis:

These zip codes represent a contiguous set of zip codes within a 10-mile radius of the proposed hospital location. Major transportation routes I-40 and Business I-40 Business [sic] *run through the region. These roads run east and west and are direct routes to either Winston-Salem or Greensboro. In addition, to the east in Greensboro I-85 intersects I-40; in North Carolina, I-85 runs from Charlotte, NC to the Virginia border in eastern North Carolina. The applicant has not projected a secondary service area. Approximately 80% of FMC-Kernersville patients will come from residents in the defined service area zip codes. The other 20 percent will come from other zip codes in Forsyth and Guilford Counties, Other North Carolina Counties, and Other States. This service area is consistent with the Kernersville market area definition used by other local development groups."*

The applicants adequately identify the population they propose to serve.

ANALYSIS OF NEED FOR THE PROPOSED SERVICES

In Section III.1, pages III-1 through III-16, the applicants state that 50 acute care beds are needed in Kernersville for the following reasons.

> *"Kernersville, a growing community of nearly 50,000 people in eastern Forsyth County, does not currently have its own hospital. Residents must therefore travel to Winston-Salem, or to Greensboro or High Point to receive hospital care, including emergency room services. For the reasons stated below, this is no longer a satisfactory answer, and the time has come for Kernersville to have a small community hospital.*
>
> *The primary objectives of this project are to improve the access to health care services for the residents of Kernersville and the Triad area and to provide an appropriate setting for high-quality patient care and satisfaction. The 2006 State Medical Facilities Plan (SMFP) identifies a need for new acute care beds in Forsyth County. This project proposes to meet that need by adding 39 of the 90 new acute care beds allocated in the 2006 SMFP and shifting 11 existing beds and services that are now located in Winston-Salem to Kernersville. Thus, this project maximizes existing resources while meeting a stated need under the SMFP.*
>
> *FMC is proposing to construct and operate a satellite hospital called FMC-Kernersville. FMC-Kernersville will be a new acute care hospital with 50 acute care beds (46 general medical/surgical acute inpatient licensed beds plus four Intensive Care licensed acute beds) and 10 observation beds. FMC-Kernersville will be located on Highway 66 South in Kernersville, near the intersection of Interstate 40 in Kernersville, North Carolina (zip code 27284). A map is included in Exhibit 15 to show the exact location of the proposed hospital.*
>
> *Kernersville, known as the "Heart of the Triad", is projected to be the fastest-growing zip code in Forsyth*

County during the next five years. New businesses and industry have chosen Kernersville as a result of its prime location and proximity to both interstate highways and air transportation. In 2006, the North Carolina Manufacturers registrar reported that there are 23 companies with more than 30 employees located in Kernersville. Of those 23 companies, 12 of them have at least 100 employees and six have over 200. Seven of the 23 major employers have been established in the last 20 years.

...

Based upon these and other new job opportunities in the area, the Kernersville Development Plan projects that by the year 2025, the job base will grow from 276,000 to 379,000, a 37% increase. As a result, the area will experience tremendous population growth and greatly increased demand for medical services.

From 2000 to 2005, the population of the Kernersville zip code area increased by 4,748 persons, more than any other area in Forsyth County .... The Kernersville zip code was also third in the top five fastest growing zip codes areas in Forsyth County from 2000 to 2005. From 2005 to 2010, the population of Kernersville is projected to grow more than 10%, faster than any other area in Forsyth County. ...

...

The population growth reported from 2000-2005 was not a one-time occurrence. Since 1970, the Kernersville population has increased 53% each decade. To accommodate the additional population growth, Kernersville has developed several new neighborhoods. ...

... Kernersville is the location of the majority of the population growth in Forsyth County. A new facility in Kernersville will help alleviate crowded conditions on the FMC campus. Thee [sic] *crowded conditions reduce ease of access and frustrates patients and their families. See Exhibit 12 for a letter of explanation from the Novant Health Triad Region President.*

...

As discussed above, Kernersville, due to its proximity to Winston-Salem, High Point and Greensboro (the Triad) and the Piedmont Triad Airport, has been and is projected to remain one of the fastest growing areas in the State. This growth is also evident in the proposed FMC-Kernersville service area.

Exhibit 21 contains an urban planning report prepared by Cheryl Roberts of the Center for Applied Research at Central Piedmont Community College in Charlotte. This report details the current and future growth of the FMC-Kernersville area. ...

As shown in the tables below, the service area for FMC-Kernersville has an estimated 2005 population of 101,379 and is projected to grow more than 25% by 2015. The Town of Kernersville has an estimated population of 22,075, a 29% increase over the 2000 Census population.

...

The two fastest-growing zip codes are High Point, 27265, and Colfax, 27235. The projected 34.3 % growth rate in High Point is due to the huge amounts of residential development. The details of this development are outlined in Exhibit 19. Colfax is the area between Kernersville and Greensboro along Business 40 and Highway 421. Neither High Point nor Colfax is in Forsyth County. ...

...

Thus, the need for this project is demonstrated: (1) by the SMFP need determination for additional beds in Forsyth County; (2) the existing population of Kernersville; (3) the projected growth of the area; (4) the fact that Kernersville does not have its own hospital at the present time; (5) FMC's long-standing presence in the area; and (5) strong and enthusiastic community support for this project.

...

As part of its utilization analysis, the applicant defined hospital service areas for the following six North Carolina Hospitals in the Triad area and for FMC-Kernersville, based on July 1, 2004 to June 30, 2005 discharge volumes.

- *Forsyth Medical Center*
- *High Point Regional Hospital*
- *Medical Park Hospital*
- *Moses H. Cone Memorial Hospital*
- *North Carolina Baptist Hospital*
- *Thomasville Medical Center*

...

Data from the annual hospital licensure renewal applications for these hospitals were used to calculate current and projected service levels and market shares. The potential for FMC-Kernersville to have a material impact of [sic] *the volume of services at each hospital was considered. Where Novant judged there was no possibility of FMC-Kernersville having a material impact on a hospital, Novant dropped the hospital from further analysis (i.e., Thomasville Medical Center and Lexington Memorial Hospital). The service areas of three existing suburban community hospitals, Presbyterian Hospital Huntersville, Presbyterian Hospital Matthews, and Thomasville Medical Center, were used as a basis for projecting service levels and market shares for the proposed FMC-Kernersville. Further details on service area definition can be found in Exhibit 20.*

The reasonableness of locating a new community hospital in the Kernersville area is shown by the projected need for services due to significant population growth experienced over the past years and projected to continue in the foreseeable future (i.e., Kernersville is the fastest-growing area in Forsyth County).

... The table below shows the projected patient days and occupancy rates for FMC-Kernersville in the first three years of operation. Note that FMC-Kernersville's occupancy rate will be well over the required project year 3 target occupancy rate required by the CON Section's

Criteria and Standards for New Acute Beds found at 10A NCAC 14C.3800). As Kernersville continues to grow, its future acute health care needs can be met by the development and expansion of FMC-Kernersville."

Acute Care Beds (including ICU) – The following table illustrates projected utilization of the 50 acute care beds at FMC-K, as reported by the applicants in Section III.1, page III-28, and Exhibit 20, Figure 26.

PROJECTED UTILIZATION OF ACUTE CARE BEDS AT FMC-K

	Year One 7/1/09 - 6/30/10	Year Two 7/1/10 - 6/30/11	Year Three 7/1/11 - 6/30/12
General Med/Surg (46 beds)			
Patient Days	9,768	12,240	14,865
ADC [1]	26.8	33.5	40.7
% Occupancy [2]	58.2%	72.9%	88.5%
ICU (4 beds)			
Patient Days	842	1,056	1,282
ADC	2.3	2.9	3.5
% Occupancy	57.7%	72.3%	87.8%
Total (50 beds)			
Discharges [3]	2,211	2,770	3,364
Average Length of Stay (ALOS) [4]	4.8	4.8	4.8
Patient Days	10,610	13,296	16,147
ADC	29.1	36.4	44.2
% Occupancy	58.1%	72.9%	88.5%

Source: Section III.1, page III-28, and Exhibit 20, Figure 26.

(1) ADC equals total number of patient days of care divided by 365.

(2) Occupancy equals ADC divided by the number of beds.

(3) The applicants did not provide the number of discharges for the 46 med/surg beds or the 4 ICU beds. They only provided the number of discharges for the total number of acute care beds.

(4) ALOS equals patient days divided by discharges.

As shown in the above table, the applicants project that the ADC of the 50 acute care beds at FMC-K in the third operating year will be 44.2 patients, which is an occupancy rate of 88.5%. The applicants provide the assumptions and methodology used to project utilization of the acute care beds at FMC-K in Exhibit 20, where they state

1. *The FMC- Kernersville service area is a collection of seven zip codes in Forsyth and Guilford Counties in North Carolina. One of these zip codes (27285) is a point zip code, a post office box, within the boundary of zip code 27284. In our analysis we combined these two zip codes. ...*

...

2. *For projecting utilization, we have used and relied upon publicly available summary information from the data in the North Carolina Hospital License Renewal Applications ('LRAs'), hospital discharge data compiled by Solucient, and internal data from Novant Health. ...*

...

3. *The applicant assumed the FMC-Kernersville would open on July 1, 2009. We prepared utilization projections for each 12-month period ending June 30, through 2012, the third year of hospital operations. The discharge data used in this study to project inpatient utilization are for discharges during the twelve month period July 1, 2004 through June 30, 2005.*

...

4. *Projecting demand for hospital services requires population data by age and gender for various counties, and zips codes. We used 2000 census data from the U.S. Census, and population estimates and projections from Claritas, Inc. Claritas provided estimates and projections for the years 2005 and 2010 by the following age cohorts:*
   - *Total Population Age 0-14*
   - *Total Population Age 15-44*
   - *Total Population Age 45-64*
   - *Total Population Age 65+*
5. *We interpolated and extrapolated the actual 2000 Census and the 2005 and 2010 Claritas projections based on compound average annual growth rates ("CAGR") to provide estimates and projections for all years from 2000 through 2015 for each age and gender cohort for each geographic area. ...*

...

6. *We used the total population (male and female) for each area to forecast demand for medical and surgical services. FMC-Kernersville will not provide obstetric and newborn services. To project inpatient services at FMC-Kernersville and other North Carolina hospitals, we refined the projection methodology to separately calculate demand for each age cohort. This enabled us to use the most detailed available Forsyth and Guilford County population discharge rates.*

...

8. ***Inpatient Discharge Rates***. *FMC-Kernersville will be a community-based hospital and will not initially offer the full range of services offered by a tertiary level provider. The projections for FMC-Kernersville include only the range of services that FMC-Kernersville will routinely provide. ... In summary, we did not include projections for Mental Health, Drug and Alcohol Abuse, Rehabilitation, Obstetrics, Normal Newborns, NICU, Inpatients* [sic] *Diagnostic Cardiac Catheterizations, and tertiary level services that FMC-Kernersville does not plan to routinely provide during the projection period. Tertiary level services were defined as discharges in DRGs with a FY 2005 Medicare DRG case weight of 2.0 or greater.*
9. *To project inpatient discharges of the limited DRGs for the service area population, we computed discharge rates limited to FMC-Kernersville medical/surgical services for Forsyth County and for Guilford County. We used the Forsyth County discharge rate for Forsyth zip codes and the Guilford County discharge rate for Guilford zip codes ....*
10. ***Inpatient Market Share***. *The applicant used the 'Novant System' market share as a starting point for calculating expected market share at FMC-Kernersville. For this analysis, the Novant System includes the applicant hospitals that are currently serving patients from the FMC-Kernersville service area: Forsyth Medical Center, Medical Park Hospital, and Thomasville Medical Center.*
11. *As an indicator of the growth that can be expected from locating a hospital in Kernersville (FMC-Kernersville), we considered our experience with a new 50-bed hospital in Huntersville, North Carolina (Presbyterian Hospital Huntersville). This hospital is part of Novant's Southern Piedmont Region. ...*
12. *For each FMC-Kernersville service area zip code, we calculated the current Novant System market shares for the limited DRGs using inpatient discharge data for the most current twelve months available: July 1, 2004 through June 30, 2005. We assumed 65% of the Novant System market share in the Forsyth County zip codes in the service area would shift to FMC-Kernersville by*

Year 3. We assumed 70% of the Novant market share in the Guilford County zip codes in the service area would shift to FMC-Kernersville since patients would have to drive past FMC-Kernersville to be served at FMC, MPH, or TMC.

13. *The applicant estimates opening of FMC-Kernersville will increase the Novant System market shares in each service area zip code between 5% and 15% due to proximity. We assumed different levels of increase in market share for each zip code, taking into account the next nearest hospital. We capped the Novant System market share in any service area zip code at 70%. ...*
14. *New hospitals take a few years to realize their full market shares. The applicant projects FMC-Kernersville will not reach the market shares shown in figure 12 until the third year of operations. We reduced the FMC-Kernersville market shares for the first two years of operation to allow for this start up period growth in FMC-Kernersville discharges. The third year market shares are reduced by 30% in Year 1 and by 15% in Year 2. Market shares for years after Year 3 are held constant at Year 3 levels. ...*
15. *In making the projections for the new hospital, the applicant relied upon the experience of similar Novant hospitals, Presbyterian Hospital Huntersville and Presbyterian Hospital Matthews. These hospitals are under Novant management and are comparable to FMC-Kernersville in their size and scope of services. All instances where we have relied upon the experience of these hospitals are noted.*
16. ***Medical/Surgical/ICU Services.*** *The applicant projected medical/surgical discharges and patient days for FMC-Kernersville using the following formulas:*
    - *Projected Zip Code Discharges = Limited discharge rate for the county X projected zip code population. Separately calculated for each age cohort.*
    - *FMC-Kernersville Zip Code Discharges = Projected zip code discharges X FMC- Kernersville zip code market share.*
    - *Discharges from FMC-Kernersville Service Area = Σ(FMC-Kernersville Zip Code discharges)*
    - *Total FMC-Kernersville Discharges = FMC-*

Kernersville discharges from services area/Percent FMC-Kernersville discharges from service area.

- *FMC-Kernersville medical/surgical patient days = Total FMC-Kernersville discharges X Average limited medical/surgical length of stay.*

17. *In applying this projection algorithm, we used the following factors and made the following assumptions:*
    - *We used the discharge rates by age cohort for only the medical/surgical services FMC- Kernersville is expected to offer. This limited discharge rate excludes Delivery DRGs (370-375), Mental Health and Drug Abuse DRGs (424-433 and 521-523), Rehab (462), Normal Newborns (391), NICU (385-390), Diagnostic Cardiac Catheterization (124,125) and all DRGs with FY 2005 relative case weight of 2.0 or greater*
    - *The discharge rates were held constant throughout the projection period.*
    - *The level of in-migration is assumed to be 20%. This is based on the experience at Presbyterian Hospital Huntersville. We believe the level of immigration is conservative because PHH serves 80% of its discharges from a 10 zip code service area, while the FMC-Kernersville service area will only be seven zip codes.*
    - *The average length of stay is 4.8 days and is assumed to remain constant during the projection period. The assumption is based on experience of residents from Forsyth and Guilford Counties for the limited DRGs FMC-Kernersville will routinely serve. ...*
    - *Patient days in the intensive care unit ('ICU') will be approximately 8% of total medical/surgical days. This assumption is based on the experience at Presbyterian Hospital Huntersville and Presbyterian Hospital Matthews reported on their 2006 Hospital License Renewal Applications. ...*

    ...

18. *The following actual numbers demonstrate the procedures for projecting medical/surgical services. The first two calculations use the zip code 27284/27285 of Kernersville in the third year of operation as an example. A spreadsheet model was used to perform*

these calculations with unrounded numbers. Sums generated in our model, using non-rounded figures, may not equal the sums replicated by the following rounded numbers.

19. *Projected Zip Code Discharges = Limited discharge rate X projected zip code population. Separately calculated for each age cohort.*

Projected Discharges for Zip Code 27284 / 27285 Year 3: Twelve months ending June 30, 2012					
	Total 0-14	*Total 15-44*	*Total 45-64*	*Total 65+*	*Total*
Limited discharge rate for Forsyth County	*18.3*	*37.6*	*80.0*	*254.9*	
Projected zip code population	*10,862*	*19,863*	*15,407*	*7,146*	*53,277*
Projected discharges	*199*	*746*	*1,232*	*1,815*	*3,993*

20. *FMC-Kernersville Zip Code Discharges = Projected zip code discharges X FMC- Kernersville zip code market share.*

FMC – Kernersville discharges for Zip Code 27284 / 27285 Year 3: Twelve months ending June 30, 2012	
Projected zip code discharges	*3,993*
FMC – Kernersville Zip Code market share	*50%*
FMC – Kernersville Zip Code Discharges	*2,011*

21. *Discharges from FMC-Kernersville Service Area = Σ (FMC-Kernersville zip code discharges).*

Discharges from FMC – Kernersville Service Area Year 3: Twelve months ending June 30, 2012	
Zip Codes	***2011-2012***
27284 / 27285	*2,011*
27051	*255*
27009	*65*
27265	*280*
27235	*46*
27310	*35*

Discharges from Service Area	*2,691*

22. *Total FMC-Kernersville Discharges = FMC-Kernersville discharges from services area / Percent FMC-Kernersville discharges from service area.*

Total FMC – Kernersville Discharges Year 3: Twelve months ending June 30, 2012	
Discharges from Service Area	*2,691*
Percent discharges from service area: the applicant Report	*80%*
Total Discharges	*3,364*
Discharges from outside Service Area	*673*

23. FMC-Kernersville medical/surgical patient days = Total FMC-Kernersville discharges X Average limited medical/surgical length of stay.

Total FMC – Kernersville Inpatient Days Year 3: Twelve months ending June 30, 2012	
Total discharges	*3,364*
Average medical/surgical length of stay	*4.8*
Medical/surgical patient days	*16,147*

...

*43. **Allocation of FMC-Kernersville Discharges**. We assume that part of the FMC-Kernersville market share will be a direct shift from other Novant System hospitals. However, FMC-Kernersville is projected to increase the total Novant System market share within its service area zip codes. This additional market share, between 5 and 15 percent in each zip code by Year 3, will come from other hospitals currently serving patients in this area. ...*

44. Our method of allocating 'Non-Novant System' discharges from FMC-Kernersville is to assume that the actual loss of inpatient volume from each zip code will be proportional to each hospital's current Non-the applicant market share for that zip code. In other words, we assumed that if a Non-Novant hospital currently provides 20 percent of the Non-Novant services to residents of a zip code, that hospital's discharges will be less by 20 percent of the FMC-Kernersville medical/surgical discharges that come from Non-Novant hospitals. The same method is used to allocate impact on the applicant System hospitals. ...

45. We also accounted for impact due to in-migration from outside the FMC-Kernersville service area. For the purposes of this analysis we assumed all in-migration would come from Forsyth and Guilford Counties and

that the impact on each hospital would be proportional to its market share from each county. For example, in the first year of operations, the impact on FMC attributed to the three Forsyth County service area zip codes was 1,046 patients. The in-migration at FMC-Kernersville is assumed to be 20% so we divided this number by 80% to arrive at the total impact to FMC in Forsyth County, 1,308 patients. The impact to FMC from service area zip codes in Guilford County was 69 patients and the total impact from Guilford County was 87 patients (69/80%). Therefore the total impact from the service area was 1,115 patients, the in-migration impact was 279 patients, and the total impact was 1,394 patients in the first year of operations.

...

49. *The applicant calculated a composite ratio of the three years of data, dividing the composite number by the inpatient medical surgical discharges summed for the same three year period from Solucient inpatient discharge data and the applicant* [sic] *internal inpatient discharge data.*
50. *Next, the applicant applied the composite ratio to the projected discharges for each hospital with FMC-Kernersville and without FMC-Kernersville. Finally, we calculated the impact of FMC-Kernersville by subtracting the number of services provided without FMC-Kernersville from the number of service* [sic] *provided with the new hospital. ...*

...

52. *... Based on a review of current and projected service volumes, FMC-Kernersville does not appear to have a material adverse impact on any existing hospitals as compared to the volume of services provided by each hospital in 2005. Medical Park Hospital will be affected more than any other hospital. However, this is simply a shift of services within the Novant Health System and will not have any adverse impact on the availability of services to patients seen at Medical Park Hospital.* (Emphasis in original.)

The applicants state that the *"opening of FMC-Kernersville will increase the Novant System market shares in each service area zip code between 5% and 15% due to proximity. We assumed different*

levels of increase in market share for each zip code, taking into account the next nearest hospital." (Emphasis added.) Further, the applicants state *"We assume that part of the FMC-Kernersville market share will be a direct shift from other Novant System hospitals. However, FMC-Kernersville is projected to increase the total Novant System market share within its service area zip codes. This additional market share, between 5 and 15 percent in each zip code by Year 3, will come from other hospitals currently serving patients in this area."* (Emphasis added.) However, the applicants did not provide documentation to support their assumption that market shares would increase 5 to 15%.

Further, the applicants state *"The level of in-migration is assumed to be 20%. This is based on the experience at Presbyterian Hospital Huntersville. We believe the level of inmigration is conservative because PHH serves 80% of its discharges from a 10 zip code service area, while the FMC-Kernersville service area will only be seven zip codes."* However, the mere fact that Presbyterian Hospital Huntersville (PHH) serves 80% of its discharges from a 10 zip code service area does not demonstrate that the applicants' assumption is *"conservative."* The applicants do not provide sufficient information in the application to show that the 10 zip codes in PHH's service area are similar to the 7 zip codes in FMC-K's proposed service area. Further, the applicants did not adequately demonstrate that it is reasonable to assume that inmigration would be 20% at FMC-K based only on the experience at one other hospital. For example, the FY 2005 patient origin for WakeMed Cary Hospital shows that inmigration for a satellite community hospital located in close proximity to two tertiary hospitals can be significantly less than 20%. The following table illustrates FY 2005 patient origin for WakeMed Cary Hospital, as reported in its 2006 Hospital License Renewal Application.

WAKEMED CARY HOSPITAL	
COUNTY	% OF TOTAL ADMISSIONS
Wake	87.14%
Harnett	3.55%
Johnston	3.16%
Chatham	0.76%
Lee	0.68%
Durham	0.65%
Other NC Counties	2.43%
Other States	1.63%
Total	100.00%

As shown in the above table, during FY 2005, only 12.86% of WakeMed Cary Hospital's inpatients were not residents of Wake County. Moreover, WakeMed Cary Hospital is licensed for more than twice as many beds as the proposed FMC-K [114 / 50 = 2.3] and, in July 2005, the population of the Town of Cary had more than five times the population of the Town of Kernersville [115,967 / 21,277 = 5.5]. Thus, based on the experience at WakeMed Cary Hospital, inmigration at the proposed FMC-K is unlikely to be as high as 20%, particularly given there are four tertiary hospitals in Forsyth and Guilford counties.

Moreover, in Section III.5(a), page III-21, the applicants state *"20 percent will come from other zip codes in Forsyth and Guilford Counties, Other North Carolina Counties, and Other States."* (Emphasis added.) Thus, the applicants state that some portion of the 20% inmigration will be residents of other Forsyth and Guilford County zip codes. However, the applicants did not identify those zip codes. Thus they did not demonstrate that residents of those zip codes would not have to drive past other hospitals to utilize the proposed FMC-K. It is unreasonable to assume that residents of Forsyth and Guilford counties would drive past one of the four tertiary acute care hospitals located in Forsyth and Guilford counties to utilize the proposed FMC-K.

In summary, the applicants did not adequately demonstrate that projected utilization of the 50 acute care beds at FMC-K is based on reasonable assumptions. Therefore, the applicants overestimate the number of persons to be served at FMC-K and consequently do not adequately demonstrate the need for 50 acute care beds in Kernersville.

Observation Beds (Unlicensed) – The applicants propose to develop 10 unlicensed observation beds, which will be located on the third floor of the hospital. The following table illustrates projected utilization of the observation beds at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 26.

	OBSERVATION DAYS OF CARE	PERCENT OCCUPANCY[(1)]
Year One (7/1/09 – 6/30/10)	1,636	44.8%
Year Two (7/1/10 – 6/30/11)	2,050	56.2%
Year Three (7/1/11 – 6/30/12)	2,489	68.2%

Source: Exhibit 20, Figure 26.
(1) Calculated by dividing days of care by 365 and then dividing the result by 10.

The applicants assume 0.74 observation days for each inpatient discharge *"Based on 10-bed Observation Unit at PHH (2006)."* See Exhibit 20, Figure 25, footnote 1 and Figure 26, footnote 1. However, according to the 2006 Hospital License Renewal Application for PHH, during FY 2005, PHH reported 1,611 observation days (excluding emergency room patients[5]) and 2,448 discharges, which is only 0.66 observation days for every inpatient discharge [1,611 / 2,448 = 0.66], not 0.74. Therefore, the applicants overestimate the number of observation days to be provided at FMC-K during each of the first three operating years. Further, since the projected number of observation days is based on the projected number of inpatient discharges and the applicants overestimated inpatient discharges at FMC-K, the projected number of observation days is also overstated. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to develop 10 observation beds at FMC-K.

Operating Rooms – The applicants propose to relocate three existing shared ORs from FMC-WS and one existing shared OR from MPH. Pursuant to the certificate of need issued for Project I.D. #G-7311-05, the applicants are authorized to relocate three existing shared ORs from FMC to Kernersville where they are to be converted to dedicated outpatient ORs operated under FMC's license. Thus, in this application, the applicants propose the following changes to Project I.D. #G-7311-05:

- The authorized site for Project I.D. #G-7311-05 is not the same as the site proposed for FMC-K. However, both sites are within the Town of Kernersville.

5 In Section II.1, page II-2, of this application, the applicants state that *"some of the treatment rooms* [in the emergency room at FMC-K] *will be used to observe emergency department patients."* Thus, the applicants do not propose to use the unlicensed observation beds on the third floor of FMC-K for emergency room patients.

- The three ORs would remain shared ORs rather than be converted to dedicated outpatient ORs.
- An additional fourth OR would be relocated.

Regarding the need for four shared ORs at FMC-K, in Section III.8(b), page III-30, the applicants state *"A hospital must have operating rooms in order to be licensed. The issue is how many rooms are needed when the hospital opens."* The applicants state that FMC-K needs four shared ORs based on the number of inpatient and outpatient surgeries projected to be performed in the third operating year. The following table illustrates projected utilization of the ORs at FMC-K during the first three operating years, as reported by the applicants in Section III.8(b), page III-30, and Exhibit 20, Figures 23 and 24.

	YEAR ONE 7/1/09 – 6/30/10	YEAR TWO 7/1/10 – 6/30/11	YEAR THREE 7/1/11 – 6/30/12
Projected # of IP Surgical Procedures	863	1,068	1,282
Projected # of OP Surgical Procedures	1,939	2,400	2,878
Total # of Surgical Procedures	2,802	3,468	4,160
Average # of procedures per room per day (1)	2.7	3.3	4.0

Source: Section III.8(b), page III-30, and Exhibit 20, Figures 23 and 24.
(1) Assumes 260 days of operation per year. Calculated by dividing total # of surgical procedures by 260 and then by 4.

As shown in the above table, during the third operating year, the applicants project that an average of four surgical procedures will be performed per day in each of the four shared ORs at FMC-K. The applicants provide the assumptions and methodology used to project utilization of the four ORs at FMC-K in Exhibit 20, where they state

> *"24. ... The applicant used the total population for each zip code and the usage rate for the zip code's county to forecast demand for inpatient and outpatient surgical services. The following steps were taken to project utilization at FMC- Kernersville.*
>
> *25. First we calculated the usage rate for inpatient and outpatient surgeries separately, using the patient origin data reported by all North Carolina hospitals and ambulatory surgical facilities on their 2006 LRAs. ...*
>
> *26. Next we multiplied the population in each FMC-Kernersville service area zip code times the usage rate for that zip code's county. ...*
>
> *27. The applicant calculated the current the* [sic]

applicant System market share for surgeries at FMC and Medical Park. FMC-Kernersville will be a community hospital and will not initially offer the full range of surgery services offered at FMC and MPH. Therefore, the base market share for the Novant System does not include C-sections or Open Heart Surgeries. ...

28. *Consistent with our inpatient projection, we assumed 65% of the Novant System market share in the Forsyth County zip codes and 70% of the market share in the Guilford County zip codes would shift to FMC-Kernersville by Year 3. The applicant estimates the Novant System market shares in each zip code will increase between 5% and 15% with FMC-Kernersville, as we did with inpatients. ...*
29. *The applicant projects FMC- Kernersville will not reach these market shares until the third year of operations. We discounted the FMC-Kernersville market shares for the first two years of operation to allow for this growth in FMC-Kernersville discharges. We hold market shares constant for years after Year 3. ...*
30. *We multiplied the FMC-Kernersville market shares times the total projected surgeries for each zip code in each year to calculate the surgeries at FMC-Kernersville. In-migration was assumed to be 20%."*

However, the applicants did not adequately demonstrate that it is reasonable to assume that inmigration would be 20% at FMC-K. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate that the projected number of surgical procedures to be performed at FMC-K is based on reasonable assumptions. Consequently, in this application, the applicants overestimate the number of surgical procedures to be performed at FMC-K and consequently do not adequately demonstrate the need for four shared ORs at FMC-K.

Emergency Room – The applicants propose to develop an ER at FMC-K with 14 treatment rooms. The following table illustrates projected utilization of the ER at FMC-K during the first three

operating years, as reported by the applicants in Exhibit 20, Figure 26.

	# OF ER VISITS
Year One (7/1/09 – 6/30/10)	13,148
Year Two (7/1/10 – 6/30/11)	16,475
Year Three (7/1/11 – 6/30/12)	20,008

Source: Exhibit 20, Figure 26.

The applicants assume 5.95 ER visits for each inpatient discharge, which they state is based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, the applicants did not provide documentation to support their assumption that the proposed ER at FMC-K requires 14 treatment rooms in order to provide those visits. Moreover, since the projected number of ER visits is based on the projected number of inpatient discharges and the projected number of inpatient discharges is not reasonable, the projected number of ER visits is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to develop 14 treatment rooms in the ER.

Laboratory – The applicants propose to develop a lab at FMC-K. The following table illustrates projected utilization of the lab at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 28.

	# OF LAB PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	37,358	37,571	74,929
Year Two (7/1/10 – 6/30/11)	46,812	47,079	93,891
Year Three (7/1/11 – 6/30/12)	56,850	57,175	114,025

Source: Exhibit 20, Figure 28.

The applicants assume that the lab at FMC-K will perform 16.9 procedures for every inpatient discharge and 1.28 procedures for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of lab procedures is based on the projected inpatient discharges and the projected inpatient discharges are not reasonable, the projected number of lab procedures is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not

adequately demonstrate the need for the projected number of lab procedures at FMC-K.

Pharmacy – The applicants propose to develop a pharmacy at FMC-K. The following table illustrates projected utilization of the pharmacy at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 28.

	# OF PHARMACY UNITS		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	176,536	81,540	258,076
Year Two (7/1/10 – 6/30/11)	221,213	102,176	323,388
Year Three (7/1/11 – 6/30/12)	268,648	124,085	392,733

Source: Exhibit 20, Figure 28.

The applicants assume that the pharmacy at FMC-K will dispense 79.86 pharmacy units for every inpatient discharge and 2.77 pharmacy units for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of pharmacy units is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of pharmacy units is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need for the projected number of pharmacy units at FMC-K.

Cardiac Cath Equipment – The applicants propose to relocate one of FMC's eight existing and approved units of cardiac cath equipment from FMC-WS to FMC-K. In Section II.1, page II-3, the applicants state *"It is anticipated that the cath lab at FMC-Kernersville will be used for diagnostic cardiac catheterization procedures, as well as peripheral vascular procedures."* In Section II.1, page II-3, the applicants state that the unit to be relocated is the one authorized in Project I.D. #G-7266-05 (acquire eighth unit of cardiac cath equipment), which is not yet operational. The proposed new project results in the following changes to the previously approved project.

- The eighth unit of cardiac cath equipment will be located in Kernersville rather than in Winston-Salem with the other units of cardiac cath equipment.

- The eighth unit of cardiac cath equipment would not be used to perform therapeutic cardiac cath procedures at FMC-K. In Project I.D. #G-7266-05, the applicants proposed to perform therapeutic cardiac cath procedures on the eighth unit of cardiac cath equipment.
- The eighth unit of cardiac cath equipment will be used to perform peripheral vascular procedures at FMC-K. In Project I.D. #G-7266-05, the applicants did not propose to perform peripheral vascular procedures on the eighth unit of cardiac cath equipment.

In Section III.8, pages III-27 & 28 and III-30 & 31, the applicants state

> *"Locating this laboratory at the new hospital will improve the accessibility of services for residents of Forsyth County. The laboratory will be used only for diagnostic cardiac catheterizations and peripheral vascular procedures by appropriately credentialed cardiologists, vascular surgeons and interventional radiologists. ... No therapeutic cardiac catheterizations will be performed at FMC-Kernersville per the requirement stated in 10A NCAC 14C.1604(a).*
>
> *There are presently six cardiac catheterization laboratories in operation on the main FMC campus that are used for inpatient, outpatient, scheduled, emergency, diagnostic and therapeutic procedures. Often patients scheduled for diagnostic catheterization procedures can be delayed or bumped by other patients with more emergent needs. Dedicating a catheterization laboratory at Kernersville to diagnostic catheterization procedures and to peripheral vascular procedures will improve geographic accessibility for residents of the eastern portion of Forsyth County and will substantially eliminate delays in scheduled procedures due to bumping. The six laboratories at the main campus have adequate capacity to meet the needs of these other patients. ...*
>
> *Locating this laboratory at the main campus would require more expensive construction, would not improve geographic accessibility as much as locating the catheterization laboratory at FMC-Kernersville, and would*

not promote easier access to peripheral vascular procedures for the residents of Kernersville.

...

This application does not propose to relocate a cath lab that has already been constructed and equipped. The proposal is to relocate a previously CON-approved FMC cath lab from Winston-Salem to Kernersville, within Forsyth County. The lab will continue to be operated under the acute care hospital license of FMC, when it is in Kernersville. Many of the patients to be served by the laboratory should be essentially the same as shown in the prior application. FMC centrally schedules all of its cardiac catheterization laboratories. As part of the relocation of the laboratory, FMC is designating it for diagnostic cardiac catheterizations and peripheral vascular procedures to be performed by appropriately credentialed FMC medical staff members who are specialists in cardiology, interventional radiology, and vascular surgery procedures. It will thus draw patients who can be more conveniently provided these types of procedures at the FMC-Kernersville location."

Projected Cardiac Cath Utilization- Table A below illustrates projected utilization of the eight units of cardiac cath equipment as reported by the applicants in Section II.8, page 18, of Project I.D. #G-7266-05. All of the procedures in the following table were previously projected to be performed at FMC-WS.

TABLE A
PROJECTED CARDIAC CATH UTILIZATION FROM PROJECT I.D. #G-7266-05

	YEAR ONE 7/1/08 – 6/30/09	YEAR TWO 7/1/09 – 6/30/10	YEAR THREE 7/1/10 – 6/30/11
# of Diagnostic Cardiac Cath Procedures	6,031	6,110	6,189
# of Adult Therapeutic Cardiac Cath Procedures	2,334	2,362	2,393
Total # of Cardiac Cath Procedures	8,365	8,472	8,582
Total # of Diagnostic-Equivalent Cardiac Cath Procedures (1)	10,116	10,244	10,377
Average # of Diagnostic-Equivalent Procedures/Unit (8 units) (2)	1,265	1,281	1,297
Percent of capacity (3)	84.3%	85.4%	86.5%

Source: Section II.8, page 18, of Project I.D. #G-7266-05.

(1) Pursuant to 10A NCAC 14C .1601(2), *"One therapeutic cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient age 14 or under is valued at two diagnostic-equivalent procedures. All other procedures are valued at one diagnostic-equivalent procedure."*

(2) Calculated by dividing the total number of diagnostic-equivalent cardiac cath procedures by eight.

(3) Pursuant to 10A NCAC 14C .1601(2), capacity of one unit of cardiac cath equipment is 1,500 diagnostic-equivalent procedures per year. Calculated by dividing the average number of diagnostic-equivalent procedures per unit by 1,500.

Table B below illustrates the previously projected number of procedures to be performed on the eighth unit of cardiac cath equipment in Winston-Salem, as reported by the applicants in Section II.8, page 26, of Project I.D. #G-7266-05.

TABLE B
PROJECTED UTILIZATION OF THE EIGHTH UNIT OF CARDIAC CATH EQUIPMENT IN WINSTON-SALEM FROM PROJECT I.D. #G-7266-05

	YEAR ONE 7/1/08 – 6/30/09	YEAR TWO 7/1/09 – 6/30/10	YEAR THREE 7/1/10 – 6/30/11
# of Diagnostic Cardiac Cath Procedures	754	764	774
# of Adult Therapeutic Cardiac Cath Procedures	292	296	300
Total # of Cardiac Cath Procedures	1,046	1,059	1,073
Total # of Diagnostic-Equivalent Cardiac Cath Procedures (1)	1,265	1,282	1,299
Percent of capacity (2)	84.3%	85.5%	86.5%

Source: Section II.8, page 26, of Project I.D. #G-7266-05.
(1) Pursuant to 10A NCAC 14C .1601(2), *"One therapeutic cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient age 14 or under is valued at two diagnostic-equivalent procedures. All other procedures are valued at one diagnostic-equivalent procedure."*
(2) Pursuant to 10A NCAC 14C .1601(2), capacity of one unit of cardiac cath equipment is 1,500 diagnostic-equivalent procedures per year. Calculated by dividing the average number of diagnostic-equivalent procedures per unit by 1,500.

Table C below illustrates the projected number of peripheral vascular procedures to be performed at FMC-K and the projected number of cardiac cath procedures to be performed at FMC-WS and FMC-K during the first three operating years, as reported by the applicants in Exhibit 4, page 13, of this application.

TABLE C
PROJECTED CARDIAC CATH UTILIZATION FROM THIS APPLICATION (PROJECT I.D. #G-7604-06) (1)

	YEAR ONE 7/1/09 – 6/30/10	YEAR TWO 7/1/10 – 6/30/11	YEAR THREE 7/1/11 – 6/30/12
# of Peripheral Vascular Procedures at FMC-K	230	285	343
# of Diagnostic Cardiac Cath Procedures at FMC-K (1 unit)	284	326	370
# of Diagnostic Cardiac Cath Procedures at FMC-WS (7 units)	5,232	5,291	5,351
Total # of Diagnostic Cardiac Cath Procedures (8 units) (2)	5,520	5,622	5,726
# of Adult Therapeutic Cardiac Cath Procedures at FMC-WS	1,952	1,976	1,999
Total # of Cardiac Cath Procedures	7,471	7,596	7,724
Total # of Diagnostic-Equivalent Cardiac Cath Procedures (2) (3)	8,934	9,076	9,222
Average # of Diagnostic-Equivalent Procedures/Unit (8 units) (4)	1,117	1,135	1,153
% Capacity (5)	74.5%	75.7%	76.9%

Source: Exhibit 4, page 13.
(1) The applicants state that *"Some numbers may not add precisely to totals due to rounding in formulas."*
(2) Does not include the peripheral vascular procedures to be performed at FMC-K.
(3) Pursuant to 10A NCAC 14C .1601(2), *"One therapeutic cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient age 14 or under is valued at two diagnostic-equivalent procedures. All other procedures are valued at one diagnostic-equivalent procedure."*
(4) Calculated by dividing the total number of diagnostic-equivalent cardiac cath procedures by eight.
(5) Pursuant to 10A NCAC 14C .1601(2), capacity of one unit of cardiac cath equipment is 1,500 diagnostic-equivalent procedures per year. Calculated by dividing the average number of diagnostic-equivalent procedures per unit by 1,500.

As shown in Tables A and C above, the applicants project that the eight units of cardiac cath equipment will perform fewer diagnostic-equivalent procedures in each of the first three operating years at FMC-K than at FMC-WS. This projected reduction in the number of procedures to be performed is despite the fact that the unit at FMC-K will begin operation one year later than proposed in Project I.D. #G-7266-05. The applicants do not explain in this application why they now assume they will perform fewer cardiac cath procedures. Further, as shown in Tables B and C above, taken from Project I.D. #G-7266-05, the applicants previously projected that the eighth unit of cardiac cath equipment would perform 1,297 diagnostic-equivalent cardiac cath procedures in the third operating year, which is 86.5% of capacity. However, in this application, the eighth unit of cardiac cath equipment is projected to perform only 370 diagnostic-equivalent cardiac cath procedures in the third operating year or 24.7% of capacity [370 / 1,500 = 0.247], which is less than the required minimum of 60% of capacity. Therefore, the applicants do not adequately demonstrate the need for cardiac cath equipment at FMC-K.

In Exhibit 4, pages 6-7, the applicants provide the assumptions and methodology used to project utilization of the cardiac cath equipment, where they state

> *"1. Estimate July 2005 – June 2006 FMC cardiac catheterization utilization by annualizing nine month* [sic] *of data from July 2005 – March 2006. ...*
> *2. Increase volume using population growth rate for cardiac cath service area weighted by patient origin. ...*
> *3. Increase to reflect positive impact of location in Kernersville. ...*
> *4. Calculate ICD-9 Code for cardiac cath volumes based on historical 2005 utilization at FMC."*

Regarding #3 above, the table following this sentence in the application shows that the applicants assume a 5% increase in FMC's market share for cardiac cath procedures due to providing services in Kernersville. The applicants provide the assumptions and methodology used to project utilization for all eight units of cardiac cath equipment combined. However, they did not provide the assumptions or the methodology used to project the number of

peripheral vascular and cardiac cath procedures to be performed at FMC-K. Therefore, the applicants did not adequately demonstrate that projected utilization of the cardiac cath equipment to be located at FMC-K is based on reasonable assumptions.

CT Scanner – The applicants propose to acquire a CT scanner to be located at FMC-K for a total of five CT scanners on FMC's license (there are four existing CT scanners located at FMC-WS). The following table illustrates the projected number of CT scans to be performed on the proposed CT scanner at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 26, and Exhibit 7, pages 3-6.

	# OF CT SCANS (not HECT Units)		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	1,527	6,943	8,469
Year Two (7/1/10 – 6/30/11)	1,913	8,700	10,613
Year Three (7/1/11 – 6/30/12)	2,323	10,565	12,888

Source: Exhibit 20, Figure 26, and Exhibit 7, pages 3-6.

The applicants assume that the CT scanner at FMC-K will perform 0.69 CT scans for every inpatient discharge and 0.43 CT scans for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of CT scans to be performed at FMC-K is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of CT scans to be performed at FMC-K is also not reasonable. See discussion above regarding acute care beds. Moreover, the applicants did not adequately demonstrate conformance with all the required rules for acquisition of a CT scanner in 10A NCAC 14C .2303. See 10A NCAC 14C .2303 for discussion. Therefore, the applicants did not adequately demonstrate the need for the CT services proposed to be provided at the proposed FMC-K campus.

Ultrasound (US) – In Section II.1, page II-3, the applicants state that FMC-K will have one US unit. However, according to the list of equipment to be acquired provided in Exhibit 18, the applicants propose to acquire one cardiac US unit, one *"Imaging, Handheld"* US unit and two *"Therapeutic, Genera* [sic]*"* US units for a total of four units of US equipment. The following table illustrates projected US utilization at FMC-K during the first three operating

years, as reported by the applicants in Exhibit 20, Figure 28. However, the applicants did not adequately demonstrate if the following projections represent utilization for all four proposed units.

	# OF US PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	345	2,088	2,434
Year Two (7/1/10 – 6/30/11)	433	2,617	3,050
Year Three (7/1/11 – 6/30/12)	526	3,178	3,704

Source: Exhibit 20, Figure 28.

The applicants assume the US equipment at FMC-K will perform 0.16 procedures for every inpatient discharge and 0.07 procedures for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of US procedures is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of US procedures is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to acquire four units of US equipment for the proposed FMC-K campus.

Nuclear Medicine Camera – The applicants propose to acquire one nuclear medicine camera (without coincidence circuitry) to be located at FMC-K. The following table illustrates the projected number of procedures to be performed on the proposed nuclear medicine camera at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 26.

	# OF NUCLEAR MEDICINE CAMERA PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	458	1,485	1,943
Year Two (7/1/10 – 6/30/11)	573	1,861	2,434
Year Three (7/1/11 – 6/30/12)	696	2,260	2,956

Source: Exhibit 20, Figure 26.

The applicants assume that the nuclear medicine camera at FMC-K will perform 0.21 procedures for every inpatient discharge and 0.09 procedures for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of nuclear medicine camera procedures to be

performed at FMC-K is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of nuclear medicine camera procedures to be performed at FMC-K is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to acquire a nuclear medicine camera (without coincidence circuitry) for the proposed FMC-K campus.

Mammography Unit – The applicants propose to acquire one mammography unit to be located at FMC-K. The following table illustrates the projected number of procedures to be performed on the proposed mammography unit at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 26.

	# OF MAMMOGRAPHY PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	2	2,736	2,738
Year Two (7/1/10 – 6/30/11)	2	3,428	3,431
Year Three (7/1/11 – 6/30/12)	3	4,163	4,166

Source: Exhibit 20, Figure 26.

The applicants assume that the mammography unit at FMC-K will perform 0.09 procedures for every inpatient discharge and 0.17 procedures for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of mammography procedures to be performed at FMC-K is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of mammography procedures to be performed at FMC-K is also not based reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to acquire a mammography unit for the proposed FMC-K campus.

X-ray Equipment – In Section II.1, page II-3, the applicants state that they will acquire one x-ray unit and one x-ray/fluoroscopy unit for FMC-K. However, according to the list of equipment to be acquired provided in Exhibit 18, the applicants also propose to acquire three mobile C-arms and two mobile X-ray units. The following table illustrates projected utilization of *"Other Imaging"*

equipment[6] at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 26. However, the applicants did not adequately demonstrate if the following projections represent utilization for all seven proposed units.

	# OF X-RAY PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	3,574	12,942	16,516
Year Two (7/1/10 – 6/30/11)	4,478	16,218	20,696
Year Three (7/1/11 – 6/30/12)	5,438	19,695	25,133

Source: Exhibit 20, Figure 26.

The applicants assume that the x-ray equipment at FMC-K will perform 1.62 procedures for every inpatient discharge and 0.79 procedures for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of x-ray procedures is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of x-ray procedures is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to acquire the proposed x-ray equipment for the proposed FMC-K campus.

Other Equipment – Based on the list of equipment to be acquired provided in Exhibit 18 and the design schematic provided in Exhibit 15, the applicants also propose to acquire the following equipment:

- 2 stress testing systems with treadmill
- echocardiography equipment (quantity not provided)
- 1 electroencephalograph (EEG) unit
- 3 electrocardiograph (ECG) units
- 1 pulmonary function testing system

However, the applicants did not provide any discussion of the need for this equipment. Therefore, the applicants did not adequately demonstrate the need to acquire the equipment listed above for the proposed FMC-K campus.

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6 The Project Analyst assumes that *"Other Imaging"* equipment means the x-ray equipment since projected utilization is provided separately for the nuclear medicine camera, the mammography equipment, US and the CT scanner.

equipment[6] at FMC-K during the first three operating years, as reported by the applicants in Exhibit 20, Figure 26. However, the applicants did not adequately demonstrate if the following projections represent utilization for all seven proposed units.

	# OF X-RAY PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (7/1/09 – 6/30/10)	3,574	12,942	16,516
Year Two (7/1/10 – 6/30/11)	4,478	16,218	20,696
Year Three (7/1/11 – 6/30/12)	5,438	19,695	25,133

Source: Exhibit 20, Figure 26.

The applicants assume that the x-ray equipment at FMC-K will perform 1.62 procedures for every inpatient discharge and 0.79 procedures for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, since the projected number of x-ray procedures is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable, the projected number of x-ray procedures is also not reasonable. See discussion above regarding acute care beds. Therefore, the applicants did not adequately demonstrate the need to acquire the proposed x-ray equipment for the proposed FMC-K campus.

Other Equipment – Based on the list of equipment to be acquired provided in Exhibit 18 and the design schematic provided in Exhibit 15, the applicants also propose to acquire the following equipment:

- 2 stress testing systems with treadmill
- echocardiography equipment (quantity not provided)
- 1 electroencephalograph (EEG) unit
- 3 electrocardiograph (ECG) units
- 1 pulmonary function testing system

However, the applicants did not provide any discussion of the need for this equipment. Therefore, the applicants did not adequately demonstrate the need to acquire the equipment listed above for the proposed FMC-K campus.

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6 The Project Analyst assumes that *"Other Imaging"* equipment means the x-ray equipment since projected utilization is provided separately for the nuclear medicine camera, the mammography equipment, US and the CT scanner.

In summary, the applicants adequately identified the population proposed to be served. However, they did not adequately demonstrate the need for all proposed services. Therefore, 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.

NC

The applicants propose to relocate the following beds and services from Winston-Salem to Kernersville:

- 11 existing acute care beds
- 1 existing shared OR (3 shared ORs were previously approved to be relocated to Kernersville)
- 1 unit of cardiac cath equipment

Acute Care Beds – In Section III.8, page III-31, the applicants state

"This CON proposes to relocate eleven existing licensed beds (seven acute inpatient beds; four ICU beds) from the FMC campus in Winston-Salem to FMC-Kernersville. In doing so, the needs of the patients remaining at the existing facility (FMC in Winston-Salem) will be adequately met with the remaining beds. ... Due to patient relocation to FMC-Kernersville, FMC will have more resources to devote to its acute and ICU patients. The relocation will also help alleviate overcrowding on the FMC campus. See, e.g., Exhibit 12 for a letter from Gregory J. Beier, FMC's President, documenting this point."

The following table illustrates projected utilization of the acute care beds at FMC-WS (including NICU beds), as reported by the applicants in Exhibit 5, page 4.

	YEAR ONE 7/1/09 – 6/30/10	YEAR TWO 7/1/10 – 6/30/11	YEAR THREE 7/1/11 – 6/30/12
Total Acute Care Beds			
Patient Days	213,810	215,902	218,017
ADC [1]	586	592	597
# of Beds (including NICU)	740	740	740
% Occupancy [2]	79.2%	80.0%	80.7%

(1) ADC was calculated by dividing the number of patient days by 365.
(2) % occupancy was calculated by dividing the ADC by the number of acute care beds.

As shown in the above table, the applicants project that the ADC at FMC-WS would be 597 acute care patients (including NICU patients) during the third operating year, which is an occupancy rate of 80.7%. According to its 2006 Hospital License Renewal Application, during FY 2005, FMC provided a total of 206,071 acute patient days of care (including NICU patients), which was an ADC of 565 [206,071 / 365 = 564.6] and an occupancy rate of 88.7% [ADC of 565 divided by 637 licensed acute care beds = 0.887]. The applicants adequately demonstrate that 740 acute care beds would be sufficient to meet the needs of the patients utilizing FMC-WS.

Shared Operating Rooms – In Section III.8, page 27, the applicants state

> *"The new hospital will have four operating rooms. One operating room will be relocated from Medical Park Hospital (MPH). The other three operating rooms were previously CON-approved for relocation to Kernersville as part of an ambulatory surgery center to be operated under the license of and as a department of FMC. ... Neither the relocation from FMC nor MPH is expected to negatively impact those facilities. In fact, as the Agency will recall, in Project I.D. # G-7311-05, FMC was already approved to relocate three of those ORs to Kernersville. FMC proposes to relocate the three exact same ORs from FMC in this project, along with one OR from MPH."*

The certificate of need for Project I.D. #G-7311-05 authorizes the applicants to reduce the number of shared ORs at FMC-WS by three. The proposed project does not affect the previous determination regarding relocation of three existing shared ORs from FMC-WS.

Regarding the impact on MPH of relocating one of the 13 shared ORs to FMC-K, in Section III.8, page III-32, the applicants provide the following projected utilization for the 12 shared ORs remaining at MPH during the first three operating years of FMC-K.

	PROJECTED # OF SURGICAL PROCEDURES TO BE PERFORMED AT MPH	AVERAGE # OF PROCEDURES PER DAY PER SHARED OR [1]
Year One (7/1/09 to 6/30/10)	11,132	3.6
Year Two (7/1/10 to 6/30/11)	11,077	3.6
Year Three (7/1/11 to 6/30/12)	11,012	3.5

Source: Section III.8, page III-32.
(1) Calculated by dividing the total number of surgical procedures by 260 days per year and then dividing by 12.

As shown in the table above, the applicants project that the number of surgical procedures to be performed at MPH will decrease each year through the third operating year at FMC-K. According to its 2006 Hospital License Renewal Application, during FY 2005, a total of 11,674 surgical procedures were performed in the 13 shared ORs at MPH, which is an average of 3.5 procedures per room per day per OR [11,674 / 260 / 13 = 3.5]. Therefore, utilization of the ORs at MPH currently exceeds the minimum threshold of 3.2 procedures per room per day, indicating that all 13 rooms are well utilized at their present location. Regardless, the applicants project surgical utilization at MPH will decrease. However, the applicants do not provide the methodology and assumptions that were used to project decreasing surgical utilization at MPH. Further, the applicants do not state in the application their reasons for projecting that surgical utilization at MPH will decrease. Therefore, the applicants did not demonstrate that 12 shared ORs would be sufficient to meet the needs of the patients that will continue to utilize MPH for surgical services.

Cardiac Cath Equipment – In Section III.8, page III-33, the applicants state

> *"The main campus currently has six cardiac catheterization laboratories in operation. In addition to the CON-approved laboratory (# 8) that will be implemented at Kernersville, FMC has one other (# 7) CON-approved laboratory that has not yet been implemented; this catheterization laboratory (CCL #7 – Project I.D. # G-6990-04) is scheduled to be developed.*

> *Therefore, there is ample existing and approved cardiac catheterization laboratory capacity remaining for the main campus. ...*

Moreover, in Section III.8, page III-35, the applicants state

> *"The implementation of the cardiac catheterization laboratory at FMC-Kernersville does not represent a reduction in existing capacity at the main campus. There will still be six operating cardiac catheterization laboratories and one approved but not operational laboratories at the main campus. The laboratories are centrally scheduled, including the one at Kernersville."*

However, this proposal does reduce the total number of existing and approved units of cardiac cath equipment at FMC-WS. The applicants previously demonstrated the need for a total of eight units of cardiac cath equipment at FMC-WS and were approved to acquire additional units based on that demonstration of need. If this proposal were approved, there would be only seven units of cardiac cath equipment located at FMC-WS. Thus, this proposal represents a reduction in services needed by the population served at FMC-WS.

Further, in Section III.8, page 30, the applicants state *"Many of the patients to be served by the laboratory should be essentially the same as shown in the prior application."* In Section II.8, page 26, of Project I.D. #G-7266-05, the applicants projected that the eighth unit of cardiac cath equipment would perform 774 diagnostic and 300 therapeutic cardiac cath procedures in the third operating year, which is a total of 1,073 cardiac cath procedures. However, in Exhibit 4, pages 13 and 17, of this application, the applicants project that 370 diagnostic and 0 therapeutic cardiac cath procedures will be performed on the eighth unit of cardiac cath equipment at FMC-K. Thus, only 34.5% of the patients projected to be served by the eighth unit of cardiac cath equipment in Project I.D. #G-7266-05 are now projected to have the procedure performed at FMC-K [370 / 1,073 = 0.345].

In summary, the applicants failed to provide sufficient information to demonstrate that seven units of cardiac cath equipment at FMC-WS would be sufficient capacity for the patients who will continue to utilize FMC-WS for cardiac cath services.

In summary, the applicants did not adequately demonstrate that the needs of the population presently served would be adequately met following the proposed relocation of beds and services to Kernersville. Therefore, the application is nonconforming 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

In Section II.5, pages II-8 through II-10, the applicants discussed several alternatives they considered prior to submission of this application. However, the application is not conforming to all applicable statutory and regulatory review criteria. See Criteria (3), (3a), (5), (6), (13c) and the Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300. Therefore, the applicants did not adequately demonstrate that their proposal is an effective alternative and the application is nonconforming with 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.

NC

In Section VIII.1, page VIII-2, the applicants project that the total capital cost of the project will be $84,893,635, as illustrated below.

Site Costs		
Purchase Price of the Land	$2,925,000	
Site Preparation Costs	$3,060,883	
Subtotal Site Costs		**$5,985,883**
Construction Costs		
Construction Contract	$52,597,600	
Contingency	$500,000	
Subtotal Construction Costs		**$53,097,600**
Miscellaneous Costs		
Equipment	$16,214,174	
Furniture	$1,000,000	
Architect & Engineering Fees	$2,807,924	
Other Consultants	$250,000	
Interest during Construction [7]	$2,726,187	
Contingency	$2,811,867	
Subtotal Miscellaneous Costs		**$25,810,152**
Total Capital Cost		**$84,893,635**

In Section IX, page IX-1, the applicants also project that start up and initial operating expenses will be $8,775,555. In Section VIII.3, page VIII-3, and Section IX, page IX-1, the applicants state that the capital and working capital needs of the project will be financed with the accumulated reserves of Novant. Exhibit 9 contains a letter signed by the Chief Financial Officer for Novant, which states

> *"As the Chief Financial Officer for Novant Health, Inc., I have authority to obligate funds from accumulated reserves of Novant Health for projects undertaken by Forsyth Medical Center (FMC). Novant Health, Inc. is the not-for-profit parent company of FMC. I am familiar with the CON Application where FMC proposes to construct a new 50-bed acute care hospital in Kernersville, NC. I can and will commit Novant's reserves to cover all of the capital costs associated with this project, including the project capital cost (of approximately $85 Million) working capital, and start-up costs. Please see the line items in the Novant Health CY 2005 audited financial statements entitled 'Cash and Short-Term Equivalents,' 'Net Patient Services Accounts Receivable,' 'Other Current Assets,' and 'Long-Term Investments.' These balance sheet amounts*

[7] The applicants project "Interest during Construction" in the event they choose to pursue bond financing.

are available to fund the proposed project. Novant Health, Inc. also had a Total Assets balance of $2.2 Billion at the end of CY 2005.

In addition, FMC reserves the right to consider in the future funding of all or a portion of this project using bond proceeds. FMC financial staff will make this determination based on market and economic conditions at the time the capital is required. A letter from Citigroup Global Markets, Inc. indicating the appropriateness of this project for tax-exempt bond financing is also included as an Exhibit with our CON application.

Novant Health also has sufficient cash to cover the working capital needs for the proposed new hospital project in the amount specified in section IX of the CON application. Please see the Current Assets section of the Novant Health Balance sheet contained in Novant Health's 2005 audited financial statements, which are included as an exhibit with our CON application.

I confirm to you that Novant has now and will have available the funds from reserves for the project. This will not impact Novant's ability to finance CON projects that are approved and not yet operational or currently under CON review."

Exhibit 9 also contains a letter signed by the Managing Director of Citigroup Global Markets, Inc., which states

"You have advised Citigroup Global Markets Inc. ('Citigroup') that Novant Health ('Novant') may finance the above-referenced Project from cash and accumulated reserves, through tax-exempt bond financing (the 'Bond Issue'), or through some combination thereof depending on market conditions at the time funding is required. The borrower would be Novant, a 501(c)(3) private not-for-profit corporation. The debt would be issued under the Novant Master Trust Indenture through the North Carolina Medical Care Commission. We understand that Forsyth Medical Center and Novant will be applying for a Certificate of Need ('CON') on May 15, 2006. The CON will be for a new 50-bed Hospital with an Emergency

Department, Operating Rooms, Imaging, Laboratory, Pharmacy and Cardiac Catheterization Lab. It is our understanding that the total cost of the project is estimated to be $90-105 million. For purposes of this letter, 'Citigroup' shall include Citigroup Global Markets Inc. and/or any affiliate thereof.

...

Based upon your financial strength, Citigroup would expect to offer a publicly sold tax-exempt bond issue that would either be insured or issued with Novant's stand-alone ratings. We believe that this funding would result in an investment grade rating for the financing."

Exhibit 9 includes the audited financial statements for Novant. As of December 31, 2005, Novant had $207,586,000 in cash and cash equivalents, $25,000,000 in short-term investments, $651,166,000 in long-term investments, $2,252,656,000 in total assets, and $1,268,873,000 in total net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project.

In the projected revenue and expense statement, the applicants project that revenues will exceed operating costs at FMC-K in each of the first three years of operation. The assumptions used by the applicants in preparation of the pro formas are in the Financials Tab of the application. However, the applicants' utilization projections for FMC-K are unsupported and unreliable. Consequently, costs and revenues that are based on this projected utilization are also not reliable. See Criterion (3) for discussion of projected utilization. Therefore, the applicants did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is nonconforming with 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.

NC

Novant and FMC propose to establish an additional campus of FMC in Kernersville for the provision of the following services:

- 46 general med/surg acute care beds (39 new and 7 existing to be relocated from FMC-WS)
- 4 ICU beds (4 existing to be relocated from FMC-WS)
- 10 unlicensed observation beds
- 4 shared ORs (3 existing shared ORs to be relocated from FMC-WS and 1 existing shared OR to be relocated from MPH)
- a 24 hour ER, with 14 treatment rooms
- lab services, including phlebotomy, blood bank, pathology, chemistry, hematology coagulation, micro urinalysis and accessioning
- pharmacy
- 1 cardiac cath unit (to be relocated from FMC-WS)
- 1 new CT scanner
- 1 new x-ray unit
- 1 new x-ray/fluoroscopy unit
- 3 mobile C-arms
- 2 mobile x-ray units
- 1 new nuclear medicine camera (without coincidence circuitry)
- 1 new mammography unit
- 1 new *"Cardiac"* US unit
- 1 new *"Imaging, Handheld"* US unit
- 2 new *"Therapeutic, Genera"* [sic] US units
- 2 stress testing systems with treadmill
- echocardiography equipment (quantity not provided)
- 1 EEG unit
- 3 ECG units
- 1 pulmonary function testing system

However, the applicants did not adequately demonstrate the need for all of the services they propose to provide in Kernersville. See Criterion (3) for discussion. Therefore, the applicants did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is nonconforming with 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

In Section VII.2, pages VII-1 through VII-4, the applicants provide the projected staffing for FMC-K for the first three operating years. The applicants project to employ a total of 303.9 full-time equivalent (FTE) positions in Year One, 334.9 FTE positions in Year Two and 370.0 FTE positions in Year Three. The applicants propose 8.0 FTE management positions in the first three operating years. In Section VII.3, page VII-6, the applicants state

> *"It is anticipated that FMC-Kernersville staff will be new hires, except for those existing FMC personnel who may choose to apply for the Kernersville positions when the jobs are posted. ... FMC will use its regional human resources personnel to recruit the needed personnel for the proposed new hospital located in Kernersville. ... Based on past experience FMC's COO, CNO, ED Director, Cath Lab Director, Radiology Director, Pharmacy Director, and Surgical Services Vice President do not foresee any major difficulty or significant challenges in recruiting needed personnel for the new hospital, FMC-Kernersville. In fact, during the past two years, FMC has had more new graduate applications than FMC has had positions to offer them."*

In Exhibits 4, 5, 6, 7, 8, 11 and 19, the applicants provide letters from physicians who have agreed to act as medical directors for FMC-K. See also Section II.3, pages II-6 through II-7. In Section VII.6, page VII-11, the applicants state

> *"The support staff ... at FMC-Kernersville will report to management at FMC-Kernersville and will also coordinate with their respective departments at FMC in Winston-Salem to ensure consistency and quality. Other corporate support functions will be provided directly to FMC-Kernersville by FMC in Winston-Salem or by existing NHTR regional corporate resources. Costs for these support services will be charged to FMC-Kernersville as part of administrative overhead expense and are reflected in the pro forma income statements for FMC-Kernersville. These services will include but not be limited to: finance functions such as billing, collections, payroll, accounts*

payable, general ledger, budget, and financial reporting; education and training; information technology services; marketing and public relations; strategic and business planning; legal affairs; materials management and purchasing; risk management; infection control; medical staff affairs and credentialing."

In the pro formas, the applicants project adequate operating expenses for the proposed staffing for the first three operating years. The applicants demonstrate the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to 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

In Section IV.5, page IV-12; Section II.1, pages II-1 through II-4; and Section II.3, pages II-6 through II-7, the applicants describe the ancillary and support services that will be provided at FMC-K and the services available from FMC-WS or Novant. Exhibit 10 contains a transfer agreement between FMC-WS and FMC-K. Exhibit 10 also contains a list of the facilities with which FMC currently has transfer agreements and a sample agreement. Exhibit 11 contains letters from area physicians supporting the proposal to establish a new site for provision of acute inpatient services in Kernersville. The applicants adequately demonstrated that the necessary ancillary and support services would be available and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to 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

NA

(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

The applicants propose to construct 194,994 square feet of new space to establish a new campus of FMC in Kernersville. In Exhibit 16, the architect certifies that the site preparation and construction costs are projected to be $56,158,483. In Section XI.7,

page XI-7, the applicants state that applicable energy savings features will be incorporated into the construction plans. The applicants adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. The application is conforming 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

The following table illustrates the current payor mix for all services provided at FMC during CY 2005, as reported in Section VI.10, page VI-8.

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS / PROCEDURES
Self Pay / Indigent / Charity	12.25%
Medicare	30.19%
Medicaid	16.12%
Commercial Insurance & Managed Care	17.37%
BCBS of NC	18.64%
State Employees Health Plan	2.79%
Other (other Government & Workers Comp.)	2.64%
TOTAL	100.00%

The applicants demonstrated that medically underserved populations currently have adequate access to the services provided at FMC. Therefore, the application 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;

C

An examination of the licensure and certification files in the Division of Facility Services for FMC indicates there have been no civil rights access complaints filed against the hospital within the last five years.

(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

NC

The following table illustrates the projected payor mix for all of the services to be provided at FMC-K during Year Two, as reported in Section VI.12, page VI-11, and the current payor mix for all services provided at FMC during CY 2005, as reported in Section VI.10, page VI-8.

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS / PROCEDURES	
	FMC-K YEAR TWO (PROJECTED)	FMC CY 2005 (ACTUAL)
Self Pay / Indigent / Charity	4.19%	12.25%
Medicare	45.13%	30.19%
Medicaid	4.69%	16.12%
Commercial Insurance & Managed Care	18.75%	17.37%
BCBS of NC	22.87%	18.64%
State Employees Health Plan	2.58%	2.79%
Other (other Government & Workers Comp.)	1.79%	2.64%
TOTAL	100.00%	100.00%

As shown in the above table, the applicants project a significantly different payor mix for FMC-K compared to the actual payor mix for FMC during CY 2005. Specifically, 16.12% of the patients served at FMC during CY 2005 were Medicaid recipients. However, the applicants project that

only 4.69% of the patients to be served at FMC-K during Year Two would be Medicaid recipients, which is 71% lower [16.12% – 4.69% = 11.43%; 11.43% / 16.12% = 0.71]. Medicaid recipients are one of the underserved groups identified in the CON law. Further, 12.25% of the patients served at FMC during CY 2005 were classified as self pay/indigent/charity care. However, the applicants project that only 4.19% of the patients to be served at FMC-K would be classified as self pay/indigent/charity care, which is 65.8% lower [12.25% - 4.19% = 8.06%; 8.06% / 12.25% = 0.658]. Patients classified as self pay/indigent/charity care are also underserved groups.

The applicants provide the projected payor mix for the proposed FMC-K, but failed to provide the assumptions on which the FMC-K payor mix is based. Given that the projected FMC-K payor mix significantly differs from the current payor mix for FMC, the applicants did not demonstrate that Medicaid and self pay/indigent/charity care patients would have adequate access to the proposed services offered at FMC-K. Consequently, the application is nonconforming to 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

See Section VI.7 and referenced exhibits, for documentation of the range of means by which patients would have access to the services to be provided at FMC-K. The information provided 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

See Section V.1 and referenced exhibits for documentation that FMC currently accommodates the clinical needs of health professional training programs in the area and that FMC-K will do

the same. The information provided is reasonable and credible and supports a finding of conformity with 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

The applicants did not adequately demonstrate that the proposal would have a positive impact upon the cost effectiveness and access to the proposed services. See Criteria (3), (3a), (5), and (13c). Therefore, the application is not conforming to 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.

C

FMC and MPH are accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DFS, 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 on either hospital. 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

The application is conforming to all applicable Criteria and Standards for Acute Care Beds, as promulgated in 10A NCAC 14C .3800. However, the application is not conforming to all applicable Criteria and Standards for Computed Tomography Equipment, as promulgated in 10A NCAC 14C .2300. The specific criteria are discussed below.

The applicants do not propose to acquire any major medical equipment, as defined in N.C. Gen. Stat. §131E-176(14f), other than the CT scanner. Therefore, the Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100 are not applicable to this review. In addition, the applicants do not propose to increase the total number of ICU beds for which FMC would be licensed. Therefore, the Criteria and Standards for Intensive Care Services promulgated in 10A NCAC 14C .1200 are not applicable to this review. Further, the applicants do not propose to increase the number of operating rooms for which FMC would be licensed. Therefore, the Criteria and Standards for Surgical Services and Operation Rooms promulgated in 10A NCAC 14C .2100 are not applicable to this review. Moreover, the applicants do not propose to increase the total number of cardiac cath units for which FMC would be licensed. Therefore, the Criteria and Standards for Cardiac Catheterization Equipment promulgated in 10A NCAC 14C .1600 are not applicable to this review.

SECTION .3800 CRITERIA AND STANDARDS FOR ACUTE CARE BEDS

.3802 INFORMATION REQUIRED OF APPLICANT

.3802(a) This rule states *"An applicant that proposes to develop new acute care beds shall complete the Acute Care Facility/Medical Equipment application form."*

-C- The applicants completed the Acute Care Facility/Medical Equipment application form.

.3802(b)(1) This rule states *"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- In Exhibit 5, page 2, the applicants state that they propose to add 39 new acute care beds to FMC for a total of 790 licensed and operational acute care beds upon completion of Project I.D. #G-7011-04 and this project. The following table illustrates the current and proposed number of licensed acute care beds for the two licensed hospitals owned by Novant in Forsyth County.

	# OF LICENSED ACUTE CARE BEDS	
	2006 HOSPITAL LICENSE	PROPOSED
FMC-WS	637	740
FMC-K	0	50
Total FMC	637	790
MPH	136	22
Total Novant	773	812

.3802(b)(2) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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- In Exhibit 5, page 2, the applicants state *"FMC guarantees the proposed services will follow all applicable facility, programmatic and service-specific licensure, certification, and JCAHO accreditation standards. Please see the letter from Sallye Liner, Executive Vice President and Chief Operating Officer for FMC-Winston-Salem included in Exhibit 5."*

.3802(b)(3) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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- In Exhibit 5, page 2, the applicants state *"FMC assures the proposed services at FMC-Kernersville shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies. Please see the letter from David McMillan, Corporate Facilities Planning Director, Novant Health Triad Region found in Exhibit 5."*

.3802(b)(4) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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- In Exhibit 5, page 3, the applicants provide the number of inpatient days of care provided in the existing licensed acute care beds at FMC during the last operating year (CY 2005) by medical diagnostic category (MDC), as classified by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the 2006 SMFP.

.3802(b)(5) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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- In Exhibit 5, page 4, the applicants provide 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. The applicants provide the assumptions, data and methodology in Exhibit 20. See Criterion (3) for discussion of reasonableness of projections and assumptions.

.3802(b)(6) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (6)*

documentation that the applicant shall be able to communicate with emergency transportation agencies 24 hours per day, seven days per week."

-C- In Exhibit 5, page 4, the applicants state *"FMC-Kernersville will be able to communicate with emergency transportation 24 hours a day, seven days a week. Please see the confirmation letter from Robin Voss, Director or* [sic] *Emergency and Trauma Services for FMC, found in Exhibit 5."*

.3802(b)(7) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (7) documentation that services in the emergency care department shall be provided 24 hours per day, seven 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- In Exhibit 5, page 4, the applicants state *"Please see the letter from Robin Voss, Director or* [sic] *Emergency and Trauma Services for FMC, found in Exhibit 5. In which she describes the scope of services and staffing in the emergency department."*

.3802(b)(8) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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- Exhibit 9 contains a copy of Novant's EMTALA policy, which prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay. The policy states that it applies to all Novant Health care facilities, including FMC-WS and FMC-K.

.3802(b)(9) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (9) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs."*

-C- In Exhibit 5, the applicants provide a letter signed by the Executive Vice President and Chief Operating Officer for FMC, which states *"I confirm to you FMC's commitment to continue to participate in and comply with the conditions of participation for the Medicare and Medicaid programs."*

.3802(b)(10) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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- In Exhibit 5, the applicants identify the following facilities owned by Novant in North Carolina:

Forsyth Medical Center
Thomasville Medical Center
Medical Park Hospital
Hawthorne Surgical Center
Salem MRI
The Breast Center
Presbyterian Hospital
Presbyterian Hospital Matthews
Presbyterian Hospital Orthopedic
Presbyterian Hospital Huntersville
Presbyterian Same Day Surgery
Presbyterian Imaging Center
Presbyterian Breast Center
Presbyterian South Park Surgical

The applicants provide the number of patient days of care provided to Medicare, Medicaid and self pay patients during the last two operating years at these facilities. In Section VI.6(a), page VI-5, the applicants state that, during CY 2005, FMC provided $18,847,644 in charity care to patients who were unable to pay for their care. Further, the applicants state *"in March 2006 Novant Health, Inc. announced that the system had set a target of providing $300 Million worth of free services during the next three years."*

.3802(b)(11) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (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."*

-C- In Exhibit 5, the applicants provide a letter signed by the Executive Vice President, Forsyth Medical Group, which states *"I am the Executive Vice President for the Forsyth Medical Group (employed physician group in the Novant Health Triad Region). ... As executive vice president overseeing the employed physician practices, I can attest that physicians employed by Forsyth Medical Group (FMG) will provide care to patients at FMC-Kernersville regardless of the patient's ability to pay in accordance with 10A NCAC 14C .3802(b)(11). ... FMG practices are not the same as private physician practices. Just like Forsyth Medical Center and our other affiliated hospitals, we have a charitable mission – to improve community health. As such, our physician practices have a charity care policy which is attached. In 2004, our practices provided more than $3.6 million in indigent and charity care."* Exhibit 5 contains a copy of the charity care policy for Forsyth Medical Group.

.3802(b)(12) This rule states *"An applicant proposing to develop new acute care beds shall submit the following information: ... (13) 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- In Exhibit 5, the applicants provide a letter signed by the Executive Vice President and Chief Operating Officer for FMC, which states *"The proposed new 50-bed acute care hospital in Kernersville shall operate as a hospital that provides inpatient medical services to both surgical and non-surgical patients."* Throughout the entire application, the applicants state that FMC-K will be operated under the license of FMC, an existing acute care hospital. In Exhibit 20, the applicants demonstrate that FMC currently provides inpatient medical services to both surgical and non-surgical patients. Inpatient medical services at FMC-K will also be provided to both surgical and non-surgical patients.

.3802(c)(1) This rule states *"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- In Exhibit 5, page 6, the applicants provide the projected number of inpatient days of care to be provided at FMC-K by MDC as recognized by the CMS according to the list set forth in the 2006 SMFP.

.3802(c)(2) This rule states *"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: ... (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- In Exhibit 5, page 6, the applicants provide a table showing the projected number of inpatient days of care to be provided at FMC-K by MDC for the first three operating years, which indicates that services will be provided on a daily basis in 10 of the 25 major diagnostic categories recognized by CMS.

.3802(c)(3) This rule states *"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: ... (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."

-C- In Exhibits 2, 5 and 17, the applicants provide copies of written policies and procedures for the admission and discharge of patients (including discharge planning), transfer of patients to another hospital, infection control and safety.

.3802(c)(4) This rule states *"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: ... (4) documentation that the applicant owns or otherwise has control of the site on which the proposed acute care beds will be located."*

-C- In Exhibit 15, the applicants provide a copy of the May 12, 2006 Agreement of Purchase and Sale between PM Development, LLC (seller) and Novant (buyer) for the proposed site.

.3802(c)(5) This rule states *"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: ... (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."*

-C- In Exhibit 15, the applicants provide an April 27, 2006 letter signed by the Community Development Director for the Town of Kernersville, which indicates that rezoning will be required but he states that he does *"not expect any barriers to future rezoning request* [sic]." Further, he states that the site is suitable for development of a 50-bed hospital with regard to water, sewage disposal and site development. Water, sewer and utilities are already available.

.3803 PERFORMANCE STANDARDS

.3803(a) This rule states *"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- 10A NCAC 14C .3801(4) states *"'Service Area' means the single or multi-county area as used in the development of the acute care bed need determination in the applicable State Medical Facilities Plan."* According to the 2006 SMFP, the service area is Forsyth County and Novant owns two acute care hospitals in the service area: FMC and MPH. Upon completion of the project, FMC would be licensed for a total of 790 acute care beds and MPH would be licensed for a total of 22 acute care beds. Thus, the total number of licensed acute cared beds owned by the applicants in the service area will be 812 acute care beds [790 + 22 = 812]. In Exhibit 5, page 9, the applicants project that a total of 232,220 days of care will be provided at FMC and MPH in the third operating year. Based on 812 licensed acute care beds, the ADC is projected to be 636.2 [232,220 / 365 = 636.2], an occupancy rate of 78.4% [636.2 / 812 = .784], which is greater than the 75.2% required by this rule. The Project Analyst assumes that the 3,230 patient days of care that the applicants project would be provided at FMC-K in Year Three based on their assumption of 20% inmigration at FMC-K would be served at FMC-WS or MPH instead. See Criterion (3) for discussion of projections at the proposed FMC-K campus.

.3803(b) This rule states *"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- The applicant's assumptions and data used to develop the projections required in this Rule are provided in Exhibit 20. The applicant's assumptions regarding projected inpatient utilization and ADC for the FMC and MPH system are

reasonable and credible and support a finding of conformity with this rule. See Criterion (3) for discussion of projections at the proposed FMC-K campus.

.3804 SUPPORT SERVICES

.3804(a) This rule states *"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, seven 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- In Exhibit 5, the applicants document that all of the items listed above are currently available 24 hours per day, seven days per week at FMC.

.3804(b) This rule states *"If any item in Paragraph (a) of this Rule will not be available in the facility 24 hours per day, seven days per week, the applicant shall document the basis for determining the item is not needed in the facility."*

-C- All of the items in Paragraph (a) of this Rule will be available 24 hours per day, seven days per week at FMC-K.

.3804(c) This rule states *"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- In Exhibit 5, page 10, the applicants states that all of the items listed in Paragraph (a) of this Rule will be available at FMC-K on a 24-hour basis.

.3805 STAFFING AND STAFF TRAINING

.3805(a) This rule states *"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- In Exhibit 5, page 11, the applicants state *"FMC assures the proposed services shall be provided in conformance with all licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals."* Exhibit 5 also includes a letter signed by the Executive Vice President and Chief Operating Officer for FMC, which states *"All staff for the new acute beds shall comply with licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals."* See Criterion (7) for additional discussion regarding staffing.

.3805(b) This rule states *"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- Exhibit 5 contains letters from the current Chief Executive Officer and Chief Nursing Executive for FMC that state they will serve in these capacities for both FMC campuses.

.3805(c) This rule states *"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- Exhibit 3 contains the job descriptions 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.

.3805(d) This rule states *"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- The applicants propose to serve patients at FMC-K in all of the MDCs listed in the 2006 SFMP, except 15, 19 and 20. See Exhibit 5, page 6. Exhibit 11 contains letters from physicians that document their willingness to admit and care for patients in each of the MDCs proposed to be provided at FMC-K.

.3805(e) This rule states *"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- See Section VII of the application for current and proposed staffing. Exhibit 3 includes a letter signed by the Director of Employment and Recruitment for Novant documenting the availability of sufficient support and clinical staff for FMC-K. Exhibit 5 includes a letter signed by the Vice President, Nursing & Patient Care Services for FMC documenting the availability of support and clinical staff to provide care in each of the MDCs to be served at FMC-K.

SECTION .2300 CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY SCANNERS

.2302 INFORMATION REQUIRED OF APPLICANT

.2302(a) This rule states *"An applicant proposing to acquire a CT scanner shall use the acute care facility/medical equipment application form."*

-C- The applicants used the acute care facility/medical equipment application form.

.2302(b) This rule states *"An applicant proposing to acquire a CT scanner shall provide the number of CT scans that have been performed on its existing CT scanners 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."

-NC- In Exhibit 7, the applicants provide the number of CT scans performed on the four existing CT scanners located at FMC-WS for each type of CT scan listed in this rule during CY 2005. MPH does not have any CT scanners. However, Novant owns Winston-Salem Health Care, a diagnostic center, which has at least one CT scanner based on representations made by Novant in Project I.D. #G-6775-03. The applicants failed to provide the number of CT scans performed on that CT scanner as required by this rule. Therefore, the application is nonconforming with this rule.

.2302(c) This rule states *"The applicant shall project the number of CT scans to be performed on the new CT scanner for each type of CT scan listed in this Paragraph for the first 12 quarters 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 Exhibit 7, the applicants provide the projected number of scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule for the first 12 quarters of operation of the proposed scanner. See Criterion (3) for discussion regarding the reasonableness of the projections.

.2302(d) This rule states *"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 plus body scan HECTs	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00 plus body scan HECTs	=	

-NC- In Exhibit 7, the applicants converted the historical and projected number of CT scans to be performed to HECT units as required by this rule. However, in converting the projected number of CT scans to be performed at FMC-K to HECT units they used a conversion factor of 1.5 for the body with contrast procedures when they should have used 1.75. Further, they used a conversion factor of 1.75 for the body without contrast procedures when they should have used 1.5. Therefore, the applicants did not convert the number of CT scans to HECT units in accordance with the factors in this rule. See Criterion (3) for discussion regarding the reasonableness of the projections.

.2302(e) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

.2302(f) This rule states *"The applicant shall provide all projected direct and indirect operating costs and all projected revenues for the provision of CT services for the first 12 quarters the new CT scanner is proposed to be operated."*

-C- In Exhibit 7, page 6, the applicants provide the projected direct and indirect operating costs and revenues during the first 12 quarters for the proposed CT scanner to be located at FMC-K.

.2302(g) This rule states *"The applicant shall provide projected costs and projected charges by CPT code for the first 12 quarters the new CT scanner is proposed to be operated."*

-NC- In Exhibit 7, page 7, the applicants state

> *"See the response to Question X.2 in the CON application for the projected CT scan procedure charges for the first three years of operation at FMC-Kernersville. It is not feasible to allocate CT scan procedure costs in such a manner as to reliably predict the average cost per CT scan by CPT code, because the mix of CT scans types (as identified by CPT code) and the inpatient-outpatient CT scan mix varies from year to year depending on patient and referring physician needs, as well as evolution in CT technology. In addition, inpatient CT scans are not generally coded and tracked by CPT code as payors do not permit a hospital to bill separately for an inpatient CPT code. Rather the hospital is paid a lump sum or case rate determined by the DRG assigned to the entire inpatient stay, and that stay includes all the ancillary services, including CT scans. However, using the expense data supplied in the table above in the response to .2302(f), the applicant calculated that the average incremental cost per CT scan at FMC-Kernersville for the first three project years would be:*
>
> - *PY 1 (7/1/09-6/30/10): $88*
> - *PY 2 (7/1/10-6/30/11): $99*
> - *PY 3 (7/1/11-6/30/12): $94*
>
> *Please note that the incremental cost per CT scan does not reflect total average costs per CT scan, as the overhead allocation and other administrative*

expenses outside the CT scan department are not included."

In Section X.2(a)(3), page X-9, the applicants provide projected charges for the CT procedures to be performed at FMC-Kernersville during the first three operating years. However, the applicants provide only the incremental cost per CT scan. The rule requires the total projected CT cost, not the incremental costs. Therefore, the application is nonconforming with this rule.

.2302(h) This rule states *"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% over its current charge per CPT code on the mobile CT scanner."*

-NA- The applicants have not been utilizing a mobile CT scanner.

.2302(i) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

.2302(j) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it has a written commitment from the radiology group of a hospital that it will accept CT readings from the applicant."*

-C- In Exhibits 7 and 11, the applicants provide a letter signed by the President and CEO of Forsyth Radiological Associates, which states *"FRA radiologists can and will staff and provide diagnostic radiology services, diagnostic ultrasound services, computed tomography services, and mobile MRI services at Forsyth Medical Center – Kernersville."* Forsyth Radiological Associates currently provides professional services at all Novant facilities in the Triad.

.2302(k) This rule states *"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 Exhibit 7, the applicants provide a letter signed by the Director of Radiology Services for FMC, which states *"I can attest that the new CT scanner at FMC-Kernersville will be ... available and staffed for performing CT scan procedures for at least 66 hours per week."*

.2303 REQUIRED PERFORMANCE STANDARDS

.2303(1) This rule states *"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 Exhibit 7, the applicants project that the proposed CT scanner to be located at FMC-K would perform 18,324 HECT units in the third year of operation following completion of the project. However, in converting the projected number of CT scans to be performed at FMC-K to HECT units they used a conversion factor of 1.5 for the body with contrast procedures when they should have used 1.75. Further, they used a conversion factor of 1.75 for the body without contrast procedures when they should have used 1.5. Further, in Exhibit 20, Figure 26, the applicants assume that the CT scanner at FMC-K will perform 0.69 CT scans for every inpatient discharge and 0.43 CT scans for every outpatient and ER visit based on the experience at Presbyterian Hospital Matthews, Presbyterian Hospital Huntersville and Thomasville Medical Center. However, the projected number of CT scans to be performed at FMC-K is based on the projected number of inpatient discharges and projected inpatient discharges are not reasonable. See Criterion (3) for discussion regarding projected acute inpatient discharges. Therefore, the projected number of CT scans to be performed at FMC-K are not reasonable. Consequently, the application is nonconforming with this rule.

.2303(2) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (2) each existing fixed CT scanner 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."*

-NC- Pursuant to 10A NCAC 14C .2301(4), *"'Computed tomography (CT) service area' means a geographical area defined by the applicant, which has boundaries that are not farther than 40 road miles from the facility."* In Exhibit 7, the applicants state *"The proposed CT service area includes several zip codes in Forsyth County and two zip codes from Guilford County as defined in Section III."* (Emphasis added.) In Section III.5(a), page III-20, the applicants state

> *"The service area for FMC-Kernersville consists of zip codes 27284 (including point zip code 27285), 27051, 27009, 27265, 27235, and 27310. ... The applicant has not projected a secondary service area. Approximately 80% of FMC-Kernersville patients will come from residents in the defined service area zip codes. The other 20 percent will come from other zip codes in Forsyth and Guilford Counties, Other North Carolina Counties, and Other States."* (Emphasis added.)

In Exhibit 7, the applicants state that the CT service area is defined in Section III. In Section III.5(a), page III-20, the applicants state that the service area consists of six zip codes, three in Forsyth County and three in Guilford County. (Note that the statement in Exhibit 7 regarding the number of zip code areas in Guilford County is not correct.) However, the applicants state that 20% of the patients projected to utilize CT services at FMC-K will be residents of *"other zip codes in Forsyth and Guilford Counties, Other North Carolina Counties, and Other States."* Thus, the applicants' CT service area also includes other zip codes in Forsyth, Guilford and other NC counties that are located within 40 road miles of FMC-K and from which the applicant proposes to serve patients needing CT services.

The applicants do not identify the other North Carolina counties included in the service area for CT services, do not identify the CT scanners operating in those counties and do not provide the historical utilization data for those CT scanners for which data is available. Moreover, the applicants do not demonstrate that those other North Carolina counties are located within 40 road miles of FMC-K. Further, the applicants do not identify all CT scanners operating in Forsyth and Guilford counties and do not provide the historical utilization data for those CT scanners for which data is available, which includes all of the existing hospitals in Forsyth and Guilford counties and diagnostic centers owned by Novant. Therefore, the applicants failed to demonstrate that each existing fixed CT scanner in its CT service area performed at least 5,100 HECT units in the 12 month period prior to submittal of the application as required by this rule. Consequently, the application is nonconforming to this rule.

.2303(3) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (3) each existing and approved fixed CT scanner 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."*

-NC- In Exhibit 7, page 10, in response to this rule, the applicants provide projected utilization for the proposed CT scanner. However, the proposed CT scanner is not an existing or approved CT scanner as those terms are defined in 10A NCAC 14C .2301. The applicants do not identify the existing and approved fixed CT scanners operating in Forsyth and Guilford counties and did not provide projected utilization data for those CT scanners, which includes all of the existing hospitals in Forsyth and Guilford counties and diagnostic centers owned by Novant.

Further, the applicants did not identify the other North Carolina counties included in the service area for CT services, did not identify the existing and approved CT scanners operating in those counties and did not provide projected utilization data for those CT scanners. Moreover,

the applicants do not demonstrate that those other North Carolina counties are located within 40 miles of FMC-K.

Therefore, the applicants failed to demonstrate that each existing and approved fixed CT scanner in its CT service area is reasonably expected to perform at least 5,100 HECT units in the third operating year of the proposed CT scanner as required by this rule. The application is nonconforming to this rule.

.2303(4) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (4) each existing mobile CT scanner in the proposed CT service area performed at least an average of 20 HECT units per day per site in the CT scanner service area in the 12 months prior to submittal of the application."*

-NC- In Exhibit 7, page 10, the applicants state *"FMC is not aware of any existing mobile CT scanner in the 7-zip code service area for FMC-Kernersville."* However, the service area includes more than these seven zip codes given the applicants statement that 20% of the CT patients projected to be served are from other zip codes in Forsyth and Guilford counties and other NC counties. The applicants did not discuss existing mobile CT scanners operating in the rest of its CT service area. Therefore, they did not demonstrate that each mobile CT scanner operating in the service area performed an average of 20 HECT units per day per site in the 12 months prior to submittal of the application as required by this rule. Consequently, the application is nonconforming with this rule.

.2303(5) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (5) each existing and approved mobile CT scanner shall perform at least an average of 20 HECT units per day per site in the CT scanner service area in the third year of operation of the proposed equipment."*

-NC- In Exhibit 7, page 11, the applicants state *"FMC is not aware of any existing mobile CT scanner in the 7-zip code service area for FMC-Kernersville."* However, the service area includes more than these seven zip codes given the

applicants statement that 20% of the CT patients projected to be served are from other zip codes in Forsyth and Guilford counties and other NC counties. The applicants did not discuss the existing and approved mobile CT scanners operating in the rest of its CT service area. Therefore, they did not demonstrate that each existing and approved mobile CT scanner operating in the service area is projected to perform an average of 20 HECT units per day per site in the third operating year as required by this rule. Consequently, the application is nonconforming with this rule.

.2304 **REQUIRED SUPPORT SERVICES**

.2304(a) This rule states *"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- In Exhibit 7, page 11, the applicants state that all of the services listed above will be available at FMC-K. See also, Section II.1, page II-3. Exhibit 7 also contains a letter signed by the President and CEO of Forsyth Radiological Associates, which states that x-ray, fluoroscopy, ultrasound, computed tomography and mobile MRI services will be available at FMC-K. FMC-WS and FMC-K will be operated as a single licensed hospital.

.2304(b) This rule states *"An applicant proposing to acquire a CT scanner shall document the availability of services through written affiliation or referral agreements to treat patients with the following conditions:*

(1) neurological conditions;
(2) thoracic conditions;
(3) cardiac conditions;
(4) abdominal conditions;
(5) medical oncological conditions;
(6) radiological oncological conditions;
(7) gynecological conditions;
(8) neurosurgical conditions; and
(9) genitourinary and urogenital conditions."

-C- In Section I.12(d), page I-10, the applicants state *"FMC has an active medical staff of over 540 physicians in all of the major specialties."* In Section VII.10, page VII-17, the applicants list the 543 members of the active Medical Staff by specialty. There is one or more specialties represented for all of the conditions listed in this rule. FMC-WS and FMC-K will be operated as a single licensed hospital.

.2304(c) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

.2305 REQUIRED STAFFING AND STAFF TRAINING

.2305(a)(1) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements:*
(1) one board certified radiologist who 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 qualified diagnostic radiologist; or
(C) at least six months of fellowship training, or its equivalent, in CT; or
(D) an appropriate combination of CT experience and fellowship training equivalent to Parts (a)(1) (A), (B), or (C) of this Rule."

-C- In Exhibit 7, page 12, the applicants state that Dr. Vito Basile has agreed to serve as medical director for CT services at FMC-K. Exhibit 7 also contains Dr. Basile's resume, which indicates that he is a board-certified radiologist and a member of Forsyth Radiological Associates and meets all of the above requirements. In Exhibits 7 and 11, the applicants provide a letter signed by the President and CEO of Forsyth Radiological Associates, which states *"FRA radiologists can and will staff and provide diagnostic radiology services, diagnostic ultrasound services, computed tomography services, and mobile MRI services at Forsyth Medical Center – Kernersville."* Forsyth Radiological Associates currently provides professional services at all Novant facilities in the Triad.

.2305(a)(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements: ... (2) at least one radiology technologist registered by the American Society of Radiologic Technologists shall be present during the hours of operation of the CT unit."*

-C- In Section VII.2, page VII-3, the applicants project that they will employ 4.8 FTE CT technologist positions in Year One, 6.8 FTE CT technologist positions in Year Two and 7.8 FTE CT technologist positions in Year Three at FMC-K. In Exhibit 7, the applicants provide a letter signed by the Director of Radiology for FMC, which states *"the new CT scanner at FMC-Kernersville will be ... staffed by at least one radiology technologist who will be registered by the American Society of Radiologic Technologists and who will be present during all hours when the CT scanner is in operation at FMC-Kernersville."*

.2305(a)(3) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements: ... (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- Exhibit 7 contains a letter signed by the Radiation Safety Officer for FMC, which states that she is a radiation physicist with training in medical physics and *"over 15 years experience."* She is currently employed by FMC to provide such things as annual equipment evaluations, CT dose profiles and consultative medical physics services. She states she will be *"available for consultation for the calibration and maintenance of the proposed CT scanner."*

.2305(b) This rule states *"The applicant shall provide documentation that the diagnostic radiologist has completed CT training in head, spine, body and musculoskeletal imaging."*

-C- Exhibit 7 contains a copy of Dr. Basile's resume, which indicates that he is a board-certified radiologist, a member of Forsyth Radiological Associates, and has experience interpreting CT scans in the required areas. In Exhibit 7, page 13, the applicants state that he currently serves as medical director for CT services at FMC.

.2305(c)(1) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided: (1) certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support."*

-C- In Exhibit 7, the applicants provide a letter signed by the Director of Radiology Services at FMC, which states *"the new CT scanner at FMC-Kernersville will be ...staffed by personnel who are trained and certified in cardiopulmonary resuscitation (CPR) and basic cardiac life support and who participate in FMC's organized program of staff education and training, which is integral to the CT scanner program and ensures improvements in technique and the proper training of new CT scanner personnel."*

.2305(c)(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided: ... (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 Exhibit 7, the applicants provide a letter signed by the Director of Radiology Services at FMC, which states *"the new CT scanner at FMC-Kernersville will be ...staffed by personnel who are trained and certified in cardiopulmonary resuscitation (CPR) and basic cardiac life support and who participate in FMC's organized program of staff education and training, which is integral to the CT scanner program and ensures improvements in technique and the proper training of new CT scanner personnel."*

.2305(d) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

ATTACHMENT #1

Immigration 10%
Pages 20-21, 23

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: December 22, 2006

PROJECT ANALYST: Martha J. Frisone
CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBER: F-7648-06/ Presbyterian Hospital Mint Hill, LLC/ Relocate 50 existing acute care beds and 5 existing operating rooms from Presbyterian Orthopedic Hospital and 1 existing gastrointestinal endoscopy room from Presbyterian Hospital Matthews to establish a new hospital in Mint Hill/ Mecklenburg 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.

C

Presbyterian Hospital Mint Hill, LLC (**PH-Mint Hill**), a wholly-owned subsidiary of Novant Health, Inc. (**Novant**), proposes to relocate 50 existing acute care beds and 5 existing operating rooms from Presbyterian Orthopaedic Hospital and 1 existing gastrointestinal endoscopy procedure room from Presbyterian Hospital Matthews to establish a new hospital in Mint Hill in Mecklenburg County. Both Presbyterian Orthopaedic Hospital (**POH**) and Presbyterian Hospital Matthews (**PH-Matthews**) are owned by Novant. See Criterion (3) for a detailed description of all the services the applicant proposes to provide in Mint Hill.

The proposal does not result in an increase in the total number of licensed beds, operating rooms or gastrointestinal endoscopy procedure rooms located in Mecklenburg County. Further, the applicant does not propose to acquire any medical equipment or develop any health service facility beds or services for which there is a need determination in the 2006 State Medical Facilities Plan (2006 SMFP). Therefore, there are no need determinations that are applicable to this proposal.

However, there is a policy in the 2006 SMFP that is applicable to this review. Because the applicant proposes to construct new space to replace 50 existing acute care beds to be relocated from Charlotte to Mint Hill, Policy AC-5 is applicable to this review. There are no other policies in the 2006 SMFP that are applicable to this review.

POLICY AC-5: REPLACEMENT OF ACUTE CARE BED CAPACITY states

> *"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to the utilization targets found below. In determining utilization of acute care beds, only acute care bed 'days of care' shall be counted. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application.*

Facility Average Daily Census	*Target Occupancy of Licensed Acute Care Beds (Percent)*
1 – 99	*66.7%*
100 – 200	*71.4%*
Greater than 200	*75.2%*

Projected Utilization of PH-Mint Hill

In Section III.1(b), pages 52 & 59, Section IV.1, page 104, and Exhibit 20, Tables 18 & 22, the applicant provides projected utilization for the total number of acute care beds at PH-Mint Hill during the first three operating years of the proposed project, as illustrated in the following table.

	TOTAL # OF PROJECTED ACUTE CARE PATIENT DAYS		
	YEAR ONE (10/1/09-9/30/10)	YEAR TWO (10/1/10-9/30/11)	YEAR THREE (10/1/11-9/30/12)
PH-Mint Hill (50 acute care beds)	9,244	11,455	13,753
Average Daily Census (ADC) [1]	25.3	31.4	37.7
% Occupancy [2]	50.7%	62.8%	75.4%

Source: Section III.1(b), pages 52 & 59, Section IV.1, page 104, and Exhibit 20, Tables 18 & 22.
[1] ADC was calculated by dividing projected acute patient days by 365.
[2] Occupancy was calculated by dividing ADC by 50.

As shown in the above table, in the third operating year, the applicant projects an ADC of 37.7 at PH-Mint Hill, which is an occupancy rate of 75.4%. The target occupancy rate for a hospital with an ADC between 1 and 99 is 66.7%. See Section III.1(b), pages 53-60, and Exhibit 20, Tables 1-23, for the applicant's assumptions and methodology used to project utilization of the acute care beds at PH-Mint Hill.

Projected Utilization of The Presbyterian Hospital and POH

Upon completion of Project I.D. #F-7386-05, The Presbyterian Hospital (**TPH**), which is located in Mecklenburg County and owned by Novant, would be licensed for 539 acute care beds and POH would be licensed for 14 acute care beds. However, the applicant states that Novant would apply for a single license for TPH and POH following completion of this project. Therefore, upon completion of this project and Project I.D. #F-7386-05, TPH would be licensed for 553 acute care beds [539 + 14 = 553]. On page 4 of the Impact Analysis in Exhibit 20, the applicant projects a total of 174,613 acute patient days of care would be provided at TPH during FY 2012 (Year Three), which is an ADC of 478.4 [174,613 / 365 = 478.4] and an occupancy rate of 86.5%. The target occupancy rate for this size facility is 75.2%. In Tables 70 & 72 in Exhibit 20, the applicant projects that utilization would increase at the same rate the population of the service area is projected to increase. The applicant adjusted its utilization projections for TPH to account for the patients currently served by TPH and POH that are expected to use the proposed hospital in Mint Hill. See the Impact Analysis in Exhibit 20 for all of the applicant's assumptions and methodologies used to project utilization for TPH. The applicant adequately demonstrates the need to maintain the total acute care bed capacity proposed in the application. See Criterion (3) for additional

discussion. Therefore, the application is consistent with Policy AC-5 and conforming to this criterion.

(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.

CA

PH-Mint Hill, a wholly-owned subsidiary of Novant, proposes to relocate 50 existing acute care beds and 5 existing operating rooms from POH and 1 existing gastrointestinal endoscopy procedure room from PH-Matthews to establish a new hospital in Mint Hill in Mecklenburg County. Both POH and PH-Matthews are owned by Novant. Novant owns and operates the following separately licensed acute care hospitals in Mecklenburg County:

- The Presbyterian Hospital (**TPH**)
- Presbyterian Orthopedic Hospital (**POH**)
- Presbyterian Hospital Matthews (**PH-Matthews**)
- Presbyterian Hospital Huntersville (**PH-Huntersville**)

The following table illustrates the current number of licensed acute care beds, operating rooms and gastrointestinal endoscopy procedure rooms at TPH, POH, PH-Matthews and PH-Huntersville.

	TPH	POH	PH-MATTHEWS	PH-HUNTERSVILLE
Total # Acute Care Beds	463	140	102	50
ORs	32	12	10	5
Endo Rooms	8	0	4	3

As shown in the above table, TPH is currently licensed for 463 acute care beds and POH is currently licensed for 140 acute care beds. TPH and POH are located in downtown Charlotte, across the street from each other. Pursuant to the certificate of need issued for Project I.D. #F-7386-05, TPH is authorized to relocate 76 existing acute care beds from POH to TPH. Thus, upon completion of Project I.D. #F-7386-05 and this project, POH would be licensed for a total of 14 acute care beds [140 – (76 + 50) = 14], and TPH

would be licensed for a total of 539 acute care beds. However, in Exhibit 20 of this application, the applicant states

> *"it is likely that POH and TPH will be combined operationally under a single NC acute care hospital license upon the relocation of beds to PHMH."*

Based on the applicant's representations in Section II.1, pages 17-21, the design schematics in Exhibit 16, and the list of equipment to be acquired provided in Exhibit 18, the applicant proposes to offer the following services at PH-Mint Hill:

- 38 existing general medical-surgical (med/surg) acute care beds
- 8 labor delivery recovery post partum (LDRP) beds (currently these are existing general med/surg beds at POH)
- 4 intensive care unit (ICU) beds (currently these are existing general med/surg beds at POH)
- 10 new unlicensed observation beds
- 4 existing shared operating rooms (ORs)
- 1 dedicated C-section OR (currently this is an existing shared OR at POH)
- 1 existing gastrointestinal endoscopy (GI endoscopy) procedure room
- a new 24 hour Emergency Room (ER), with 16 treatment rooms
- laboratory (lab) services, including phlebotomy, blood bank, pathology, chemistry, hematology coagulation, micro urinalysis and accessioning
- pharmacy
- 1 new CT scanner
- 2 new x-ray/fluoroscopy units [1]
- 2 new portable x-ray units
- 2 new mobile C-arms
- 1 new nuclear medicine camera (without coincidence circuitry)
- 1 new mammography unit [2]
- 2 new portable ultrasound (US) units

---

[1] In Section II.1, page 20, and the design schematic in Exhibit 16, the applicant shows space for two combined x-ray/fluoroscopy units. However, in Exhibit 18, the applicant lists two general x-ray units and 1 x-ray/fluoroscopy unit in its list of equipment to be acquired for the proposed hospital.

[2] In Section II.1, page 20, and the design schematic in Exhibit 16, the applicant states that it will acquire one mammography unit. However, in Exhibit 18, the applicant does not list a mammography unit in its list of equipment to be acquired for the proposed hospital.

- 1 new *"Imaging, Handheld"* US unit
- 2 new stress testing systems with treadmill
- new echocardiography equipment (quantity not provided)
- 1 new electroencephalograph (EEG) unit
- 3 new electrocardiograph (ECG) units
- 1 new pulmonary function testing system

The applicant does not propose to develop any non-surgical procedure rooms at PH-Mint Hill.

POPULATION TO BE SERVED

The following table illustrates the current patient origin for TPH, POH, PH-Huntersville and PH-Matthews, as reported by the applicant in Section III.4(a), page 84.

HOSPITAL/COUNTY	% OF TOTAL # OF PATIENTS	
TPH		
Mecklenburg	73.8%	
Gaston	5.6%	
Union	5.4%	
South Carolina	4.4%	
In-migration	10.7%	
Total		100.0%
PH-Matthews		
Mecklenburg	56.3%	
Union	35.2%	
In-migration	8.4%	
Total		100.0%
PH-Huntersville		
Mecklenburg	72.4%	
Lincoln	8.1%	
Iredell	6.9%	
In-migration	12.6%	
Total		100.0%
POH		
Mecklenburg	55.1%	
South Carolina	10.4%	
Gaston	6.9%	
Union	5.9%	
In-migration	21.7%	
Total		100.0%

In Section III.5(a), pages 88-89, the applicant states

> *"The proposed service area* [for PH-Mint Hill] *includes a five zip code area consisting of: zip code 28215, an*

incorporated area of Mecklenburg County and the proposed location of PHMH; the Township of Mint Hill (28227); another incorporated area of Charlotte in Mecklenburg County (28213); the Township of Harrisburg (28075); and the Township of Midland (28107). Zip code 28215 is adjacent to the Township of Mint Hill. The Townships of Harrisburg and Midland are in Cabarrus County. ... Once the proposed location was determined, actual utilization of hospital acute inpatient services by residents of the service area was determined by reviewing Solucient data and calculating future need, based on market share and population growth of each zip code in the service area."

The following table illustrates the projected patient origin for PH-Mint Hill in the third operating year, as reported by the applicant in Section III.1(b), page 59, and Exhibit 20, Table 18.

TOTAL ACUTE CARE DISCHARGES

ZIP CODE	COUNTY	FROM SECTION III.1(B), PAGE 59 AND EXHIBIT 20, TABLE 18	
		# OF DISCHARGES	% OF TOTAL
28215	Mecklenburg	2,032	47.3%
28227	Mecklenburg	976	22.7%
28213	Mecklenburg	576	13.4%
28075	Cabarrus	162	3.8%
28107	Cabarrus	117	2.7%
Other in-migration [1]		429	10.0%
Total		4,293	99.9%

[1] In Section III.5(c), page 90, the applicant states *"Other Inmigration represents volume from outside the proposed zip code service area, surrounding zip codes in surrounding counties."*

The applicant adequately identifies the population it proposes to serve.

ANALYSIS OF NEED FOR THE PROPOSED SERVICES

In Section III.1(a), pages 37-51, the applicant states

"The Mint Hill area represents a growing community of over 120,000 people in eastern Mecklenburg County that does not have a community hospital. Residents travel to downtown Charlotte acute care facilities or to other Mecklenburg County community hospitals to receive hospital care, including emergency room services. ...

incorporated area of Mecklenburg County and the proposed location of PHMH; the Township of Mint Hill (28227); another incorporated area of Charlotte in Mecklenburg County (28213); the Township of Harrisburg (28075); and the Township of Midland (28107). Zip code 28215 is adjacent to the Township of Mint Hill. The Townships of Harrisburg and Midland are in Cabarrus County. ... Once the proposed location was determined, actual utilization of hospital acute inpatient services by residents of the service area was determined by reviewing Solucient data and calculating future need, based on market share and population growth of each zip code in the service area."

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...

The unmet need for inpatient acute care services in the Mint Hill service area of Mecklenburg County is substantiated by the rapidly growing population and the lack of comprehensive inpatient and outpatient services in the Mint Hill service area. The increasing utilization of PHS inpatient facilities throughout Mecklenburg County, and Novant Health's commitment to provide quality health care services at the community level to the residents of the proposed service area also support the need for the proposed project.

...

... [F]*rom 2000 to 2005, the population of the proposed Mint Hill zip code service area increased by 29,617 persons. The population of the proposed service area is projected to grow by an additional 15,000 persons in the next five years, for a total projected population of 151,117 in 2010.*

...

... [F]*rom 2000 to 2005 the population in these five zip codes grew 11.9% or an average rate of 2.5% annually. The proposed service area population is projected to continue growing an additional 11.1 %, or an estimated average rate of 2.2 % annually from 2005 to 2010. Four of the five zip codes will experience double digit growth during this timeframe.*

...

The nine-county Charlotte metropolitan area grew by 29 percent from 1990 to 2000; only five U.S. metro areas of 1 million or more had a higher rate of population growth. The area grew an additional 10 percent from 2000 to 2004, and now has almost 2 million people, according to U.S. Census data. This growth is projected to continue well into the next decade. ...

...

The trend is similar across the region in Cabarrus, Catawba, Gaston, Iredell, Lincoln, Union, Lancaster, and York counties. Population and job growth are major factors in the rebound. ... Economists see the region gaining nearly 30,000 net new jobs in 2006 and likely adding almost 50,000 people a year through the end of the decade. In addition, as I-485 is completed over the next nine years, planners see more retailers and employers heading to the interchanges and more warehouses, corporate offices and call centers spilling over the Mecklenburg line. Exhibit 21 includes further documentation of the actual and projected growth throughout the Charlotte Metropolitan Area.

Mint Hill just 10 miles southeast of downtown Charlotte, is poised for phenomenal growth. Mint Hill is served by five interchanges of the I-485 southern bypass and each are only minutes away from the proposed PHMH. With the opening of the last part of the southern I-485 bypass in November 2003, development specific to the proposed service area has increased. ...

...

Currently over 80% of all existing acute care hospital beds are located in downtown Charlotte. ...

...

Mileage and driving time from Mint Hill to each of the existing four closest hospital emergency rooms in the area are shown in the following table. Emergency services for this growing population are 14 minutes to 24 minutes away depending on location within the proposed service area. When traffic on I-485 is heavy, or during rush hours, driving time will be even greater.

Distance and Travel Time From Proposed Mint Hill Location to Closest Existing Inpatient Hospitals

Hospital	*Distance*	*Travel Time*
Presbyterian Hospital Matthews	*12.4 miles*	*14 minutes*
The Presbyterian Hospital	*11.8 miles*	*18 minutes*
CMC-University	*11.6 miles*	*14 minutes*
NorthEast Regional Medical Center	*22.4 miles*	*24 minutes*

Source: MapQuest; Exhibit 20, Table 5

The proposed PHMH will decrease driving time by 50% for many residents of the five zip codes [sic] *service area currently seeking care at one of the four PHS inpatient facilities as shown in Exhibit 20, Table 5. The result is improved access to health care services for residents in eastern Mecklenburg County.*

Furthermore, according to a recent American College of Emergency Physicians (ACEP) report, The National Report Card on the State of Emergency Medicine, North Carolina earned a 'C-overall for its support of emergency care.' In comparison with other states, North Carolina ranked 37th in the number of emergency departments per million population. One recommendation ACEP made to North Carolina is to build more emergency medicine facilities. The proposed project will provide increased accessibility to emergency medicine facilities for residents of a growing market located in eastern Mecklenburg County.

...

PHMH analyzed zip code level Solucient data to establish the current inpatient volume from the proposed zip code service area utilizing PHS facilities in Mecklenburg County. As previously discussed, the proposed PHMH will be a community hospital. Obstetric services will be provided; cardiac surgery and other tertiary level services will not. Therefore, to determine the potential medical/surgical patient days to be included in the analysis the following exclusions were made from the total Solucient patient days from the five zip code service area:

Solucient Database Exclusions

Medical Surgical Exclusions
Mental Health and Drug Abuse DRGs (424-433 and 521-523)
Rehab (462)
Normal Newborns (391)
NICU (385-390)
Diag Cardiac Cath (124, 125)
DRGs with FY2005 Relative Weight > = 2.0

Source: Exhibit 20, Table 8

Based upon the defined medical/surgical Solucient database, approximately 65% of inpatient services received by the residents of the defined Mint Hill service area are provided in downtown Charlotte. In addition, PHS facilities provide over 40% of all inpatient acute care days for the population of the proposed facility as shown in the following table.

Presbyterian Hospital Mint Hill Defined Service Area
Market Share FFY 2005

Hospital	***FFY 2003 Acute Bed Days***	***FFY 2004 Acute Bed Days***	***FFY 2005 Acute Bed Days***	***FFY 2003 Market Share***	***FFY 2004 Market Share***	***FFY 2005 Market Share***
The Presbyterian Hospital	*10,571*	*10,234*	*11,765*	*29.8%*	*28.4%*	*31.8%*
Carolinas Medical Center	*11,064*	*11,689*	*10,377*	*31.2%*	*32.5%*	*28.1%*
CMC University	*5,001*	*5,006*	*4,619*	*14.1%*	*13.9%*	*12.5%*
Presbyterian Hospital Matthews	*3,093*	*3,103*	*3,289*	*8.7%*	*8.6%*	*8.9%*
NorthEast Medical Center	*2,631*	*2,540*	*3,134*	*7.4%*	*7.1%*	*8.5%*
CMC Pineville/Mercy	*2,042*	*2,402*	*2,082*	*5.7%*	*6.7%*	*5.6%*
Presbyterian Orthopaedic Hospital	*305*	*408*	*409*	*0.9%*	*1.1%*	*1.1%*
Presbyterian Hospital Huntersville	*0*	*0*	*130*	*0.0%*	*0.0%*	*0.4%*
CMC Union	*57*	*124*	*83*	*0.2%*	*0.3%*	*0.2%*
Stanly Memorial Hospital	*21*	*23*	*57*	*0.1%*	*0.1%*	*0.2%*
All Other Providers	*701*	*476*	*996*	*2.0%*	*1.3%*	*2.7%*
Total	*35,519*	*36,005*	*36,941*	*100%*	*100%*	*100%*
Total PHS Market Share	***13,969***	***13,745***	***15,593***	***39.3%***	***38.2%***	***42.2%***

Source: Solucient; Exhibit 20, Tables 9, 10, 11

The following table shows PHS market share by service for FFY 2005, including general inpatient medical/surgical services, obstetric services, inpatient and outpatient surgical services, and endoscopy.

PHS Market Share of Mint Hill Zip codes
Discharges FFY 2005

Zip Code	*Inpt*	*Obstetrics*	*Inpt Surgery*	*Outpt Surgery*	*Endoscopy*
28075	*16.6%*	*20.1%*	*13.4%*	*15.6%*	*14.1%*
28107	*22.2%*	*22.8%*	*23.6%*	*22.8%*	*39.9%*
28213	*33.2%*	*24.0%*	*24.0%*	*25.0%*	*24.3%*
28215	*41.0%*	*38.0%*	*36.1%*	*35.5%*	*42.9%*
28227	*55.2%*	*47.3%*	*51.0%*	*53.5%*	*57.9%*
Total Service Area	***40.7%***	***35.2%***	***34.9%***	***35.6%***	***40.2%***

Source: PHS Trendstar; 2006 Hospital Licensure Renewal Applications; Exhibit 20, Tables 10, 19, 24, 30, 42

As shown in the previous table, PHS enjoys a substantial market share of all five PHMH zip codes. In addition, in the two largest zip codes, 28215 and 28227, PHS's market share ranges from 35% to 57% of these services. PHMH will be located in 28215 at the intersection of Albemarle Road and I-485, where these two zip codes meet, resulting in improved access to health care services for that sizable population.

...

Historic utilization across all PHS acute care inpatient facilities increased more than 16% from CY 2001 to CY 2005. In 2003, utilization decreased as managed care organizations began to selectively direct patients to 'preferred providers.' As a result, utilization throughout PHS inpatient facilities experienced a downward movement in utilization beginning early in 2003 which lasted through the third quarter of 2004. After a change in leadership at Novant Health Southern Piedmont Region, successful negotiation with managed care organizations, completion of major construction and renovation projects at TPH, PHM, and POH, and the opening of PHH, this trend has reversed.

...

During the last several years, PHS has analyzed a variety of options to maximize utilization of its downtown Charlotte assets. The demand for inpatient services at TPH has resulted in a projected need for additional acute care beds in the annual State Medical Facilities Plan for the last

three years. In the 2004 SMFP, a need for 46 acute inpatient beds was identified for TPH. In the 2005 SMFP, a need for 71 acute inpatient beds was identified for TPH. In the 2006 SMFP, a need for 97 acute inpatient beds was identified for TPH. During this time utilization of the 140 acute care beds at POH remained significantly underutilized which has offset the need for new acute beds generated by the other Presbyterian acute care hospitals.

In September 2005, PHS submitted a CON application to relocate 76 of POH's 140 acute care beds. That application was denied and is under appeal. PHS is confident that the appeal will be settled and a CON to relocate the beds will be forthcoming. At the same time, PHS submitted a CON to replace the remaining 74 acute care beds at POH and develop a new orthopaedic specialty hospital in downtown Charlotte. The Agency denied that application questioning the need for a dedicated specialty hospital in downtown Charlotte. PHS elected not to appeal and revisited options for the underutilized beds at POH.

The Proposed 2007 SMFP includes an identified need for 119 additional acute care beds at TPH. The additional demand for beds at TPH reflects the increasing number of patients from all areas of Mecklenburg County and surrounding areas coming to downtown Charlotte for all levels of health care services, including residents of the proposed service area. As previously discussed, PHS currently has a 42.2% market share of the proposed PHMH service area. Of that volume over 75% of the total discharges representing over 30% of the market share are from TPH downtown ....

...

The development of the proposed PHMH will result in a shift of much of this volume to the proposed community hospital. The projected patient shift to the community hospital will open up more capacity at TPH in the future. Additional discussion of the impact of the proposed PHMH on TPH and POH is included in response to Section III.1.b."

In Section III.8(a), pages 93-95, the applicant states

"The proposed project is necessitated by [sic] *physical inadequacy of the existing Presbyterian Orthopaedic Hospital facility in downtown Charlotte. The proposed project also seeks to improve the geographic accessibility of services to residents of the proposed Mint Hill service area.*

...

The existing POH facility was constructed in two phases. The 'patient wing' was constructed in the 1950s as a residential hotel. The surgical, diagnostic, and administrative areas were constructed during the 1970s. Since that time, only minor construction and renovations have been completed at the existing facility. As with most hospitals constructed during the 1950's and 1960's, the buildings have aged considerably and require significant cost to upgrade the infrastructure and physical environment to continue as an acute care hospital. Perhaps more importantly, the existing physical plant was designed at a time when outpatient services were an insignificant part of a hospital's total business and inpatient rooms were semi-private.

With the continuing move toward more technology in every department, POH cannot consider technological upgrades in the current facility. The configuration of space is not conducive to patient privacy and some of the mechanical systems are in need of significant upgrading and/or replacement.

While the existing POH can still be utilized for outpatient and administrative services, the facility is ill-configured and unresponsive to the needs of inpatients and physicians who refer patients to POH for care. Following are specific facility issues associated with the existing hospital.

- *Existing 2nd floor Surgical Suite has 12 operating rooms.*
  - *Built to manage the sterilization and flow patients and employees of 4 operating rooms.*

- *Operating rooms are small and some cannot. accommodate equipment required for many newer orthopaedic surgical procedures.*
- *Daily complaints and delays due to inability to sterilize instruments quickly; however, cannot relocate due to insufficient plumbing.*
- *Too many access points to operating rooms.*
- *Storage facilities non-existent. Old patient rooms used for storage of supplies, equipment, and administrative offices.*
- *The limited space capacity limits the ability of POH to attract physicians who want to perform revenue producing procedures, e.g., spines, hands and foot and ankle.*

- *All rooms are semi-private.*
  - *A major source of physician and patient dissatisfaction.*
  - *Limits admissions due to mix of male and female patients.*
  - *Bathrooms not built to handicapped standards.*
- *Elevators within the existing facility are outdated, small, only one can move stretcher patients, and all elevators do not go to all floors, resulting in way-finding difficulties for patients and families.*
- *Frequent complaints from physicians, patients, and employees about the physical plant.*
- *Floor to floor ceiling height low; restrictions prevent appropriate power, HVAC and water systems from being installed.*
  - *Cannot install wireless paging system in ceilings.*
  - *Antiquated nurse call systems.*
  - *New Hill-Rom beds, but old electrical system prevents use of all bed functions.*
- *Lack of classroom space and cramped administrative areas.*
- *Lack of staff bathrooms and support space on all units.*
- *Electrical distribution system.*
  - *Emergency power generator needs to be replaced.*
  - *Some areas of the old building do not have emergency power.*

- *Power cannot be segmented in DFS-required equipment, critical and life safety branches.*

- *HVAC Systems.*
  - *Multiple (about 90) through the wall heat pumps in older building.*
  - *Split package rooftop units experiencing 3 compressor failures per year.*
  - *High operating cost; poor energy consumption management.*
- *Life Safety Systems.*
  - *Lack of sprinkler systems in some sections of the older building.*

The deficiencies in the existing facility do not, at the present time, compromise patient care. They do make providing patient [sic] *more staff intensive and challenging. The complaints about POH relate only to facilities issues. Despite facility issues, there is high patient satisfaction. It is becoming more and more expensive to maintain the existing POH facility, and it is becoming impossible to implement newer technologies in the building as a result of the facility deficiencies noted above."*

In Section III.1(b), pages 53-56, the applicant summarizes the assumptions and methodologies used to project utilization for the proposed hospital as follows:

"PHMH used two basic methodologies to project future utilization for the proposed project.

1. A Use Rate Methodology

Projected Utilization = (Defined Service Area Population x Use Rate x Market Share) + Other Inmigration was used to project:

- *Acute care inpatient discharges, days, and bed need;*
- *ICU days and ICU bed need;*
- *Observation bed days and observation bed need;*
- *LDRP births, days, and bed need;*

- *C-section procedures and C-section operating room need;*
- *Inpatient and outpatient surgical procedures and shared operating room need;*
- *GI endoscopy procedures and GI endoscopy procedure room need;*
- *Outpatient visits; and*
- *Emergency Department visits and emergency treatment rooms need.*

2. *Ancillary utilization projections were calculated based upon existing ancillary utilization patterns at Presbyterian Healthcare's existing community hospitals: Presbyterian Hospital Matthews (PHM) and Presbyterian Hospital Huntersville (PHH). As existing PHS community hospitals in the Charlotte area, with comparable medical staffs, many of whom are on the medical staff at both facilities or are partners in a group with physicians on the staff at both hospitals, PHMH assumes that projected ancillary utilization at PHMH will imitate current ancillary utilization patterns at PHM and PHH.*

...

Market Share Shift Assumptions

1. Percent Market Share Shift to PHMH

The following percent market share shift was used in all use rate methodologies except in the projection of emergency department visits. Due to the nature of emergency services, a larger percent of market share was shifted from existing PHS facilities to PHMH.

Percent Market Share Shift from Existing PHS Facilities to PHMH

Zip Code	*Percent Market Share Shift*
28075	*55.0%*
28107	*55.0%*
28213	*40.0%*
28215	*65.0%*
28227	*40.0%*

Source: Exhibit 20

The following factors were considered important to the determination of the percent of market share, reflected in the previous table, projected to shift from each zip code:

- *PHMH is closer to areas of each of the five zip codes than existing PHS facilities as reflected in Exhibit 20, Table 4 and Map 7;*
- *new physician offices with easier access will be developed in the future on the PHMH campus;*
- *congestion and traffic in downtown Charlotte will increase;*
- *PHMH offers a choice for inpatient care in the suburban Charlotte market area;*
- *the proposed location of PHMH adjacent to Interstate I-485 will result in ease of access to the existing population in the defined zip code service area;*
- *Interstate I-485 will result in population growth in the defined zip code service area;*
- *a smaller percent of 28227 will shift as parts of this zip code are closer to PHM;*
- *a smaller percent of 28213 will shift as parts of this zip code are closer to TPH; and*
- *some patients will continue to seek care at other PHS hospitals, therefore 100% of the demand for services in the five zip codes will not shift to PHMH.*

2. *Market Share Resulting From Proposed Project*

PHMH expects a slight market share increase once PHMH becomes operational, as shown in the following table.

Projected Increase in PHMH Market Share

Zip Code	*Projected Market Share Increase*
28075	*5.0%*
28107	*5.0%*
28213	*5.0%*
28215	*15.0%*
28227	*5.0%*

Source: Exhibit 20

The expected increase in market share of the defined service area is based upon the following factors:

- *there is no existing acute care hospital in the five zip code service area;*
- *projected population growth in the defined zip code service area is projected to exceed 15% between 2005 and 2012;*
- *PHMH offers a choice for inpatient care in the suburban Charlotte market area;*
- *many of the residents of 28215, in the home zip code of PHMH, will be closer to PHMH than other hospitals;*
- *PHMH is closer to areas of each of the five zip codes than existing PHS facilities and competitor hospitals;*
- *new physician offices with easier access will be developed on the PHMH campus;*
- *congestion and traffic in downtown Charlotte, the University area of Charlotte, and Matthews will increase;*
- *the proposed location adjacent to the 1-485 Beltway will result in ease of access to existing population; and*
- *the new I-485 Beltway will result in population growth in areas of the zip codes closer to PHMH.*

Other Inmigration Assumption

While not part of the defined service area, PHMH recognizes that patients from other North Carolina counties may choose to travel across service areas to receive services at PHMH. As a result, 10.0% of the total projected utilization in each of the project years has been allocated to the category of 'Other Inmigration.' This estimate is consistent with the 'Other Inmigration' experienced by other acute care facilities in the region, as detailed in Exhibit 20, Tables 71 – 80."

Regarding "Other Inmigration," in a footnote on page 56, the applicant states

"'Other Inmigration' 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, 'Other Inmigration' is historically between 10% to 20% of total utilization."

Essentially, the applicant projects that some individuals who live or work in the 16 zip codes contiguous to the five zip code service area will choose to utilize the proposed hospital in Mint Hill if it is closer to their home or workplace than an existing hospital. The projected number of patients at PH-Mint Hill from any one of these 16 zip codes would be minimal.

On pages 1-2 of the Impact Analysis provided in Exhibit 20, the applicant states

"As part of the Presbyterian Hospital Mint Hill utilization analysis, PHMH defined hospital service areas for the following ten North Carolina Hospitals in the Charlotte area to assist with the assessment of whether PHMH would have a material adverse impact on these facilities in the future.

- *The Presbyterian Hospital;*
- *Presbyterian Orthopaedic Hospital;*
- *Presbyterian Hospital Matthews;*
- *Presbyterian Hospital Huntersville;*
- *Carolinas Medical Center – University;*
- *Carolinas Medical Center – Union;*
- *Carolinas Medical Center – Mercy/Pineville;*
- *Carolinas Medical Center;*
- *NorthEast Medical Center; and,*
- *Stanly Memorial Hospital.*

Data from Solucient and Annual Hospital Licensure Renewal Applications for these hospitals were used to calculate current and projected service areas and market shares. The potential for Presbyterian Hospital Mint Hill

to have a material impact on the volume of services at each hospital was evaluated.

...

PHMH determined that the positive impact of continued population growth in the region far exceeded any negative impact of the proposed project on existing facilities. Every hospital analyzed enjoys significant growth from 2005 to 2010 and the impact of PHMH is minimal, if any. Results of the analysis are included in Exhibit 20, Table 67. Projections are included in Tables 68-82."

Acute Care Beds (including ICU and Obstetrics) – The following table illustrates projected utilization of the 50 acute care beds at PH-Mint Hill, as reported by the applicant in Section IV.1, page 104.

	Year One 10/1/09 - 9/30/10	Year Two 10/1/10 - 9/30/11	Year Three 10/1/11 - 9/30/12
General Med/Surg (38 beds)			
Discharges	2,354	2,928	3,530
Average Length of Stay (ALOS)	3.0	3.0	3.0
Patient Days	7,130	8,864	10,677
ADC [1]	19.5	24.3	29.3
% Occupancy [2]	51.4%	63.9%	77.0%
Obstetrics (8 LDRP beds)			
Discharges	531	647	763
Average Length of Stay (ALOS)	2.6	2.6	2.6
Patient Days	1,380	1,681	1,984
ADC [1]	3.8	4.6	5.4
% Occupancy [2]	47.3%	57.6%	67.9%
ICU (4 beds)			
Discharges	282	350	420
Average Length of Stay (ALOS)	2.6	2.6	2.6
Patient Days	734	910	1,092
ADC [1]	2.0	2.5	3.0
% Occupancy [2]	50.3%	62.3%	74.8%
Total (50 beds)			
Discharges	2,885	3,575	4,293
Average Length of Stay (ALOS)	3.2	3.2	3.2
Patient Days	9,244	11,455	13,753
ADC [1]	25.3	31.4	37.7
% Occupancy [2]	50.7%	62.8%	75.4%

Source: Section IV.1, page 104.
[1] ADC equals total number of patient days of care divided by 365.
[2] Occupancy equals ADC divided by the number of beds.

As shown in the above table, the applicant projects that the ADC of the 50 acute care beds at PH-Mint Hill in the third operating year

will be 37.7 patients, which is an occupancy rate of 75.4%. In Section III.1(b), pages 56-60, the applicant describes the methodology and assumptions used to project utilization of the acute care beds as follows:

"PHMH analyzed FFY 2003-2005 zip code level Solucient data to determine the acute care inpatient discharge use rate per 1,000 population. ...

...

The three year average acute care inpatient discharge use rate for each zip code was used to determine total acute care inpatient discharges and PHS market share by zip code in the defined service area for the first three years of the proposed project.

...

Using the Solucient FFY 2005 inpatient discharge data, PHMH calculated the PHS acute care inpatient market share for each zip code in the defined service area. ...

...

Actual PHS acute care inpatient market share was then adjusted to reflect the percent market shift and the projected increase in market share. ...

...

PHMH also assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share [shift] *in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected acute care inpatient discharges by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected acute care inpatient discharges for the first three years of operation using the following methodology:

> *Projected Acute Care Inpatient Discharges = (Defined Service Area Population x Three Year Average Acute Care Inpatient Discharge Use Rate x Market Share) + 'Other Inmigration'*

...

FFY 2005 Solucient PHS acute care inpatient discharge and inpatient day data specific to the defined zip code service area was used to determine an average length of stay of 3.2 days. Actual data is included in Exhibit 20, Table 19. Annual total acute care inpatient discharges were multiplied by average length of stay to project acute care bed need in each of the three project years."

The applicant adequately demonstrates that projected utilization of the 50 acute care beds at PH-Mint Hill is based on reasonable assumptions, and that the beds are needed in Mint Hill.

The applicant provides an Impact Analysis in Exhibit 20, regarding utilization of POH and TPH following the relocation of beds, as discussed below. (See also Section III.8, pages 93-100, and Section III.9, pages 100-102.) Upon completion of this project and Project I.D. #F-7386-05, POH would have 14 acute care beds and TPH would have 539 acute care beds. The applicant assumes that TPH and POH would be operated as one hospital following completion of this project. Thus, upon completion of this project and Project I.D. #F-7386-05, the applicant assumes TPH would be licensed for 553 acute care beds [539 + 14 = 553]. On page 4 of the Impact Analysis provided in Exhibit 20, the applicant projects a total of 174,613 acute patient days of care will be provided at TPH during FY 2012 (operating Year Three at PH-Mint Hill), which is an ADC of 478.4 [174,613 / 365 = 478.4] and an occupancy rate of 86.5%. In Tables 70 & 72 in Exhibit 20, the applicant projects that utilization at TPH would increase at the same rate as the population of the service area is projected to increase. Further, the applicant adjusted its utilization

projections for TPH to account for the patients currently served by TPH and POH that are expected to use the proposed hospital in Mint Hill. See the Impact Analysis in Exhibit 20 for all of the applicant's assumptions and methodology used to project utilization for TPH. The applicant adequately demonstrates that 553 acute care beds would be sufficient to meet the needs of the patients utilizing TPH after relocation of beds to Mint Hill.

Further, on page 3 of Exhibit 20, the applicant provides an impact analysis regarding utilization at PH-Matthews following the relocation of beds, as illustrated in the following table.

PH-MATTHEWS	FY 2005 (Actual)	FY 2012 (Projected)
Without PH-Mint Hill		
# of Acute Patient Days	22,342	27,162
Average Daily Census	61.2	74.4
Occupancy Rate	60.0%	72.9%
With PH-Mint Hill		
Total Acute Patient Days		25,487
Average Daily Census		69.8
Occupancy Rate		68.4%

As shown in the above table, during FY 2012 (the third operating year of PH-Mint Hill), the applicant projects an occupancy rate of 68.4% at PH-Matthews compared to an occupancy rate at PH-Matthews of 72.9% if PH-Mint Hill is developed. Thus, PH-Mint Hill will not have a significant impact on utilization of PH-Matthews.

ICU Beds – Regarding the methodology and assumptions used to project the need for four ICU beds, in Section III.1(b), pages 60, the applicant states

> *"Projected ICU beds were determined using total projected inpatient days and FFY 2005 ICU utilization data from PHM and PHH, included in Exhibit 20, Table 18. Intensive care days at PHM and PHH represented 7.9% of total inpatient days in FFY 2005. The following table shows projected ICU patient days and the resulting ICU bed need."*

projections for TPH to account for the patients currently served by TPH and POH that are expected to use the proposed hospital in Mint Hill. See the Impact Analysis in Exhibit 20 for all of the applicant's assumptions and methodology used to project utilization for TPH. The applicant adequately demonstrates that 553 acute care beds would be sufficient to meet the needs of the patients utilizing TPH after relocation of beds to Mint Hill.

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ICU Beds – Regarding the methodology and assumptions used to project the need for four ICU beds, in Section III.1(b), pages 60, the applicant states

> *"Projected ICU beds were determined using total projected inpatient days and FFY 2005 ICU utilization data from PHM and PHH, included in Exhibit 20, Table 18. Intensive care days at PHM and PHH represented 7.9% of total inpatient days in FFY 2005. The following table shows projected ICU patient days and the resulting ICU bed need."*

Projected ICU Patient Days and Bed Need

	FFY 2010	FFY 2011	FFY 2012
Total Inpatient Days	*9,244*	*11,455*	*13,753*
Projected ICU Days (7.9%)	*734*	*910*	*1,092*
Average Daily Census	*2.0*	*2.5*	*3.0*
ICU Bed Need @ 66.7% Occupancy	*3*	*4*	*4*
Occupancy @ 4 ICU Beds	*50.3%*	*62.3%*	*74.8%*

Source: Exhibit 20, Table 18"

The applicant adequately demonstrates that projected utilization of the four ICU beds at PH-Mint Hill is based on reasonable assumptions, and that the beds are needed in the proposed hospital.

LDRP Beds – Regarding the methodology and assumptions used to project the need for eight LDRP beds, in Section III.1(b), pages 61-64, the applicant states

> *"Claritas population projections for the defined service area were obtained for 2010-2012. Gender/age-specific population data for the defined service area is included in Exhibit 20, Table 17.*
>
> ...
>
> *Estimated gender/age-specific 2005 population data from the North Carolina Office of State Demographics was used to calculate a 2005 birth rate per 1,000 female population ages 16-44 for Mecklenburg and Cabarrus County, respectively. Solucient data for total births from Mecklenburg and Cabarrus County for FFY 2005 is included in Exhibit 20, Table 26. ...*
>
> ...
>
> *The 2005 county specific birth rate use rate for each zip code was used to determine total LDRP cases and PHS market share by zip code in the defined service area for the first three years of the proposed project.*
>
> ...
>
> *Using Solucient FFY 2005 obstetric discharge data, included in Exhibit 20, Table 26, PHMH calculated the*

PHS market share for obstetric services for each zip code in the defined service area. ...

...

Actual PHS market share was then adjusted to reflect the percent market shift and the projected increase in market share. ...

...

PHMH also assumed that the proposed market share shift will occur over the first three years of operation, realizing 70 % of projected market share [shift] *in Project Year 1, 85 % in Project Year 2 and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected obstetric discharges by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected LDRP discharges for the first three years of operation using the following methodology:

> *Projected LDRP Discharges = (Defined Service Area Female Population Age 16-44 x 2005 Birth Rate x Market Share) + 'Other Inmigration'*

...

FFY 2005 Solucient PHS LDRP discharge and patient day data specific to the defined zip code service area was used to determine an obstetric average length of stay of 2.6 days at PHM and PHH. Actual FFY 2005 Solucient data is included in Exhibit 20, Table 27."

The applicant adequately demonstrates that projected utilization of the 8 LDRP beds at PH-Mint Hill is based on reasonable assumptions, and that the proposed services are needed in Mint Hill.

Observation Beds (Unlicensed) – The applicant proposes to develop 10 unlicensed observation beds, six of which will be located on the second floor of the hospital with the general med/surg beds and four of which will be located on the third floor of the hospital with the eight LDRP beds. The following table illustrates the projected need for the ten proposed observation beds at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 60.

PH-MINT HILL	OBSERVATION DAYS OF CARE	PERCENT OCCUPANCY[1]
Year One (10/1/09 – 9/30/10)	1,685	46.2%
Year Two (10/1/10 – 9/30/11)	2,088	57.2%
Year Three (10/1/11 – 9/30/12)	2,506	68.7%

Source: Section III.1(b), pages 52 and 60.
(1) Calculated by dividing days of care by 365 and then dividing the result by 10.

In Section III.1(b), pages 60-61, the applicant states

> *"Projected observation patient days were determined using total projected inpatient days and FFY 2005 observation bed utilization data from PHH. PHH is the only community hospital in the Novant SPR with designated observation beds. FFY 2005 observation patient days were equal to 18.2 % of total inpatient days at PHH. PHH FFY 2005 data is included in Exhibit 20, Table 29."*

The applicant references PH-Huntersville, which currently operates 50 licensed acute care beds and 10 unlicensed observation beds. The following table illustrates the number of acute and observation days of care provided at PH-Huntersville during FY 2005, as reported by the applicant in Exhibit 20, Table 29.

PH-HUNTERSVILLE	ACCORDING TO TRENDSTAR	FROM THE 2006 HOSPITAL LICENSE RENEWAL APPLICATION
Total Acute Care Patient Days	8,813	8,617
Total Observation Days	1,606	1,611
Observation Days as a % of Total Acute Care Patient Days	18.2%	18.7%

The following table illustrates the methodology used to project the number of observation days to be provided at PH-Mint Hill during the first three operating years.

PH-MINT HILL	YEAR 1	YEAR 2	YEAR 3
Total Acute Care Patient Days	9,244	11,455	13,753
Observation Days as a % of Total Acute Care Patient Days	18.2%	18.2%	18.2%
Total Observation Days	1,685	2,088	2,506

The applicant adequately demonstrates that projected utilization of the 10 unlicensed observation beds at PH-Mint Hill is based on reasonable assumptions, and that the beds are needed in the proposed hospital.

Operating Rooms – The applicant proposes to relocate five existing shared ORs from POH to Mint Hill. One of the five shared ORs will be converted to a dedicated C-section room at PH-Mint Hill.

Shared ORs - The applicant states that PH-Mint Hill needs four shared ORs based on the number of inpatient and outpatient surgeries projected to be performed in the third operating year. The following table illustrates the number of surgical procedures projected to be performed at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 68.

	YEAR ONE 10/1/09 – 9/30/10	YEAR TWO 10/1/10 – 9/30/11	YEAR THREE 10/1/11 – 9/30/12
Projected # of IP Surgical Cases	782	970	1,164
Projected # of OP Surgical Cases	1,908	2,365	2,840
Total # of Surgical Cases	2,690	3,335	4,004
Average # of cases per room per day [1]	2.6	3.2	3.9

Source: Section III.1(b), pages 52 and 68
[1] Assumes 260 days of operation per year. Calculated by dividing total # of surgical cases by 260 and then by 4.

As shown in the above table, during the third operating year, the applicant projects that an average of 3.9 surgical cases will be performed per day in each of the four shared ORs at PH-Mint Hill. The applicant provides the assumptions and methodology used to project utilization of the four shared ORs at PH-Mint Hill in Section III.1(b), pages 65-69, where it states

> *"Inpatient and outpatient surgical cases from Cabarrus and Mecklenburg County were aggregated from the 2006 Hospital Licensure Renewal Applications and the 2006 Freestanding Ambulatory Surgery Center Annual Licensure Renewal Applications. County population estimates for 2005 were obtained from the North Carolina*

Office of State Demographics. Inpatient and outpatient surgical use rates for FFY 2005 were calculated for Cabarrus and Mecklenburg Counties, respectively....

...

Surgical utilization varied significantly between Cabarrus and Mecklenburg Counties in FFY 2005. Use rate variations reflect different surgical practice patterns in the two counties. ... The county specific surgical use rate for each zip code was used to determine total inpatient and outpatient surgery and PHS market share in the defined service area for the first three years of the proposed project.

...

Using FFY 2005 inpatient and outpatient surgical case data from the PHS internal Trendstar database, PHMH calculated the PHS surgical market share for each zip code in the defined service area. Trendstar data is included in Exhibit 20, Table 33. ...

...

Actual PHS market share was then adjusted to reflect the percent market shift and the projected increase in market share. ...

...

PHMH also assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share [shift] *in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected inpatient and outpatient surgical cases by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected surgical utilization for the first three years of operation using the following methodology:

Projected Inpatient Surgical Cases = (Defined Service Area Population x Inpatient Surgical Use Rate x Market Share) + 'Other Inmigration'

AND

Projected Outpatient Surgical Cases = (Defined Service Area Population x Outpatient Surgical Use Rate x Market Share) + 'Other Inmigration.'"

The applicant projects it will perform an average of 3.9 surgical cases per shared OR per day in Year Three, which exceeds the minimum threshold of 3.2 surgical cases per shared OR per day. The applicant adequately demonstrates that projected utilization of the four shared ORs at PH-Mint Hill is based on reasonable assumptions, and that the shared ORs are needed in Mint Hill.

The applicant provides an Impact Analysis in Exhibit 20, regarding utilization of ORs at POH and TPH following the relocation of five shared ORs from POH to Mint Hill, as discussed below. (See also Section III.8, pages 93-100, and Section III.9, pages 100-102.) The applicant provides the following projected utilization in FY 2012 of the ORs remaining at POH and TPH. The applicant provides the methodology and assumptions used to project surgical utilization at POH and TPH in the Impact Analysis in Exhibit 20, pages 33-34.

	TPH	POH	TPH & POH COMBINED
Current # of shared ORs [1]	26	12	38
# of Shared ORs to be relocated to PH-Mint Hill	0	5	5
# of shared ORs remaining at TPH & POH	26	7	33
Projected # of Surgical Cases in FY 2012	20,295	8,460	28,755
Average # of cases per room per day [2]	3.0	4.6	3.4

(1) TPH does not have any dedicated inpatient ORs other than three dedicated open-heart and three dedicated C-section ORs. POH does not have any dedicated inpatient ORs.

(2) Calculated by dividing the total number of surgical cases by 260 days per year and then dividing by the total number of ORs.

As shown in the table above, the applicant projects that the 33 shared ORs at TPH and POH combined will perform an average of 3.4 surgical cases per day per OR during the third operating year of PH-Mint Hill.

The following table illustrates the number of surgical cases performed in the shared ORs at TPH and POH during FY 2005, as reported in their 2006 Hospital License Renewal Applications.

	TPH	POH
# of shared ORs [1]	22	12
# of surgical cases performed in the shared ORs	20,340	7,633
Average # of cases per shared OR per day	3.6	2.4

[1] During the reporting period for the 2006 Hospital License Renewal Application (10/1/04 – 9/30/05), TPH was licensed for only 22 shared ORs.

As shown in the above table, during FY 2005, a total of 20,340 surgical cases were performed in the 22 shared ORs at TPH, which is an average of 3.6 cases per OR per day [20,340 / 260 / 22 = 3.6]. However, subsequent to the end of the reporting period for the 2006 Hospital License Renewal Application (10/1/04 – 9/30/05), TPH opened four additional shared ORs for a total of 26 shared ORs. Thus, assuming 20,340 surgical cases were performed in 26 shared ORs, the average number of cases per OR per day would be only 3.0, which is less than the minimum threshold of 3.2 cased per OR per day. Further, as shown in the above table, during FY 2005, a total of 7,633 surgical cases were performed in the 12 shared ORs at POH, which is an average of 2.4 cases per OR per day [7,633 / 260 / 12 = 2.4], which is also less than the minimum threshold of 3.2 cases per OR per day. Assuming TPH and POH were licensed as one hospital and five shared ORs are relocated to PH-Mint Hill, the average number of surgical cases per OR per day would be 3.26 [(20,340 + 7,633) / 260 / (26 +7) = 3.26] based on actual utilization in FY 2005. In fact, the average would be lower than this, given the number of patients who would use the proposed PH-Mint Hill rather than TPH or POH. Consequently, the applicant adequately demonstrated that 7 shared ORs would be sufficient to meet the needs of the patients that will continue to utilize POH and TPH for surgical services following relocation of five shared ORs to Mint Hill.

Dedicated C-Section OR – The applicant states that PH-Mint Hill needs one dedicated C-section OR based on the number of obstetrical patients projected to be admitted in the third operating year. The following table illustrates projected utilization of the

dedicated C-section OR at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 64.

	YEAR ONE 10/1/09 – 9/30/10	YEAR TWO 10/1/10 – 9/30/11	YEAR THREE 10/1/11 – 9/30/12
Projected # of Obstetric Cases	531	647	763
Projected # of C-section Cases (29.9%)	158	193	228
Average # of procedures per room per day [1]	0.6	0.7	0.9

Source: Section III.1(b), pages 52 and 64.
[1] Assumes 260 days of operation per year. Calculated by dividing total # of C-sections by 260.

As shown in the above table, during the third operating year, the applicant projects that it will perform 228 C-sections. The applicant provides the assumptions and methodology used to project the number of C-sections to be performed at PH-Mint Hill in Section III.1(b), pages 64-65, where it states

> *"Projected PHMH C-Section cases and C-Section operating room need were determined using total projected obstetric cases and the average FFY 2005 C-Section rate from PHH and PHM. In FFY 2005 C-Sections represented 29.9% of all births at PHH and PHM. FFY 2005 data for PHH and PHM is included in Exhibit 20, Table 24. ...*
>
> ...
>
> *... One C-Section operating room is necessary to meet the needs of women unable to have a vaginal delivery. ... The proposed C-Section operating room will not located in the Surgical Services at PHMH and will be located in the LDRP suite."*

Pursuant to 10A NCAC 13B .4301, a hospital that offers obstetrical services must be capable of performing cesarean deliveries within 30 minutes of the decision to perform a C-section. The applicant projects that the four shared ORs at PH-Mint Hill would perform an average of 3.9 surgical cases per shared OR per day. Without the proposed C-section room, the four shared ORs would be projected to average almost 4.9 surgical cases and C-sections per OR per day. The applicant adequately demonstrates that projected utilization of the one dedicated C-section OR at PH-Mint Hill is based on reasonable assumptions, and that one C-section operating room is

needed in the proposed hospital to meet minimum licensure requirements.

Gastrointestinal Endoscopy Room – The applicant proposes to relocate one existing GI endoscopy room from PH-Matthews to Mint Hill. The applicant states that PH-Mint Hill needs one GI endoscopy room based on the number of GI endoscopy procedures projected to be performed in the third operating year. The following table illustrates the number of GI endoscopy procedures to be performed at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 72.

	TOTAL # OF GI ENDOSCOPY PROCEDURES	AVERAGE # OF PROCEDURES PER DAY PER GI ENDOSCOPY ROOM
YEAR ONE (10/1/09 – 9/30/10)	1,535	5.9
YEAR TWO (10/1/10 – 9/30/11)	1,909	7.3
YEAR THREE (10/1/11 – 9/30/12)	2,292	8.8

Source: Section III.1(b), pages 52 and 72.
(1) Assumes 260 days of operation per year. Calculated by dividing total # of GI endoscopy procedures by 260.

As shown in the above table, during the third operating year, the applicant projects that an average of 8.8 endo procedures will be performed per day in the GI endoscopy room at PH-Mint Hill. The applicant provides the assumptions and methodology used to project the number of GI endoscopy procedures to be performed at PH-Mint Hill in Section III.1(b), pages 69-72, where it states

> *"GI endoscopy cases from Cabarrus and Mecklenburg County were aggregated from the 2006 Hospital Licensure Renewal Applications and the 2006 Freestanding Ambulatory Surgery Center Annual Licensure Renewal Applications. County population estimates for 2005 were obtained from the North Carolina Office of State Demographics. The GI endoscopy use rate per 1,000 population for FFY 2005 was calculated for Cabarrus and Mecklenburg Counties, respectively ....*
>
> ...
>
> *GI endoscopy utilization varied between Cabarrus and Mecklenburg Counties in FFY 2005. Use rate variations reflect different medical practice patterns in the two*

counties. The county specific GI endoscopy use rate was used to determine total GI endoscopy cases and PHS market share by zip code in the defined service area for the first three years of the proposed project.

...

Using FFY 2005 GI endoscopy case data from the PHS internal Trendstar database, PHMH calculated the PHS market share for each zip code in the defined service area. Trendstar data is included in Exhibit 20, Table 44. ...

...

Actual PHS market share was adjusted to reflect the percent market shift and the projected increase in market share. ...

...

PHMH also assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share [shift] *in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected GI endoscopy cases by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected GI endoscopy cases for the first three years of operation using the following methodology:

> *Projected GI Endoscopy Cases = (Defined Service Area Population x GI Endoscopy Use Rate x Market Share) + "Other Inmigration"*

...

Total projected GI endoscopy cases ... for FFY 2010-2012 were used to project GI endoscopy procedures and GI endoscopy procedure rooms needed for PHMH.

...

PHS Trendstar data and 2006 Hospital Licensure Renewal Application GI endoscopy data, included in Exhibit 20, Table 45, were analyzed to determine that 1.1 GI endoscopy procedures are performed per endoscopy case. Projected GI endoscopy cases were multiplied by average 1.1 procedures per case to determine projected GI endoscopy procedures."

The applicant adequately demonstrates that projected utilization of the endo room at PH-Mint Hill is based on reasonable assumptions, and thus, that the GI endoscopy room is needed in the proposed hospital.

In Section III.8(d), page 99, the applicant states

"PHM is aware that certain physicians in the Matthews community are seeking to add GI endoscopy capacity in their office settings and this will create additional local outpatient GI endoscopy capacity. In addition, PHM and its physicians are committed to expanding the hours of operation of its three remaining GI endoscopy rooms as required by demand and to preserve patient access and convenience."

Regarding the impact on PH-Matthews of relocating one of its four GI endoscopy rooms to PH-Mint Hill, in Exhibit 20, the applicant provides the following projected utilization for the 3 GI endoscopy rooms remaining at PH-Matthews during the third operating year of PH-Mint Hill (FY 2012). The applicant provides the methodology and assumptions used to project GI endoscopy utilization at PH-Matthews in Exhibit 20, Tables 45-46.

	PH-MATTHEWS
Current # of GI endoscopy rooms	4
# of GI endoscopy rooms to be relocated to PH-Mint Hill	1
# of GI endoscopy rooms remaining at PH-Matthews	3
Projected # of GI endoscopy procedures in FY 2012	5,131
Average # of procedures per room per year [1]	1,710

[1] Calculated by dividing the total number of GI endoscopy procedures by the total number of GI endoscopy rooms.

As shown in the table above, the applicant projects that the three GI endoscopy rooms at PH-Matthews will perform an average of 1,710 GI endoscopy procedures per room during the third operating year of PH-Mint Hill. The following table illustrates the number of GI endoscopy procedures performed in the four rooms at PH-Matthews during FY 2005, as reported in its 2006 Hospital License Renewal Application.

	PH-MATTHEWS
# of GI endoscopy rooms	4
# of GI cases performed in the GI endoscopy rooms	5,195
Average # of procedures per room per year	1,299

As shown in the above table, during FY 2005, a total of 5,195 GI endoscopy procedures were performed in the 4 GI endoscopy rooms at PH-Matthews, which is an average of only 1,299 GI endoscopy procedures per room per year [5,195 / 4 = 1,298.75]. The applicant demonstrated that three GI endoscopy rooms would be sufficient to meet the needs of the patients that will continue to utilize PH-Matthews for GI endoscopy services.

Emergency Room – The applicant proposes to develop an ER at PH-Mint Hill with 16 treatment rooms. The following table illustrates projected utilization of the ER at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 77.

	# OF ER VISITS
Year One (10/1/09 – 9/30/10)	13,855
Year Two (10/1/10 – 9/30/11)	17,378
Year Three (10/1/11 – 9/30/12)	21,121

Source: Section III.1(b), pages 52 and 77.

As shown in the above table, during the third operating year, the applicant projects that 21,121 patients will be seen in the ER at PH-

Mint Hill. The applicant provides the assumptions and methodology used to project utilization of the ER at PH-Mint Hill in Section III.1(b), pages 75-77, where it states

"PHMH used the North Carolina Emergency Department Visit Use Rate for community hospitals defined by the American Hospital Association (AHA) to project emergency department visits. Data compiled from the AHA Annual Survey are used to calculate state specific utilization rates. The 2004 North Carolina Emergency Department Visit Use Rate was 408.0 visits per 1,000 population as reflected in Exhibit 20, Table 57. In addition, the 2004 North Carolina Emergency Department Visit Use Rate was increased 1.3 % annually to reflect the increasing use of emergency services in North Carolina and nationally. The projected North Carolina Emergency Department Visit Use Rate was used to determine total emergency department visits and PHS market share by zip code in the defined service area for the first three years of the proposed project.

...

Using 2005 emergency department visit data from the PHS internal Trendstar database, PHMH calculated the PHS market share for each zip code in the defined service area. Trendstar data for PHS emergency visits is included in Exhibit 20, Table 55. ...

...

Actual PHS market share was adjusted to reflect the percent market shift and the projected increase in market share. Due to proximity of the proposed PHMH Emergency Department, more patients in the defined service area will choose the closer facility for emergency services. Therefore, the percent market share shift for emergency department visits was projected at a slightly higher percent than for other services....

...

PHMH also assumed that the proposed market share shift will occur gradually over the first three years of operation,

realizing 70 % of projected market share [shift] *in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected emergency department visits by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected emergency department visits for the first three years of operation using the following methodology:

> *Projected Emergency Department Visits = (Defined Service Area Population x North Carolina Hospital Emergency Department Visit Use Rate x Market Share) + 'Other Inmigration'*

...

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 [sic] *per Treatment Room for Emergency Departments with 20,000 Visits, included in Exhibit 20, Table 56, which results in a need at PHMH for 16 emergency treatment rooms in FFY 2012."*

The applicant projects 21,121 ER visits in Year Three. Based on a planning capacity of 1,333 visits per treatment room for an ER with 20,000 visits annually, the proposed ER needs 16 treatment rooms [21,121 / 1,333 = 15.8]. See Table 56 in Exhibit 20 for the American College of Emergency Physicians ER planning recommendations. Further, the American College of Emergency Physicians ranked North Carolina 37th in the number of ERs per million residents and recommended that North Carolina develop additional ERs. The applicant adequately demonstrates that the projected number of ER visits at PH-Mint Hill is based on

realizing 70 % of projected market share [shift] *in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected emergency department visits by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected emergency department visits for the first three years of operation using the following methodology:

> *Projected Emergency Department Visits = (Defined Service Area Population x North Carolina Hospital Emergency Department Visit Use Rate x Market Share) + 'Other Inmigration'*

...

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 [sic] *per Treatment Room for Emergency Departments with 20,000 Visits, included in Exhibit 20, Table 56, which results in a need at PHMH for 16 emergency treatment rooms in FFY 2012."*

The applicant projects 21,121 ER visits in Year Three. Based on a planning capacity of 1,333 visits per treatment room for an ER with 20,000 visits annually, the proposed ER needs 16 treatment rooms [21,121 / 1,333 = 15.8]. See Table 56 in Exhibit 20 for the American College of Emergency Physicians ER planning recommendations. Further, the American College of Emergency Physicians ranked North Carolina 37th in the number of ERs per million residents and recommended that North Carolina develop additional ERs. The applicant adequately demonstrates that the projected number of ER visits at PH-Mint Hill is based on

reasonable assumptions and adequately demonstrates the need for an ER with 16 treatment rooms.

Outpatient Visits – The following table illustrates the projected number of outpatient visits (e.g., lab tests, prescriptions filled, diagnostic imaging procedures, etc.) at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 74.

	# OF OUTPATIENT VISITS
Year One (10/1/09 – 9/30/10)	24,349
Year Two (10/1/10 – 9/30/11)	30,185
Year Three (10/1/11 – 9/30/12)	36,257

Source: Section III.1(b), pages 52 and 74.

As shown in the above table, during the third operating year, the applicant projects a total of 36,257 outpatient visits at PH-Mint Hill. The applicant provides the assumptions and methodology used to project the total number of outpatient visits at PH-Mint Hill in Section III.1(b), pages 72-75, where it states

> *"PHMH used the North Carolina Hospital Outpatient Visit Use Rate for community hospitals defined by the American Hospital Association (AHA) to project PHMH outpatient visits. Data compiled from the AHA Annual Survey are used to calculate state specific utilization rates.*
>
> *The 2004 North Carolina Outpatient Visit Use Rate was 179.3 visits per 1,000 population as reflected in Exhibit 20, Table 57. PHMH used the 2004 North Carolina Outpatient Visit Use Rate to determine total outpatient visits and PHS market share by zip code in the defined service area for the first three years of the proposed project.*
>
> ...
>
> *Using 2005 outpatient visit data from the PHS internal Trendstar database, PHMH calculated the PHS market share for each zip code in the defined service area. Trendstar data is included in Exhibit 20, Table 55. ...*
>
> ...

Actual PHS market share was adjusted to reflect the percent market shift and the projected increase in market share. ...

...

PHMH also assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share [shift] *in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.*

...

The projected market share for each zip code was used to determine projected outpatient visits by zip code in the defined service area for the first three years of the proposed project.

...

PHMH projected outpatient visits for the first three years of operation using the following methodology:

> *Projected Outpatient Visits = (Defined Service Area Population x North Carolina Hospital Outpatient Visit Use Rate x Market Share) + 'Other Inmigration.'"*

The applicant adequately demonstrates that the projected number of outpatient visits to be handled at PH-Mint Hill is based on reasonable assumptions and that the proposed outpatient services are needed.

Laboratory – The applicant proposes to develop a lab at PH-Mint Hill. The following table illustrates projected utilization of the lab at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF LAB PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	50,161	52,104	102,265
Year Two (10/1/10 – 9/30/11)	62,157	64,869	127,026
Year Three (10/1/11 – 9/30/12)	74,628	78,254	152,883

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the lab at PH-Mint Hill will perform 17.38 procedures for every inpatient discharge and 3.04 procedures for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 59, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 17.38 lab procedures for every inpatient discharge and 3.04 lab procedures for every outpatient and ER visit. The applicant adequately demonstrates that projected utilization of the lab at PH-Mint Hill is based on reasonable assumptions and that the proposed lab is needed.

Pharmacy – The applicant proposes to develop a pharmacy at PH-Mint Hill. The following table illustrates projected utilization of the pharmacy at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF PHARMACY UNITS		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	228,732	116,301	345,034
Year Two (10/1/10 – 9/30/11)	283,435	144,795	428,230
Year Three (10/1/11 – 9/30/12)	340,304	174,672	514,976

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the pharmacy at PH-Mint Hill will dispense 79.28 pharmacy units for every inpatient discharge and 1.36 pharmacy units for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 59, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals dispensed an average of 79.28 pharmacy units for every inpatient discharge and 1.36 pharmacy units for every outpatient and ER visit. The applicant adequately demonstrates that projected utilization of the pharmacy at PH-Mint Hill is based on reasonable assumptions and that the proposed pharmacy is needed.

	# OF LAB PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	50,161	52,104	102,265
Year Two (10/1/10 – 9/30/11)	62,157	64,869	127,026
Year Three (10/1/11 – 9/30/12)	74,628	78,254	152,883

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the lab at PH-Mint Hill will perform 17.38 procedures for every inpatient discharge and 3.04 procedures for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 59, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 17.38 lab procedures for every inpatient discharge and 3.04 lab procedures for every outpatient and ER visit. The applicant adequately demonstrates that projected utilization of the lab at PH-Mint Hill is based on reasonable assumptions and that the proposed lab is needed.

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	# OF PHARMACY UNITS		
	INPATIENT	OUTPATIENT AND ER	TOTAL
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Year Three (10/1/11 – 9/30/12)	340,304	174,672	514,976

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the pharmacy at PH-Mint Hill will dispense 79.28 pharmacy units for every inpatient discharge and 1.36 pharmacy units for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 59, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals dispensed an average of 79.28 pharmacy units for every inpatient discharge and 1.36 pharmacy units for every outpatient and ER visit. The applicant adequately demonstrates that projected utilization of the pharmacy at PH-Mint Hill is based on reasonable assumptions and that the proposed pharmacy is needed.

CT Scanner – The applicant proposes to acquire a CT scanner to be located at PH-Mint Hill. The following table illustrates the projected number of CT scans to be performed on the proposed CT scanner at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF CT SCANS (not HECT Units)		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	1,775	9,823	11,598
Year Two (10/1/10 – 9/30/11)	2,200	12,230	14,429
Year Three (10/1/11 – 9/30/12)	2,641	14,753	17,394

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the CT scanner at PH-Mint Hill will perform 0.615 CT scans for every inpatient discharge and 0.257 CT scans for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 58, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 0.615 CT scans for every inpatient discharge and 0.257 CT scans for every outpatient and ER visit. See also Exhibit 7. However, the applicant did not adequately demonstrate conformance to the required rules for acquisition of a CT scanner in 10A NCAC 14C .2303. See 10A NCAC 14C .2303 for discussion. Therefore, the applicant did not adequately demonstrate the need to acquire a new CT scanner and is conditioned to relocate one of Novant's existing CT scanners currently located in Mecklenburg County to the new hospital instead. See Criterion (4) for the condition.

Ultrasound (US) – In Section II.1, page 20, the applicant states that PH-Mint Hill will have two portable US units. However, according to the list of equipment to be acquired provided in Exhibit 18, the applicant proposes to acquire two portable US units and one *"Imaging, Handheld"* US unit for a total of three units of US equipment. The following table illustrates projected US utilization at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

CT Scanner – The applicant proposes to acquire a CT scanner to be located at PH-Mint Hill. The following table illustrates the projected number of CT scans to be performed on the proposed CT scanner at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF CT SCANS (not HECT Units)		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	1,775	9,823	11,598
Year Two (10/1/10 – 9/30/11)	2,200	12,230	14,429
Year Three (10/1/11 – 9/30/12)	2,641	14,753	17,394

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the CT scanner at PH-Mint Hill will perform 0.615 CT scans for every inpatient discharge and 0.257 CT scans for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 58, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 0.615 CT scans for every inpatient discharge and 0.257 CT scans for every outpatient and ER visit. See also Exhibit 7. However, the applicant did not adequately demonstrate conformance to the required rules for acquisition of a CT scanner in 10A NCAC 14C .2303. See 10A NCAC 14C .2303 for discussion. Therefore, the applicant did not adequately demonstrate the need to acquire a new CT scanner and is conditioned to relocate one of Novant's existing CT scanners currently located in Mecklenburg County to the new hospital instead. See Criterion (4) for the condition.

Ultrasound (US) – In Section II.1, page 20, the applicant states that PH-Mint Hill will have two portable US units. However, according to the list of equipment to be acquired provided in Exhibit 18, the applicant proposes to acquire two portable US units and one *"Imaging, Handheld"* US unit for a total of three units of US equipment. The following table illustrates projected US utilization at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF US PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	549	3,316	3,866
Year Two (10/1/10 – 9/30/11)	681	4,129	4,810
Year Three (10/1/11 – 9/30/12)	817	4,981	5,798

Source: Section III.1(b), pages 52 and 78.

The applicant projects the US equipment at PH-Mint Hill will perform 0.19 procedures for every inpatient discharge and 0.09 procedures for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 59, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 0.19 US procedures for every inpatient discharge and 0.09 US procedures for every outpatient and ER visit. In Year Three, the three US units are projected to perform an average of 5.3 procedures per unit per day [5,798 / 3 / 365 = 5.3]. The applicant adequately demonstrates that projected utilization of the US units at PH-Mint Hill is based on reasonable assumptions and that the proposed US units are needed given the services to be provided to obstetrical patients.

Nuclear Medicine Camera – The applicant proposes to acquire one nuclear medicine camera (without coincidence circuitry) to be located at PH-Mint Hill. The following table illustrates the projected number of procedures to be performed on the proposed nuclear medicine camera at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF NUCLEAR MEDICINE CAMERA PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	507	1,995	2,502
Year Two (10/1/10 – 9/30/11)	628	2,484	3,113
Year Three (10/1/11 – 9/30/12)	754	2,997	3,751

Source: Section III.1(b), pages 52 and78.

The applicant projects that the nuclear medicine camera at PH-Mint Hill will perform 0.176 procedures for every inpatient discharge and 0.052 procedures for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 58, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these

hospitals performed an average of 0.176 nuclear medicine procedures for every inpatient discharge and 0.052 nuclear medicine procedures for every outpatient and ER visit. The applicant adequately demonstrates that projected utilization of the nuclear medicine equipment at PH-Mint Hill is based on reasonable assumptions and that the nuclear medicine equipment is needed.

Mammography Unit – The applicant proposes to acquire one mammography unit to be located at PH-Mint Hill. The following table illustrates the projected number of procedures to be performed on the proposed mammography unit at PH-Mint Hill during the first three operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF MAMMOGRAPHY PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	0	1,830	1,830
Year Two (10/1/10 – 9/30/11)	0	2,269	2,269
Year Three (10/1/11 – 9/30/12)	0	2,725	2,725

Source: Section III.1(b), pages 52 and78.

The applicant projects that the mammography unit at PH-Mint Hill will perform 0.075 procedures for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 58, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 0.075 mammography procedures for every outpatient and ER visit. The applicant adequately demonstrates that projected utilization of the mammography unit at PH-Mint Hill is based on reasonable assumptions and that the mammography unit is needed.

X-ray Equipment – In Section II.1, page 20, the applicant states that they will acquire two mobile x-ray units, two mobile C-arms and two x-ray/fluoroscopy units for PH-Mint Hill. However, according to the list of equipment to be acquired provided in Exhibit 18, the applicant proposes to acquire two mobile x-ray units, two mobile C-arms, two general x-ray units and one x-ray/fluoroscopy unit for PH-Mint Hill. The following table illustrates projected utilization of *"Other Imaging"* equipment[3] at PH-Mint Hill during the first three

[3] The Project Analyst assumes that *"Other Imaging"* equipment means all x-ray equipment since projected utilization is provided separately for the nuclear medicine camera, the mammography equipment, the US units and the CT scanner.

operating years, as reported by the applicant in Section III.1(b), pages 52 and 78.

	# OF X-RAY PROCEDURES		
	INPATIENT	OUTPATIENT AND ER	TOTAL
Year One (10/1/09 – 9/30/10)	3,800	15,096	18,895
Year Two (10/1/10 – 9/30/11)	4,708	18,794	23,502
Year Three (10/1/11 – 9/30/12)	5,653	22,672	28,325

Source: Section III.1(b), pages 52 and 78.

The applicant projects that the x-ray equipment at PH-Mint Hill will perform 1.317 procedures for every inpatient discharge and 0.395 procedures for every outpatient and ER visit based on the experience at PH-Matthews and PH-Huntersville. In Exhibit 20, Table 58, the applicant provides data for PH-Matthews and PH-Huntersville which shows that, during FY 2005, combined, these hospitals performed an average of 1.317 x-ray procedures for every inpatient discharge and 0.395 x-ray procedures for every outpatient and ER visit. In Year Three, the seven units of x-ray equipment are projected to perform an average of 11.1 procedures per unit per day [28,325 / 7 / 365 = 11.1]. The applicant adequately demonstrates that the projected number of the x-ray procedures to be performed at PH-Mint Hill is based on reasonable assumptions and that the seven proposed units of x-ray equipment are needed.

Other Equipment – Based on the list of equipment to be acquired provided in Exhibit 18 and the design schematic provided in Exhibit 16, the applicant also proposes to acquire the following equipment:

- 2 stress testing systems with treadmill
- echocardiography equipment (quantity not provided)
- 1 electroencephalograph (EEG) unit
- 3 electrocardiograph (ECG) units
- 1 pulmonary function testing system

The above equipment is needed to support the other services proposed to be provided at PH-Mint Hill, particularly the services provided by the ER.

In summary, the applicant adequately identified the population proposed to be served and adequately demonstrated the need for the proposed services, with the exception of acquiring a new CT

scanner. Therefore, the application is conforming to this criterion subject to the condition in Criterion (4) regarding the CT scanner.

(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

The applicant proposes to relocate the following beds and services to Mint Hill:

- 50 existing acute care beds from POH
- 5 existing shared ORs from POH
- 1 existing GI endoscopy room from PH-Matthews

Acute Care Beds – The applicant provides an Impact Analysis in Exhibit 20, in which it demonstrates that the needs of the patients currently served at POH will be adequately met following the relocation of 50 acute care beds, as discussed below. (See also Section III.8, pages 93-100, and Section III.9, pages 100-102.) Upon completion of this project and Project I.D. #F-7386-05, POH would be licensed for 14 acute care beds and TPH would be licensed for 539 acute care beds. The applicant assumes that TPH and POH would be operated as one hospital following completion of this project. Thus, upon completion of this project and Project I.D. #F-7386-05, the applicant assumes TPH would be licensed for 553 acute care beds [539 + 14 = 553]. On page 4 of the Impact Analysis provided in Exhibit 20, the applicant projects a total of 174,613 acute patient days of care will be provided at TPH during FY 2012 (operating Year Three at PH-Mint Hill), which is an ADC of 478.4 [174,613 / 365 = 478.4] and an occupancy rate of 86.5%. In Tables 70 & 72 in Exhibit 20, the applicant projects that utilization at TPH would increase at the same rate the population of the service area is projected to increase. Further, the applicant adjusted its utilization projections to account for the patients currently served by TPH and POH that are expected to use the proposed hospital in Mint Hill. See the Impact Analysis in Exhibit 20 for all of the applicant's assumptions and methodology used to project utilization for TPH.

The applicant adequately demonstrates that 553 acute care beds would be sufficient to meet the needs of the patients utilizing TPH.

Shared Operating Rooms – The applicant provides an Impact Analysis in Exhibit 20, in which it demonstrates that the needs of the patients currently served at POH will be adequately met following the relocation of five shared ORs, as discussed below. (See also Section III.8, pages 93-100, and Section III.9, pages 100-102.) Regarding the impact on POH of relocating 5 of its 12 shared ORs to PH-Mint Hill, in Exhibit 20, the applicant provides the following projected utilization for the ORs remaining at POH and TPH during the third operating year of PH-Mint Hill (FY 2012). The applicant provides the methodology and assumptions used to project surgical utilization at POH in the Impact Analysis in Exhibit 20, pages 33-34.

	TPH	POH	TPH & POH COMBINED
Current # of shared ORs [1]	26	12	38
# of Shared ORs to be relocated to PH-Mint Hill	0	5	5
# of shared ORs remaining at TPH & POH	26	7	33
Projected # of Surgical Cases in FY 2012	20,295	8,460	28,755
Average # of cases per room per day [2]	3.0	4.6	3.4

(1) TPH does not have any dedicated inpatient ORs other than three dedicated open-heart and three dedicated C-section ORs. POH does not have any dedicated inpatient ORs.

(2) Calculated by dividing the total number of surgical cases by 260 days per year and then dividing by the total number of ORs.

As shown in the table above, the applicant projects that the 33 shared ORs at TPH and POH combined will perform an average of 3.4 surgical cases per day per OR during the third operating year of PH-Mint Hill.

The following table illustrates the number of surgical cases performed in the shared ORs at TPH and POH during FY 2005, as reported in their 2006 Hospital License Renewal Applications.

	TPH	POH
# of shared ORs [1]	22	12
# of surgical cases performed in the shared ORs	20,340	7,633
Average # of cases per shared OR per day	3.6	2.4

(1) During the reporting period for the 2006 Hospital License Renewal Application (10/1/04 – 9/30/05), TPH was licensed for only 22 shared ORs.

As shown in the above table, during FY 2005, a total of 20,340 surgical cases were performed in the 22 shared ORs at TPH, which is an average of 3.6 cases per OR per day [20,340 / 260 / 22 = 3.6].

However, subsequent to the end of the reporting period for the 2006 Hospital License Renewal Application (10/1/04 – 9/30/05), TPH opened four additional shared ORs for a total of 26 shared ORs. Thus, assuming 20,340 surgical cases were performed in 26 shared ORs, the average number of cases per OR per day would be only 3.0, which is less than the minimum threshold of 3.2 cased per OR per day. Further, as shown in the above table, during FY 2005, a total of 7,633 surgical cases were performed in the 12 shared ORs at POH, which is an average of 2.4 cases per OR per day [7,633 / 260 / 12 = 2.4], which is also less than the minimum threshold of 3.2 cases per OR per day. Assuming TPH and POH were licensed as one hospital and five shared ORs are relocated to PH-Mint Hill, the average number of surgical cases per OR per day would be 3.26 [(20,340 + 7,633) / 260 / (26 +7) = 3.26] based on actual utilization in FY 2005. In fact, the average would be lower than this, given the number of patients who would use the proposed PH-Mint Hill rather than TPH or POH. The applicant demonstrated that 7 shared ORs would be sufficient to meet the needs of the patients that will continue to utilize POH and TPH for surgical services.

GI Endoscopy Room – In Section III.8(d), page 99, the applicant states

> *"PHM is aware that certain physicians in the Matthews community are seeking to add GI endoscopy capacity in their office settings and this will create additional local outpatient GI endoscopy capacity. In addition, PHM and its physicians are committed to expanding the hours of operation of its three remaining GI endoscopy rooms as required by demand and to preserve patient access and convenience."*

Regarding the impact on PH-Matthews of relocating one of its four GI endoscopy rooms to PH-Mint Hill, in Exhibit 20, the applicant provides the following projected utilization for the 3 GI endoscopy rooms remaining at PH-Matthews during the third operating year of PH-Mint Hill (FY 2012). The applicant provides the methodology and assumptions used to project GI endoscopy utilization at PH-Matthews in Exhibit 20, Tables 45-46.

	PH-MATTHEWS
Current # of GI endoscopy rooms	4
# of GI endoscopy rooms to be relocated to PH-Mint Hill	1
# of GI endoscopy rooms remaining at PH-Matthews	3
Projected # of GI endoscopy procedures in FY 2012	5,131
Average # of procedures per room per year [1]	1,710

[1] Calculated by dividing the total number of GI endoscopy procedures by the total number of GI endoscopy rooms.

As shown in the table above, the applicant projects that the three GI endoscopy rooms at PH-Matthews will perform an average of 1,710 GI endoscopy procedures per room during the third operating year of PH-Mint Hill. The following table illustrates the number of GI endoscopy procedures performed in the four rooms at PH-Matthews during FY 2005, as reported in its 2006 Hospital License Renewal Application.

	PH-MATTHEWS
# of GI endoscopy rooms	4
# of GI cases performed in the GI endoscopy rooms	5,195
Average # of procedures per room per year	1,299

As shown in the above table, during FY 2005, a total of 5,195 GI endoscopy procedures were performed in the 4 GI endoscopy rooms at PH-Matthews, which is an average of only 1,299 GI endoscopy procedures per room per year [5,195 / 4 = 1,298.75]. The applicant demonstrated that three GI endoscopy rooms would be sufficient to meet the needs of the patients that will continue to utilize PH-Matthews for GI endoscopy services.

In summary, the applicant adequately demonstrated that the needs of the population presently served would be adequately met following the proposed relocation of beds and services to Mint Hill. Therefore, the application is conforming to 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.

CA

In Section II.5, pages 25-30, the applicant discussed several alternatives it considered prior to submission of this application. The application is conforming, as conditioned, to all applicable

statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a), (20), the Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300, and the Criteria and Standards for Intensive Care Services promulgated in 10A NCAC 14C .1200. Therefore, the applicant adequately demonstrates that its proposal is an effective alternative and the application is conforming to this criterion subject to the following conditions.

1. **Presbyterian Hospital Mint Hill, LLC shall materially comply with all representations made in its certificate of need application, except as specifically amended by the conditions of approval.**

2. **Presbyterian Hospital Mint Hill, LLC shall not acquire a new CT scanner for the hospital, but instead shall relocate one of Novant Health, Inc.'s existing CT scanners currently located in Mecklenburg County to the new hospital.**

3. **Presbyterian Hospital Mint Hill shall be licensed for no more than 38 general acute care beds, 4 intensive care unit beds, 8 labor delivery recovery post partum beds, 10 unlicensed observation beds, 4 shared operating rooms, 1 gastrointestinal endoscopy procedure room and 1 dedicated C-section room.**

4. **Upon completion of the project, Presbyterian Hospital Mint Hill, LLC shall ensure that Novant Health, Inc. takes the steps necessary to amend the license of Presbyterian Hospital Matthews to delicense one gastrointestinal endoscopy procedure room at Presbyterian Hospital Matthews for a total of no more than three gastrointestinal endoscopy procedure rooms at Presbyterian Hospital Matthews.**

5. **Upon completion of the project, Presbyterian Hospital Mint Hill, LLC shall ensure that Novant Health, Inc. takes the steps necessary to amend the license of Presbyterian Orthopaedic Hospital to delicense five shared operating rooms at Presbyterian Orthopaedic Hospital for a total of no more than seven operating rooms at Presbyterian Orthopaedic Hospital.**

6. **Upon completion of the project, Presbyterian Hospital Mint Hill, LLC shall ensure that Novant Health, Inc. takes the steps necessary to amend the license of Presbyterian Orthopaedic Hospital to delicense 50 acute care beds at Presbyterian Orthopaedic Hospital for a total of no more than 14 acute care beds at Presbyterian Orthopaedic Hospital upon completion of this project and Project I.D. #F-7386-05 (relocate 76 acute care beds to Presbyterian Hospital).**

7. **Presbyterian Hospital Mint Hill, LLC shall not acquire, as part of this project, any equipment that is not included in the proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

8. **Presbyterian Hospital Mint Hill, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

(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.

CA

In Section VIII.1, page 155, the applicant projects that the total capital cost of the project will be $89,998,968, as illustrated below.

Site Costs		
Purchase Price of the Land	$2,580,000	
Site Preparation Costs	$3,540,545	
Subtotal Site Costs		**$6,120,545**
Construction Costs		
Construction Contract	$56,374,422	
Contingency	$400,000	
Subtotal Construction Costs		**$56,774,422**

Miscellaneous Costs		
Equipment	$17,250,000	
Furniture	$1,250,000	
Architect & Engineering Fees	$2,800,000	
Other Consultants	$250,000	
Financing Costs[4]	$3,169,804	
Contingency	$2,384,197	
Subtotal Miscellaneous Costs		**$27,104,001**
Total Capital Cost		**$89,998,968**

In Section IX, page 166, the applicant also projects that start up and initial operating expenses will be $8,591,699. In Section VIII.3, page 156, and Section IX, page 166, the applicant states that the capital and working capital needs of the project will be financed with the accumulated reserves of Novant. The audited financial statements for Novant are provided in Exhibit 9. As of December 31, 2005, Novant had $207,586,000 in cash and cash equivalents, $25,000,000 in short-term investments, $651,166,000 in long-term investments, $2,252,656,000 in total assets, and $1,268,873,000 in total net assets (total assets less total liabilities). Exhibit 9 contains a letter signed by the Chief Financial Officer for Novant, which states

> *"As the Chief Financial Officer for Novant Health, Inc., I have authority to obligate funds from accumulated reserves of Novant Health for projects undertaken by facilities in the Southern Piedmont Region. Novant Health, Inc. is the not-for-profit parent company of The Presbyterian Hospital and other inpatient and outpatient facilities in the Southern Piedmont Region. I am familiar with the CON application proposing the construction of a new 50-bed acute care hospital in Mint Hill, NC. I can and will commit Novant's reserves to cover all of the capital costs associated with this project, including the project capital cost, working capital, and start-up costs. Please see the line items in the Novant Health CY 2005 audited financial statements entitled 'Cash and Short-Term Equivalent,' 'Net Patient Services Accounts Receivable,' 'Other Current Assets,' and 'Long-Term Investments.' These balance sheet amounts are available to fund the proposed project. Novant Health, Inc. also had a Total Assets Balance of $2.2 Billion at the*

[4] The applicants project "Financing Costs" in the event they choose to pursue bond financing.

end of CY 2005.

In addition, Novant reserves the right to consider future funding of all or a portion of this project using bond proceeds. Novant financial staff will make this determination based on market and economic conditions at the time the capital is required. A letter from Citigroup Global Markets, Inc. indicating the appropriateness of this project for tax-exempt bond financing is also included as an Exhibit with our CON application.

Novant Health also has sufficient cash to cover the working capital needs for the proposed new hospital project in the amount specified in section IX of the CON application. Please see the Current Assets section of the Novant Health Balance Sheet contained in Novant Health's 2005 audited financial statements, which are included as an exhibit with our CON application."

Exhibit 9 also contains a letter signed by the Chief Executive Officer and President of Novant Health Southern Piedmont Region, LLC, which states

"The Southern Piedmont Region is committed to receiving the capital funds and working capital specified in the CON application for the above project from the reserves of its not-for-profit parent company, Novant Health, Inc. Upon receipt of those funds from Novant Health, Inc., we will use the funds to develop the above project.

In addition, we reserve the right to consider, in the future, funding all or part of this project using tax-exempt bond proceeds. Our financial staff will make this determination based on market and economic conditions at the time the capital is required. A letter from Citigroup Global Markets indicating the appropriateness of this project for tax exempt bond financing is also included as an exhibit with our CON application."

In addition, Exhibit 9 contains a letter signed by the Managing Director of Citigroup Global Markets, Inc., which states

"You have advised Citigroup Global Markets Inc.

('Citigroup') that Novant Health ('Novant') may finance the above-referenced Project from cash and accumulated reserves, through tax-exempt bond financing (the 'Bond Issue'), or through some combination thereof depending on market conditions at the time funding is required. The borrower would be Novant, a 501(c)(3) private not-for-profit corporation. The debt would be issued under the Novant Master Trust Indenture through the North Carolina Medical Care Commission. We understand that Novant Health, Inc. and Presbyterian Hospital Mint Hill will be applying for a Certificate of Need ('CON') on July 17, 2006. The CON will be for a new 50-bed Hospital with Acute, ICU, and Observation Beds, an Emergency Department, Operating and Endoscopy Rooms, Imaging, Laboratory, and Pharmacy; the proposed hospital will also deliver babies and have an obstetrical program. It is our understanding that the total cost of the project is estimated to be $85-105 million. For purposes of this letter, 'Citigroup' shall include Citigroup Global Markets Inc. and/or any affiliate thereof.

...

Based upon your financial strength, Citigroup would expect to offer a publicly sold tax-exempt bond issue that would either be insured or issued with Novant's stand-alone ratings. We believe that this funding would result in an investment grade rating for the financing."

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. However, it is not evident at this time which financial arrangement will be pursued and thus not certain if the applicant, Presbyterian Hospital Mint Hill, LLC, is the person that will be incurring the obligation for the proposed capital expenditure. Therefore, the applicant is conditioned to provide additional documentation that, Presbyterian Hospital Mint Hill, LLC, will be the person incurring the obligation for the proposed capital expenditure.

In the projected revenue and expense statement, the applicant projects that revenues will exceed operating costs at PH-Mint Hill in the second and third operating years. The assumptions used by the applicant in preparation of the pro formas are reasonable,

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In the projected revenue and expense statement, the applicant projects that revenues will exceed operating costs at PH-Mint Hill in the second and third operating years. The assumptions used by the applicant in preparation of the pro formas are reasonable,

including projected utilization. See the Financials Tab of the application for the pro formas and the assumptions and Criterion (3) for discussion of utilization projections. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion subject to the following condition.

Prior to issuance of the certificate of need, Presbyterian Hospital Mint Hill, LLC shall provide the Certificate of Need Section with documentation that Presbyterian Hospital Mint Hill, LLC is the person that will incur the obligation for the capital expenditure for this project.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

CA

The applicant adequately demonstrates the need for all of the services it proposes to provide in Mint Hill, with the exception of the acquisition of a new CT scanner. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposal, as conditioned, would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion subject to the condition in Criterion (4) regarding the CT scanner.

(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

In Section VII.2, pages 139-142, the applicant provides the projected staffing for PH-Mint Hill for the first three operating years. The applicant projects to employ a total of 265.6 full-time equivalent (FTE) positions in Year One, 295.9 FTE positions in Year Two and 329.3 FTE positions in Year Three. In Section VII.3, pages 144-146, the applicant states

> *"It is anticipated that Presbyterian Hospital Mint Hill staff will be new hires, except for those existing Presbyterian Healthcare personnel who may choose to apply for the Mint Hill positions when the jobs are posted. ... Presbyterian Healthcare uses its regional human resources personnel to recruit for these positions. ... Based on past experience The Presbyterian Hospital's COO, CNO, ED Director, Radiology Director, Pharmacy Director, and Surgical Services Director do not foresee any major difficulty or significant challenges in recruiting needed personnel for the new hospital, Presbyterian Hospital Mint Hill. In fact, during the past two years, TPH has had more new graduate applications than TPH has had positions to offer them."*

The applicant proposes 8.0 FTE management positions in the first three operating years. In Section VII.6, pages 148-149, the applicant states

> *"There will be a chief executive or administrator and a dedicated Director of Nursing on site, full-time at Presbyterian Hospital Mint Hill .... In addition, each clinical and non-clinical area at Presbyterian Hospital Mint Hill will have a dedicated on-site director, manager, or supervisor .... Other corporate support functions will be provided directly to Presbyterian Hospital Mint Hill by existing NHSPR regional corporate resources. Costs for these support services will be charged to Presbyterian Hospital Mint Hill as part of administrative overhead expense and are reflected in the pro forma income statements for Presbyterian Hospital Mint Hill. These services will include but not be limited to: finance functions such as billing, collections, payroll, accounts payable, general ledger, budget, and financial reporting; education and training; information technology services; marketing and public relations; strategic and business planning; legal affairs; materials management and purchasing; risk management; infection control; medical staff affairs and credentialing."*

In Section VII.6, page 149, the applicant states

"Presbyterian's existing acute care hospitals do contract with regional and national vendors for these services: Laundry; Food & Nutrition; Environmental Services; on-site Medical Laboratory and Reference Lab Services. Prior to the opening of Presbyterian Hospital Mint Hill, NHSPR corporate staff will negotiate with these vendors to extend these services to Presbyterian Hospital Mint Hill."

Exhibit 14 contains letters signed by the Vice President of Operations for TPH, which state that PH-Mint Hill will contract with TPH's existing vendors for laundry, dietary, housekeeping, and lab services. In Exhibits 5, 6, 7, 8, 11 and 19, the applicant provides letters from physicians who have agreed to act as medical directors for PH-Mint Hill. See also Section II.3, pages 23-24. In the pro formas, the applicant projects adequate operating expenses for the proposed staffing for the first three operating years. The applicant demonstrates the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to 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

In Section IV.5, pages 108-109; Section II.1, pages 17-21; and Section II.3, pages 23-24, the applicant describes the ancillary and support services that will be provided at PH-Mint Hill and the services available from Novant. Exhibit 10 contains a transfer agreement between TPH and PH-Mint Hill. Exhibit 10 also contains a list of the facilities with which TPH currently has transfer agreements and a sample agreement. Exhibit 11 contains letters from area physicians supporting the proposal to establish a new hospital in Mint Hill. The applicant adequately demonstrated that the necessary ancillary and support services would be available and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to 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

NA

(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

The applicant proposes to construct 199,024 square feet of new space to establish a new hospital in Mint Hill. In Exhibit 16, the architect certifies that the site preparation and construction costs are projected to be $60,314,967. In Section XI.7, pages 195-196, the applicant states that applicable energy savings features will be incorporated into the construction plans. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative for the proposed services, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. The application is conforming 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

The applicant provides the current payor mix for all services provided at TPH during CY 2005, as illustrated in the following table.

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS / PROCEDURES
Self Pay / Indigent / Charity	9.39%
Medicare	27.09%
Medicaid	17.73%
Commercial Insurance & Managed Care	23.57%
BCBS of NC	16.66%
State Employees Health Plan	2.71%
Other (other Government & Workers Comp.)	2.85%
TOTAL	100.00%

More than 78% of the patients that are projected to shift to PH-Mint Hill will come from TPH. See Exhibit 20, Table 69. The applicant demonstrated that medically underserved populations currently have adequate access to the services provided at TPH. Therefore, the application 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;

C

An examination of the licensure and certification files in the Division of Facility Services for the four existing Novant hospitals located in Mecklenburg County indicates there have been no civil rights access complaints filed against these hospitals within the last five years.

(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

In Section VI.2, page 126, the applicant states *"It is the policy of all the Novant Health Southern Piedmont Region (NHSPR) acute care hospitals (POH, TPH, PHM and PHH), including their Emergency Departments (where applicable), and Novant Health to provide necessary services to all individuals without regard to race, creed, color, or handicap. NHSPR acute care hospitals do not discriminate against ... medically underserved persons, regardless of their ability to pay."* The following table illustrates the projected payor mix for all of the services to be provided at PH-Mint Hill during Year Two, as reported in Section VI.12, page 136.

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS / PROCEDURES
Self Pay / Indigent / Charity	8.44%
Medicare	27.62%
Medicaid	20.16%
Commercial Insurance & Managed Care	22.49%
BCBS of NC	14.81%
State Employees Health Plan	3.18%
Other (other Government & Workers Comp.)	3.30%
TOTAL	100.00%

In the assumptions following the pro formas, the applicant states *"Payer mix for the proposed facility was based on the payer mix experience at Presbyterian Main Hospital for both inpatient, outpatient, and ED for patients living in the Mint Hill area."* The applicant demonstrated that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to 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

See Section VI.7 and referenced exhibits, for documentation of the range of means by which patients would have access to the services to be provided at PH-Mint Hill. The information provided 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

See Section V.1 and referenced exhibits for documentation that Novant hospitals in Mecklenburg County currently accommodate the clinical needs of health professional training programs in the area and that the proposed PH-Mint Hill will do the same. The information provided is reasonable and credible and supports a finding of conformity with 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.

CA

The applicant adequately demonstrates that the proposal, as conditioned, would have a positive impact upon the cost effectiveness, quality and access to the proposed services. See Criteria (1), (3), (3a), (5), (7), (8), (12), (13) and (20). Therefore, the application is conforming to this criterion subject to the condition in Criterion (4) regarding the CT scanner.

(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.

C

TPH, POH, PH-Matthews and PH-Huntersville are accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DFS, no incidents occurred at any of these facilities, 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.

CA

The application is conforming, as conditioned, to all applicable Criteria and Standards for Intensive Care Services promulgated in 10A NCAC 14C .1200. Further, the application is conforming, as conditioned, to all applicable Criteria and Standards for Computed Tomography Equipment, as promulgated in 10A NCAC 14C .2300. The specific criteria are discussed below.

The applicant does not propose to acquire any major medical equipment, as defined in N.C. Gen. Stat. §131E-176(14f), other than the CT scanner. Therefore, the Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100 are not applicable to this review. Further, the applicant proposes to relocate existing ORs, not increase the total number of licensed ORs located in Mecklenburg County. Therefore, the Criteria and Standards for Surgical Services and Operation Rooms promulgated in 10A NCAC 14C .2100 are not applicable to this review. In addition, the applicant does not propose to increase the total number of licensed GI endoscopy rooms in Mecklenburg County. Therefore, the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3900 are not applicable to this review.

SECTION .1200 CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

.1202 INFORMATION REQUIRED OF APPLICANT

.1202(a) This rule states *"An applicant that proposes new or expanded intensive care services shall use the Acute Care Facility/Medical Equipment application form."*

-C- The applicant proposes new or expanded intensive care services. The applicant used the Acute Care Facility/Medical Equipment application form.

.1202(b)(1) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional 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- The applicant proposes to relocate four general acute care beds from POH and convert them to four ICU beds at PH-Mint Hill. Novant owns both facilities through one of its wholly owned subsidiaries. In Exhibit 6, page 2, the applicant provides a table illustrating the current and proposed number of ICU beds at TPH, POH, PH-Matthews and PH-Huntersville. POH is not currently licensed for any intensive care beds and PH-Mint Hill will be licensed for four ICU beds. Thus, the proposal results in the development of new or expanded intensive care services.

.1202(b)(2)(A) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (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."*

-C- In Exhibit 6, page 3, the applicant provides the number of ICU days of care provided during CY 2005 at TPH (excluding NICU, PICU and Neuro), PH-Matthews and PH-Huntersville. POH is not licensed for any ICU beds, and thus, did not provide any ICU patient days during CY 2005. In its 2006 Hospital License Renewal Application, TPH reports that it provided 13,407 days of care in its NICU unit, 814 days of care in its PICU unit and 1,527 days of care in its Neuro unit during FY 2005.

.1202(b)(2)(B) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (2) documentation of the applicant's experience in treating patients at the facility during the past*

twelve months, including: ... (B) the number of patients initially treated at the facility and referred to other facilities for intensive care services."

-C- In Exhibit 6, page 3, the applicant states *"There is no data available on the number of patients initially treated at PHS Intensive Care Units during CY 2005 and referred to other facilities for intensive care services. However, TPH ICU Nursing Management estimates that such transfers have occurred at the rate of about one patient per week or approximately 52 patients per year."*

.1202(b)(2)(C) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including: ... (C) the number of patients initially treated at other facilities and referred to the applicant's facility for intensive care services."*

-C- In Exhibit 6, page 3, the applicant states *"There is no data available on the number of patients initially treated at other facilities and referred to PHS Intensive Care Units during CY 2005. However, TPH ICU Nursing Management estimates that such transfers have occurred at the rate of about one patient every other week or approximately 26 patients per year."*

.1202(b)(3) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ...(3) the number of patients from the proposed service area who are projected to require intensive care services by the patients' county of residence in each of the first 12 quarters of operation, including all assumptions and methodologies."*

-C- In Exhibit 6, page 4, and Exhibit 20, Table 23, the applicant provided the number of patients from the proposed service area who are projected to require intensive care services by the patients' county of residence in each of the first 12 quarters of operation. The applicant's assumptions and methodologies are provided in Section III.1(b), page 60, and Exhibit 20, Table 23.

.1202(b)(4) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (4) 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- The four ICU beds at PH-Mint Hill will be general med/surg ICU beds. The applicant provided the projected number of patients to be served and inpatient days of care to be provided in the four general med/surg ICU beds at PH-Mint Hill during the first twelve quarters of operation in Exhibit 6, page 4, and Exhibit 20, Table 23. The applicant's assumptions and methodologies are provided in Section III.1(b), page 60, and Exhibit 20, Table 23.

.1202(b)(5) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (5) data from actual referral sources or correspondence from the proposed referral sources documenting their intent to refer patients to the applicant's facility."*

-C- In Exhibit 6, page 6, the applicant states *"See Exhibit 11 for copies of letters from referring physicians."* Exhibit 11 contains letters from physicians that document their intent to refer patients to PH-Mint Hill.

.1202(b)(6) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (6) documentation which demonstrates the applicant's capability to communicate effectively with emergency transportation agencies."*

-C- In Exhibit 6, the applicant provides a letter signed by the Director of Emergency Services for TPH, which states that TPH has the ability to communicate effectively with emergency transportation agencies. He also states *"I can also confirm that ... the new emergency department at Presbyterian Hospital Mint Hill ... will have the same ability."*

.1202(b)(7)(A) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (7) documentation of written policies and procedures regarding the provision of care within the intensive care unit, which includes, but is not limited to the following: (A) the admission and discharge of patients; (B) infection control; (C) safety procedures; and (D) scope of service."*

-C- Exhibit 6 contains copies of the applicant's policies and procedures for provision of care in the ICU addressing each item in this rule.

.1202(b)(8) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (8) 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 6 and Exhibit 16 contain the design schematics for the proposed ICU, which show that the ICU will be operated as a physically and functionally distinct entity in a separate area with controlled access.

.1202(b)(9) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (9) 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 6 contains a letter signed by the Corporate Director of Facilities Planning and Construction for Novant's Southern Piedmont Region, which states that the physical environment of the ICU at PH-Mint Hill will conform to federal, state and local regulations.

.1202(b)(10) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (10) a detailed floor plan of the proposed area drawn to scale."*

.1202(b)(7)(A) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (7) documentation of written policies and procedures regarding the provision of care within the intensive care unit, which includes, but is not limited to the following: (A) the admission and discharge of patients; (B) infection control; (C) safety procedures; and (D) scope of service."*

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-C- Exhibit 6 contains a letter signed by the Corporate Director of Facilities Planning and Construction for Novant's Southern Piedmont Region, which states that the physical environment of the ICU at PH-Mint Hill will conform to federal, state and local regulations.

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-C- Exhibit 6 contains a letter signed by the Corporate Director of Facilities Planning and Construction for Novant's Southern Piedmont Region, which states that the physical environment of the ICU at PH-Mint Hill will conform to federal, state and local regulations.

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-C- Exhibit 6 and Exhibit 16 contain the design schematics for the proposed ICU, which show that the ICU will be operated as a physically and functionally distinct entity in a separate area with controlled access.

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-C- Exhibit 6 contains a letter signed by the Corporate Director of Facilities Planning and Construction for Novant's Southern Piedmont Region, which states that the physical environment of the ICU at PH-Mint Hill will conform to federal, state and local regulations.

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-C- Exhibit 6 and Exhibit 16 contain the design schematics for the proposed ICU, which show that the ICU will be operated as a physically and functionally distinct entity in a separate area with controlled access.

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-C- Exhibit 6 contains a letter signed by the Corporate Director of Facilities Planning and Construction for Novant's Southern Piedmont Region, which states that the physical environment of the ICU at PH-Mint Hill will conform to federal, state and local regulations.

.1202(b)(10) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (10) a detailed floor plan of the proposed area drawn to scale."*

-C- See Exhibits 6 and 16 for design schematics of the proposed ICU.

.1202(b)(11) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (11) documentation of a means for observation by unit staff of all patients in the unit from at least one vantage point."*

-C- See Exhibits 6 and 16 for design schematics of the proposed ICU.

.1203 PERFORMANCE STANDARDS

.1203(a)(1) This rule states *"The applicant shall demonstrate that the proposed project is capable of meeting the following standards: (a) (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."*

-NA- PH-Mint Hill does not yet exist, and therefore, has no ICU beds. Four existing general med/surg beds will be relocated from POH, which also does not have any ICU beds.

.1203(a)(2) This rule states *"The applicant shall demonstrate that the proposed project is capable of meeting the following standards: (a) ... (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."*

-C- In Exhibit 6, page 8, Section III.1(b), page 60, Section IV.1(c), page 104, and Exhibit 20, Table 23, the applicant projects that it will provide a total of 1,092 patient days of care in the four

ICU beds which is an occupancy rate of 74.8% [365 x 4 = 1,460; 1,092 / 1,460 = 0.748].

.1203(b) This rule states *"All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided."*

-C- The applicant's assumptions and data supporting the methodology used to project utilization are provided in Section III.1(b), page 60, and Exhibit 20, Table 23. See Criterion (3) for additional discussion.

.1204 SUPPORT SERVICES

.1204(a) This rule states *"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 ventilatory/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 6 contains a letter from the Vice President of Growth and Development for Novant's Southern Piedmont Region, which states *"I am responsible for the development of all clinical, ancillary and support services to be provided at the proposed Presbyterian Hospital Mint Hill."* He also states that

ICU beds which is an occupancy rate of 74.8% [365 x 4 = 1,460; 1,092 / 1,460 = 0.748].

.1203(b) This rule states *"All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided."*

-C- The applicant's assumptions and data supporting the methodology used to project utilization are provided in Section III.1(b), page 60, and Exhibit 20, Table 23. See Criterion (3) for additional discussion.

.1204 SUPPORT SERVICES

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(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 ventilatory/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 6 contains a letter from the Vice President of Growth and Development for Novant's Southern Piedmont Region, which states *"I am responsible for the development of all clinical, ancillary and support services to be provided at the proposed Presbyterian Hospital Mint Hill."* He also states that

all of the services listed in this rule will be provided at the proposed PH-Mint Hill.

.1204(b) This rule states *"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."*

-NA- All of the services listed in this rule will be available at the proposed PH-Mint Hill.

.1205 STAFFING AND STAFF TRAINING

.1205(1) This rule states *"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."*

-CA- Exhibit 6 contains a letter from the Vice President of Growth and Development for Novant's Southern Piedmont Region, which states *"I am responsible for the development of all clinical, ancillary and support services to be provided at the proposed Presbyterian Hospital Mint Hill."* He also states *"The nursing care in the ICU at Presbyterian Hospital Mint Hill will be provided by qualified RNs with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support."* However, the letter does not state that the nursing care in the ICU will be supervised by a qualified RN with those skills as required by this rule. Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Presbyterian Hospital Mint Hill, LLC shall provide documentation that the nursing care in the ICU will be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring and life support.

.1205(2) This rule states *"The applicant shall demonstrate the ability to meet the following staffing requirements: ... (2) direction of the*

unit shall be provided by a physician with training, experience and expertise in critical care."

-C- Exhibits 6 and 11 contain a letter signed by Arthur Patefield, MD, which states that he is currently the medical director for the ICU at TPH and has agreed to serve as medical director for the proposed ICU at PH-Mint Hill. Exhibit 6 also contains Dr. Patefield's curriculum vitae that documents he has training, experience and expertise in critical care.

.1205(3) This rule states *"The applicant shall demonstrate the ability to meet the following staffing requirements: ... (3) assurance from the medical staff that twenty-four hour medical and surgical on-call coverage is available."*

-C- Exhibit 6 contains a letter from the Executive Vice President for Medical Staff Affairs for Novant's Southern Piedmont Region, which states that hospitalist physicians will provide 24-hour medical and surgical on-call coverage at PH-Mint Hill as they do for the other Novant hospitals.

.1205(4) This rule states *"The applicant shall demonstrate the ability to meet the following staffing requirements: ... (4) inservice training or continuing education programs shall be provided for the intensive care staff."*

-C- Exhibit 6 contains documentation that PH-Mint Hill will provide inservice training and continuing education for the ICU staff.

SECTION .2300 CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY SCANNERS

.2302 INFORMATION REQUIRED OF APPLICANT

.2302(a) This rule states *"An applicant proposing to acquire a CT scanner shall use the acute care facility/medical equipment application form."*

-C- The applicant used the acute care facility/medical equipment application form.

.2302(b) This rule states *"An applicant proposing to acquire a CT scanner shall provide the number of CT scans that have been performed on its existing CT scanners 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."

-CA- In Exhibit 7, page 2, the applicant states *"Not applicable. PHMH does not own an existing CT scanner."* However, in Section I.13(a), page 15, the applicant states that Novant owns the following CT scanners located in Mecklenburg County. Therefore, the rule is applicable to Novant's existing CT scanners.

FACILITY	# OF EXISTING CT SCANNERS
The Presbyterian Hospital	6
Presbyterian Imaging Center – Randolph	1
Presbyterian Hospital – Matthews [1]	1
Presbyterian Hospital – Huntersville	1
Presbyterian Orthopaedic Hospital	1
Total	10

[1] Effective September 29, 2006, a certificate of need was issued to PH-Matthews to acquire a second CT scanner, which was after this application was submitted.

However, the applicant did not provide the number of CT scans performed on the CT scanners listed in the table above by the types of CT scans listed in this rule for the previous 12-month period. Therefore, the applicant is conditioned not to acquire a new CT scanner but to relocate an existing CT scanner to PH-Mint Hill. See Criterion (4) for condition.

.2302(c) This rule states *"The applicant shall project the number of CT scans to be performed on the new CT scanner for each type of CT scan listed in this Paragraph for the first 12 quarters 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 Exhibit 7, page 3, the applicant provides the projected number of scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule for the first 12 quarters of operation of the proposed scanner.

.2302(d) This rule states *"The applicant shall convert the historical and projected number of CT scans to HECT units as follows:*

FACILITY	# OF EXISTING CT SCANNERS
The Presbyterian Hospital	6
Presbyterian Imaging Center – Randolph	1
Presbyterian Hospital – Matthews [1]	1
Presbyterian Hospital – Huntersville	1
Presbyterian Orthopaedic Hospital	1
Total	10

[1] Effective September 29, 2006, a certificate of need was issued to PH-Matthews to acquire a second CT scanner, which was after this application was submitted.

However, the applicant did not provide the number of CT scans performed on the CT scanners listed in the table above by the types of CT scans listed in this rule for the previous 12-month period. Therefore, the applicant is conditioned not to acquire a new CT scanner but to relocate an existing CT scanner to PH-Mint Hill. See Criterion (4) for condition.

.2302(c) This rule states *"The applicant shall project the number of CT scans to be performed on the new CT scanner for each type of CT scan listed in this Paragraph for the first 12 quarters 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 Exhibit 7, page 3, the applicant provides the projected number of scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule for the first 12 quarters of operation of the proposed scanner.

.2302(d) This rule states *"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 plus body scan HECTs	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00 plus body scan HECTs	=	

-CA- In Exhibit 7, page 4, the applicant converted the projected number of CT scans to be performed on the proposed CT scanner to HECT units as required by this rule. However, the applicant did not provide the historical number of CT scans performed on the existing CT scanners owned by Novant located in Mecklenburg County by the types of CT scans listed in 10A NCAC 14C .2302(b), and did not convert them to HECT units. Therefore, the applicant is conditioned not to acquire a new CT scanner but to relocate an existing CT scanner to PH-Mint Hill. See Criterion (4) for condition.

.2302(e) This rule states *"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- The applicant does not propose to acquire a mobile CT scanner.

.2302(f) This rule states *"The applicant shall provide all projected direct and indirect operating costs and all projected revenues for the provision of CT services for the first 12 quarters the new CT scanner is proposed to be operated."*

-C- In Exhibit 7, page 5, the applicant provides the projected direct and indirect operating costs and revenues during the first 12 quarters for the proposed CT scanner to be located at PH-Mint Hill.

.2302(g) This rule states *"The applicant shall provide projected costs and projected charges by CPT code for the first 12 quarters the new CT scanner is proposed to be operated."*

-C- In Exhibit 7, page 5, the applicant provides the total operating costs for the proposed CT scanner for the first 12 operating quarters. Operating costs are assumed to not vary by CPT code. In Section X.2(a)(3), page 177, the applicant provides the projected charges by CPT code for the first 12 operating quarters, as required by this rule.

.2302(h) This rule states *"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% over its current charge per CPT code on the mobile CT scanner."*

-NA- The applicant has not been utilizing a mobile CT scanner.

.2302(i) This rule states *"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- The applicant does not propose to acquire a mobile CT scanner.

.2302(j) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it has a written commitment from the radiology group of a hospital that it will accept CT readings from the applicant."*

-C- In Exhibit 7, the applicant provides a letter signed by the CEO of Mecklenburg Radiology Associates, which states *"As the CEO of Mecklenburg Radiology Associates (MRA) in Charlotte, North Carolina, I am pleased to commit the services of my group to Presbyterian Hospital Mint Hill. ... MRA Radiologists can and will staff and provide ... computed tomography services."* Mecklenburg Radiology Associates currently provides professional services at all Novant facilities in Mecklenburg County.

.2302(k) This rule states *"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 Exhibit 7, the applicant provide a letter signed by the Director of Radiology Services for TPH, which states *"I can attest that the new CT scanner at Presbyterian Hospital Mint Hill will be ... available and staffed for performing CT scan procedures for at least 66 hours per week."*

.2303 REQUIRED PERFORMANCE STANDARDS

.2303(1) This rule states *"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."*

-C- In Exhibit 7, page 7, the applicant projects that the proposed CT scanner to be located at PH-Mint Hill would perform 23,827 HECT units in the third year of operation following completion of the project.

.2303(2) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (2) each existing fixed CT scanner 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."*

-CA- Pursuant to 10A NCAC 14C .2301(4), *"'Computed tomography (CT) service area' means a geographical area defined by the applicant, which has boundaries that are not farther than 40 road miles from the facility."* In Exhibit 7, page 8, the applicant states that the proposed CT scanner service area consists of the following zip codes:

Zip Code	County	City
Primary Service Area		
28215	Mecklenburg	Charlotte
28213	Mecklenburg	Charlotte
28227	Mecklenburg	Mint Hill
28107	Cabarrus	Midland
28075	Cabarrus	Harrisburg
In-migration		
28262	Mecklenburg	Charlotte
28206	Mecklenburg	Charlotte
28205	Mecklenburg	Charlotte
28212	Mecklenburg	Charlotte
28105	Mecklenburg	Charlotte
28204	Mecklenburg	Charlotte
28207	Mecklenburg	Charlotte
28211	Mecklenburg	Charlotte
28270	Mecklenburg	Charlotte
28104	Mecklenburg and Union	Matthews
28079	Union	Indian Trail
28110	Union	Monroe
28097	Stanly	Locust
28163	Stanly	Stanfield
28025	Cabarrus	Concord
28027	Cabarrus	Concord

Further, the applicant states that all of these zip codes are *"within a 40 mile driving distance"* of the proposed PH-Mint Hill. In Exhibit 7, page 9, the applicant identifies the following existing CT scanners as the only ones located in these zip codes and provides the number of scans performed during the 12 month period prior to submission of the application as illustrated in the following table.

Zip Code	County	City
Primary Service Area		
28215	Mecklenburg	Charlotte
28213	Mecklenburg	Charlotte
28227	Mecklenburg	Mint Hill
28107	Cabarrus	Midland
28075	Cabarrus	Harrisburg
In-migration		
28262	Mecklenburg	Charlotte
28206	Mecklenburg	Charlotte
28205	Mecklenburg	Charlotte
28212	Mecklenburg	Charlotte
28105	Mecklenburg	Charlotte
28204	Mecklenburg	Charlotte
28207	Mecklenburg	Charlotte
28211	Mecklenburg	Charlotte
28270	Mecklenburg	Charlotte
28104	Mecklenburg and Union	Matthews
28079	Union	Indian Trail
28110	Union	Monroe
28097	Stanly	Locust
28163	Stanly	Stanfield
28025	Cabarrus	Concord
28027	Cabarrus	Concord

Further, the applicant states that all of these zip codes are *"within a 40 mile driving distance"* of the proposed PH-Mint Hill. In Exhibit 7, page 9, the applicant identifies the following existing CT scanners as the only ones located in these zip codes and provides the number of scans performed during the 12 month period prior to submission of the application as illustrated in the following table.

FACILITY	COUNTY	ZIP CODE	TOTAL # OF SCANNERS	# OF SCANS PERFORMED IN THE 12 MONTH PERIOD PRIOR TO SUBMISSION OF THE APPLICATION [1]	AVERAGE # OF SCANS PER CT SCANNER
Cabarrus Diagnostic Imaging	Cabarrus	28025	1	NA	NA
Northeast Urology Associates	Cabarrus	28025	1	NA	NA
Northeast OP Imaging Ctr – Copperfield	Cabarrus	28025	2	NA	NA
Northeast Medical Center	Cabarrus	28025	4	50,842	12,710.5
Presbyterian Hospital – Matthews [2]	Mecklenburg	28105	1	22,679	22,679.0
Carolinas Imaging Services – Matthews	Mecklenburg	28105	1	NA	NA
Carolinas Cancer Center, PA	Mecklenburg	28105	1	NA	NA
University Radiation Oncology Center	Mecklenburg	28262	1	NA	NA
CMC University	Mecklenburg	28262	2	16,778	8,389.0
Presbyterian Medical Plaza	Mecklenburg	28262	1	5,331	5,331.0

(1) With the exception of Presbyterian Medical Plaza, which is owned by a subsidiary of Novant, the applicant notes that utilization data is available only for hospitals from hospital license renewal application forms on file with the Division of Facility Services. Further, the applicant notes that hospitals report only the total number of CT scans, not the types of CT scans. Thus, the number of HECT units cannot be determined from the data available.

(2) Effective September 29, 2006, a certificate of need was issued to PH-Matthews to acquire a second CT scanner.

However, the applicant did not include in the above table, the following existing CT scanners, which are also located in the proposed CT service area. The applicant also did not provide the number of scans or HECT units performed on these CT scanners during the 12 month period prior to submission of the application. Consequently, the following information was obtained from 2006 Hospital License Renewal Applications.

FACILITY	ZIP CODE	TOTAL # OF SCANNERS	# SCANS PROJECTED TO BE PERFORMED DURING FY 2011	AVERAGE # OF SCANS PER CT SCANNER
TPH	28204	6	41,924	6,987.33
POH	28207	1	2,951	2,951.00
CMC – Mercy/Pineville	28207	3	28,275	9,425.00

Source: 2006 Hospital License Renewal Applications.

As shown in the above table, the one existing CT scanner at POH performed only 2,951 CT scans. The hospital license renewal application form does not request the information necessary to convert the number of scans to HECT units. However, in Exhibit 7, page 11, the applicant states that it assumes a conversion factor of 1.6 HECT units for every scan, which would be only 4,721.6 HECT units performed at POH. Therefore, the applicant is conditioned not to acquire a new CT scanner but to relocate an existing CT scanner to PH-Mint Hill. See Criterion (4) for condition.

.2303(3) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (3) each existing and approved fixed CT scanner 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."*

-CA- In Exhibit 7, page 10, and Exhibit 20, Table 65, the applicant provides projected utilization through FY 2011 for the existing CT scanners for which utilization data was available that it identified in response to 10A NCAC 14C .2303(2). In Exhibit 7, page 10, the applicant states that it assumed that utilization would increase at the *"average projected Charlotte SMA population growth rate"* between 2005 and 2011, which is 2.01% per year. According to Table 65 in Exhibit 20, the Charlotte SMA includes Mecklenburg, Gaston, Union, Cabarrus, Lincoln, Iredell and Stanly counties. The applicant's projections are illustrated in the following table.

FACILITY	TOTAL # OF SCANNERS	# SCANS PROJECTED TO BE PERFORMED DURING FY 2011	AVERAGE # OF SCANS PER CT SCANNER
Northeast Medical Center	4	57,304	14,326.0
Presbyterian Hospital – Matthews [1]	2	25,562	12,781.0
CMC University	2	18,911	9,455.5
Presbyterian Medical Plaza	1	6,009	6,009.0

[1] Effective September 29, 2006, a certificate of need was issued to PH-Matthews to acquire a second CT scanner, which is expected to begin operations January 31, 2008, which is before PH-Mint Hill is expected to begin offering services. The second CT scanner at PH-Matthews is neither an "approved CT scanner" as that term is defined in 10A NCAC 14C .2301(1) nor an "existing CT scanner" as that term is defined in 10A NCAC 14C .2301(6).

As shown in the above table, the applicant projects that each of the existing CT scanners it identified in response to 10A NCAC 14C .2303(2) would perform an average of at least 5,100 scans during FY 2011.

However, the applicant did not provide projected utilization for the following existing CT scanners, which are also located in the proposed service area, as required by this rule.

FACILITY	ZIP CODE	TOTAL # OF SCANNERS
TPH	28204	6
POH	28207	1
CMC – Mercy/Pineville	28207	3

Source: 2006 Hospital License Renewal Applications.

Therefore, the applicant is conditioned not to acquire a new CT scanner but to relocate an existing CT scanner to PH-Mint Hill. See Criterion (4) for condition.

.2303(4) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (4) each existing mobile CT scanner in the proposed CT service area performed at least an average of 20 HECT units per day per site in the CT scanner service area in the 12 months prior to submittal of the application."*

-C- In Exhibit 7, page 11, the applicant states *"The only mobile CT scanner in use in the surrounding area of which the applicant is aware is at PHM and is on site seven days each week. The mobile CT unit at PHM has performed an average of 50 scans per day and 76 HECT units. The applicant is not aware of any other mobile CT scanners in the service area."*

.2303(5) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (5) each existing and approved mobile CT scanner shall perform at least an average of 20 HECT units per day per site in the CT scanner service area in the third year of operation of the proposed equipment."*

-NA- In Exhibit 7, page 12, the applicant states *"PHM currently hosts a mobile CT scanner seven days a week. The contract with PHM's mobile vendor expires January 2007; however, PHM intends to extend its contract on a month to month basis at current utilization rates exceeding 20 HECT units per day until the CON application for a second fixed CT scanner at PHM is approved and the equipment is operational. PHM understands that InSight will remove the mobile CT scanner from the PHM CT service area at that time."* Effective September 29, 2006, a certificate of need was issued to PH-Matthews to acquire a second CT scanner.

That scanner is expected to begin operations January 31, 2008, which is before this project is expected to be complete. The applicant assumes PH-Matthews will have two fixed CT scanners during the first three operating years of PH-Mint Hill, and no mobile CT scanners. The applicant is not aware of any other existing mobile CT scanners in the service area.

.2304 REQUIRED SUPPORT SERVICES

.2304(a) This rule states *"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- In Exhibit 7, page 12, the applicant states that all of the services listed above will be available at PH-Mint Hill. See also, Section II.1, page 20. Exhibit 7 also contains a letter signed by the CEO of Mecklenburg Radiology Associates, which states that x-ray; fluoroscopy; ultrasound; mammography; nuclear medicine; computed tomography; and mobile MRI services, pursuant to a service agreement with an existing provider, will be available at PH-Mint Hill.

.2304(b) This rule states *"An applicant proposing to acquire a CT scanner shall document the availability of services through written affiliation or referral agreements to treat patients with the following conditions:*

(1) neurological conditions;
(2) thoracic conditions;
(3) cardiac conditions;
(4) abdominal conditions;
(5) medical oncological conditions;
(6) radiological oncological conditions;
(7) gynecological conditions;
(8) neurosurgical conditions; and
(9) genitourinary and urogenital conditions."

-C- In Exhibit 7, page 13, the applicant provides a letter signed by the Vice President of Growth and Development for Presbyterian Healthcare, which states *"All of these services*

will be available for patients of Presbyterian Hospital Mint Hill." In Section VII.6(d), page 150, the applicant states *"Physicians who already have privileges at existing Presbyterian Healthcare acute care facilities in Mecklenburg County will be able to seek site specific medical staff privileges to practice at Presbyterian Hospital Mint Hill and it is expected that many will do so under the unified medical staff credentialing process that is administered by the Presbyterian Hospital Office of Medical Staff services."* In Section VII.10, page 153, the applicant lists the 913 physicians on the active staff at TPH, POH, PH-Matthews and PH-Huntersville. There is one or more specialties represented for all of the conditions listed in this rule.

.2304(c) This rule states *"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- The applicant does not propose to acquire a mobile CT scanner.

.2305 REQUIRED STAFFING AND STAFF TRAINING

.2305(a)(1) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements:*
(1) one board certified radiologist who 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 qualified diagnostic radiologist; or
(C) at least six months of fellowship training, or its equivalent, in CT; or

(D) an appropriate combination of CT experience and fellowship training equivalent to Parts (a)(1) (A), (B), or (C) of this Rule."

-C- In Exhibit 7, page 13, the applicant states that Dr. Steven Genkins has agreed to serve as medical director for CT services at PH-Mint Hill. Exhibit 7 also contains Dr. Genkins's resume, which indicates that he is a board-certified radiologist, a member of Mecklenburg Radiology Associates and meets all of the above requirements. In Exhibits 7, the applicant provides a letter signed by the CEO of Mecklenburg Radiology Associates, which states *"As the CEO of Mecklenburg Radiology Associates (MRA) in Charlotte, North Carolina, I am pleased to commit the services of my group to Presbyterian Hospital Mint Hill. ... MRA Radiologists can and will staff and provide ... computed tomography services."* Mecklenburg Radiology Associates currently provides professional services at all Novant facilities in Mecklenburg County.

.2305(a)(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements: ... (2) at least one radiology technologist registered by the American Society of Radiologic Technologists shall be present during the hours of operation of the CT unit."*

-C- In Section VII.2, page 141, the applicant projects that it will employ 4.8 FTE CT technologist positions in Year One, 6.2 FTE CT technologist positions in Year Two and 7.6 FTE CT technologist positions in Year Three at PH-Mint Hill. In Exhibit 7, the applicant provides a letter signed by the Director of Radiology for TPH, which states *"the new CT scanner at Presbyterian Hospital Mint Hill will be ... staffed by at least one radiology technologist who will be registered by the American Society of Radiologic Technologists and who will be present during all hours when the CT scanner is in operation at FMC-Kernersville* [sic]." (Note: the rest of the Director's letter correctly refers to PH-Mint Hill, not FMC-Kernersville.)

.2305(a)(3) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements: ... (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- Exhibit 7 contains a letter signed by the Radiation Safety Officer for TPH, which states that he is a radiation physicist with training in medical physics and *"24 years of experience."* He is currently employed by TPH to provide such things as annual equipment evaluations, CT dose profiles and consultative medical physics services. He states he will be *"available for consultation for the calibration and maintenance of the proposed CT scanner."*

.2305(b) This rule states *"The applicant shall provide documentation that the diagnostic radiologist has completed CT training in head, spine, body and musculoskeletal imaging."*

-C- Exhibit 7 contains a copy of Dr. Genkins' resume, which indicates that he is a board-certified radiologist, a member of Mecklenburg Radiology Associates, and has experience interpreting CT scans in the required areas. Dr. Genkins also states that he currently serves as medical director for CT services at TPH.

.2305(c)(1) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided: (1) certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support."*

-C- In Exhibit 7, the applicants provide a letter signed by the Director of Radiology Services at TPH, which states *"the new CT scanner at Presbyterian Hospital Mint Hill will be ...staffed by personnel who are trained and certified in cardiopulmonary resuscitation (CPR) and basic cardiac life support and who participate in Presbyterian Hospital's organized program of staff education and training, which is integral to the CT scanner program and ensures improvements in technique and the proper training of new CT scanner personnel."* In Section VII.6(b), page 149, the

applicant states that education and training will be provided at PH-Mint Hill through the corporate office.

.2305(c)(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided: ... (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 Exhibit 7, the applicants provide a letter signed by the Director of Radiology Services at TPH, which states *"the new CT scanner at Presbyterian Hospital Mint Hill will be ...staffed by personnel who are trained and certified in cardiopulmonary resuscitation (CPR) and basic cardiac life support and who participate in Presbyterian Hospital's organized program of staff education and training, which is integral to the CT scanner program and ensures improvements in technique and the proper training of new CT scanner personnel."* In Section VII.6(b), page 149, the applicant states that education and training will be provided at PH-Mint Hill through the corporate office.

.2305(d) This rule states *"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- The applicant does not propose to acquire a mobile CT scanner.

ATTACHMENT 1

Immigration 10%
Pages 24-25
CT Scanner
Immigration
Pages 56, 112-119

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: December 23, 2008

TEAM LEADER: Martha J. Frisone
CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBER: **Project I.D. #G-8165-08/** Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc./ Develop a 50-bed satellite campus in Clemmons by relocating 40 existing acute care beds from Forsyth Medical Center and 10 existing acute care beds and 5 existing operating rooms from Medical Park Hospital/ Forsyth 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.

C

Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center (**FMC**) and Novant Health, Inc. (**Novant**) propose to develop a 50-bed satellite campus in Clemmons (**FMC-Clemmons**) by relocating 40 existing acute care beds from FMC and 10 existing acute care beds and 5 existing operating rooms from MPH. The applicants also propose to develop one new gastrointestinal (GI) endoscopy room in Clemmons. The applicants state FMC-Clemmons will be licensed as part of FMC. The proposal does not result in an increase in the number of general acute care beds or ORs located in Forsyth County. The proposal does result in the development of one additional GI endoscopy room to be located in

Forsyth County. However, the 2008 SMFP does not include a methodology or need determinations for GI endoscopy rooms. Further, the applicants do not propose to acquire any medical equipment for which there is a need determination in the 2008 SMFP. Therefore, there are no need determinations in the 2008 SMFP applicable to the review of the proposed project.

However, because the applicants propose to construct space to replace 50 existing acute care beds, Policy AC-5 is applicable to the review. POLICY AC-5: REPLACEMENT OF ACUTE CARE BED CAPACITY states

> *"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to the utilization targets found below. In determining utilization of acute care beds, only acute care bed 'days of care' shall be counted. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application.*

Facility Average Daily Census	*Target Occupancy of Licensed Acute Care Beds (Percent)*
1 – 99	*66.7%*
100 – 200	*71.4%*
Greater than 200	*75.2%*

In Section III.1, page 113, Section III.8, page 160, Section IV.1, page 165, and Exhibit 5, Tables 54 and 67, the applicants provide historical and projected utilization of the general acute care beds at FMC and MPH, as illustrated in the following table.

YEAR	# OF ACUTE CARE PATIENT DAYS (including ICU)	AVERAGE DAILY CENSUS (ADC)	TOTAL # OF LICENSED ACUTE CARE BEDS	% OCCUPANCY
MPH				
10/1/06 – 9/30/07 (actual) [1]	5,687	15.6	136	11.5%
4/1/12 – 3/31/13 (projected) (Year One)	3,437	9.4	12	78.5%
4/1/13 –3/31/14 (projected) (Year Two)	3,179	8.7	12	72.6%
4/1/14 – 3/31/15 (projected) (Year Three)	2,921	8.0	12	66.7%
FMC (including the Kernersville and Clemmons campuses)				
10/1/06 – 9/30/07 (actual) [1]	208,327	570.8	637	89.6%
4/1/12 – 3/31/13 (projected) (Year One)	229,657	629.2	800	78.6%
4/1/13 –3/31/14 (projected) (Year Two)	232,582	637.2	800	79.7%
4/1/14 – 3/31/15 (projected) (Year Three)	235,245	644.5	800	80.6%

[1] As of 9/30/07, MPH was licensed for 136 general acute care beds and FMC was licensed for 637 general acute care beds. Effective 11/13/2007, 114 general acute care beds were transferred from MPH to FMC pursuant to the certificate of need issued for Project I.D. #G-7011-04. Thus, MPH is currently licensed for 22 general acute care beds and FMC is currently licensed for 751 general acute care beds.

As shown in the above table, MPH's average daily census (ADC) was 15.6 patients in FFY 2007 and the projected ADC during the third operating year of the project is 8 patients. Thus, the target occupancy rate for MPH is 66.7%. During the third operating year, the applicants project that the acute care occupancy rate at MPH would be 66.7%, which is equal to the target. Further, FMC's ADC was 570.8 patients in FFY 2007 and the projected ADC during the third operating year of the project is 644.5 patients. Thus, the target occupancy rate for FMC is 75.2%. During the third operating year, the applicants project that the occupancy rate would be 80.6%, which is greater than the target. In the Impact Analysis in Exhibit 5, Tables 54 and 55, the applicants assumed that acute care utilization would increase 1.1% per year, which is the same rate the population of FMC's service area[1] is projected to increase. See Criterion (3) for analysis of acute care utilization. The applicants adequately demonstrate the need to maintain the acute care bed capacity proposed in the application. Therefore, the applicants adequately demonstrate that the proposal is consistent with Policy AC-5 in the 2008 SMFP.

Further, because the applicants propose to develop a new satellite campus, Policy GEN-3 is applicable to the review. Policy GEN-3 states

[1] The service area for FMC includes Forsyth, Davie, Davidson, Guilford, Stokes, Surry, Wilkes and Yadkin counties.

YEAR	# OF ACUTE CARE PATIENT DAYS (including ICU)	AVERAGE DAILY CENSUS (ADC)	TOTAL # OF LICENSED ACUTE CARE BEDS	% OCCUPANCY
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[1] As of 9/30/07, MPH was licensed for 136 general acute care beds and FMC was licensed for 637 general acute care beds. Effective 11/13/2007, 114 general acute care beds were transferred from MPH to FMC pursuant to the certificate of need issued for Project I.D. #G-7011-04. Thus, MPH is currently licensed for 22 general acute care beds and FMC is currently licensed for 751 general acute care beds.

As shown in the above table, MPH's average daily census (ADC) was 15.6 patients in FFY 2007 and the projected ADC during the third operating year of the project is 8 patients. Thus, the target occupancy rate for MPH is 66.7%. During the third operating year, the applicants project that the acute care occupancy rate at MPH would be 66.7%, which is equal to the target. Further, FMC's ADC was 570.8 patients in FFY 2007 and the projected ADC during the third operating year of the project is 644.5 patients. Thus, the target occupancy rate for FMC is 75.2%. During the third operating year, the applicants project that the occupancy rate would be 80.6%, which is greater than the target. In the Impact Analysis in Exhibit 5, Tables 54 and 55, the applicants assumed that acute care utilization would increase 1.1% per year, which is the same rate the population of FMC's service area[1] is projected to increase. See Criterion (3) for analysis of acute care utilization. The applicants adequately demonstrate the need to maintain the acute care bed capacity proposed in the application. Therefore, the applicants adequately demonstrate that the proposal is consistent with Policy AC-5 in the 2008 SMFP.

Further, because the applicants propose to develop a new satellite campus, Policy GEN-3 is applicable to the review. Policy GEN-3 states

[1] The service area for FMC includes Forsyth, Davie, Davidson, Guilford, Stokes, Surry, Wilkes and Yadkin counties.

"A CON application to meet the need for new healthcare facilities, services or equipment shall be consistent with the three Basic Principles governing the State Medical Facilities Plan (SMFP); promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services. The Applicant shall document plans for providing access to services for patients with limited financial resources, commensurate with community standards, as well as the availability of capacity to provide those services. The Applicant shall also document how its projected volumes incorporate the three Basic Principles in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area."

In Section III.2, pages 148-150, the applicants state

"Access for the Medically Underserved

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 of this Application, the Applicant 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 Gross Revenue by payor category, as prescribed by the Agency. A large majority of residents from Forsyth County and the surrounding service area, as documented in the patient origin information in CON Application Section III and Exhibit 3, receive acute care inpatient services from the applicants facilities and affiliated medical staff, including the Novant Medical Group physicians in the [Clemmons Medical Center (CLMC)] *service area. The proposed project will result in improved access for all residents of the service area. The Applicant has the availability of capacity to provide those services now and in the future.*

Please see the Applicant's responses to Section VI., Questions 2 through 6 and Exhibit 9 for a copy [sic] *Novant's policies on Charity Care, Uninsured Discount, Catastrophic Discount & Payment Plan, for documentation of the* [sic] *CLMC's plans for providing services for patients with limited financial resources, commensurate with community standards, as well as the availability of capacity to provide those services. These four Charity Care policies apply today to the inpatient services provided at FMC and will continue to apply when CLMC, operating under FMC's hospital license, opens. For example, based on the government's 2008 Federal Poverty Level (FPL) definitions a family of four with annual income of $63,600 is eligible for a full Charity Care write-off of all charges with the completion of a simple one-page form that is attached to the Novant Charity Care policy. See Exhibit 9 for a copy of that form. This means these patients will get no bill from Novant for services rendered. It is the applicant's belief that Novant's Charity Care policy set at 300% of FPL is one of the most generous in North Carolina and today it applies at 12 North Carolina Hospitals, as well as 130 outpatient facilities that provide imaging, surgery, rehabilitation, etc. Furthermore, Novant's 'Uninsured Discount' policy ensures that those patients who do not qualify for the above Charity Care Write-Off, but remain unable to pay the full cost of their care have access to* [sic] *discount off Novant's charges that is based on the average regional discount given by Novant to managed care payors. Then, if the patient's remaining balance after the application of the uninsured discount is more than $5,000, the patient may be eligible for Novant's 'Catastrophic Discount.' All these policies and processes are fully described in Novant Health's Charity Care policies included in CON application Exhibit 9.*

In addition, 'community benefit' information for all Novant Health's providers in North Carolina (hospitals, physician practices, and outpatient services) shows the following. During CY 2007 (January 1 - December 31,2007), Novant Health provided $300 Million in Total Community Benefit, which includes the costs of treating charity care patients, unreimbursed costs of treating patients with Medicare, Medicaid, amid other government health coverage, and

estimated costs of treating Bad Debt patients. Bad Debt is inherent in providing health services to all individuals without regard for their willingness or ability to pay. The $300 Million in Novant's Total Community Benefit dollars is an increase of about 50% when compared to Novant Health's CY 2006 Total Community Benefit dollars, driven in part by Novant Health's Charity Care policies previously described. During CY 2007 Novant Health's Charity Care portion of Direct Community Benefit was $68 Million and Novant Health's Bad Debt portion of Direct Community Benefit was $33 Million. This is further evidence of Novant Health's overall commitment to accessible health services for medically underserved populations, including those patients receiving inpatient care at CLMC. CLMC has the availability of capacity to provide those services as 'community benefit' when necessary, including inpatient services, now and in the future.

Quality Healthcare Services Including Patient Safety

Please see the Applicant's responses to Section II., Questions 6 and 7 and Exhibits 2, 3, and 13 for a copy [sic] *Novant's policies and procedures related to quality care. As discussed in Section II of this application, CLMC 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. These quality processes, tools, and activities will apply to CLMC's services.*

In 2007 Novant Health, Inc and its providers and facilities began participating in the 'National ePrescribing Patient Safety Initiative,' designed to address preventable medication errors. This effort includes a coalition of the nation's most prominent technology companies and heading healthcare organizations, such as Aetna, Allscripts, Cisco, Dell, Fujitsu, Google, Intel, Microsoft, Sprint Nextel, SureScripts, WellPoint, Wolters Kluwer Health, Novant Health, University of South Florida Physicians Group (Tampa), LSU Health Network (New Orleans), George Washington University [sic] *Medical*

Faculty Associates (Washington D.C), Maine General Health (Augusta, ME), Advocate Health Partners (Mt Prospect, IL), University of Mississippi Medical Center, Holston Medical Group (Kingsport, TN), Healthcare Partners Medical Group (Torrence, CA), Sierra Health Services & Southwest Medical Associates (Las Vegas), UMass Memorial Healthcare (Worcester, MA). See the article in Exhibit 13. This reflects Novant's focus on continuing to improve key processes of patient care delivery in the future and this initiative will be undertaken at CLMC when it opens.

Novant Health continues to invest major capital in the installation of an electronic medical record (EMR) at six locations within the next two years and eventually with the remaining 256 Novant Health locations. Novant's commitment to the EMR conversion represents a mindset for capturing essential medical and patients [sic] *information to allow providers speedier access to patient information and to give nurses and physicians more decision making tools. The EMR will also serve to decrease harmful errors caused by handwritten notes and will significantly improve access to medical information from almost any location. See the article in Exhibit 13.*

Novant Health is one of the first health systems in the nation to invest in the Microsoft Amalga system, which pulls together patient medical information from multiple sources, such as imaging, lab, pharmacy and surgery and presents it all in one single view for physicians. Novant believes this system will reduce the administrative burden (of gathering this information from (disparate sources) on physicians, so that they can better spend their time and expertise on patient care management and decision making. See the article in Exhibit 13. The EMR, Amalga, and ePrescribing initiative illustrate Novant and CLMC's commitment to the improvement of patient care, including clinical ancillary services such as lab, imaging, and pharmacy, through the simplification and error-proofing of key processes of care.

Furthermore, in May 2007 Novant Health, Inc. announced its participation with a group of the nation's leading

hospitals to address medical errors by developing a comprehensive approach to patient safety. Other participants in the "Safest Hospital Alliance" include Wellmont Health System and Adventist Health System. The Alliance's Safest Hospital Initiative improves safety by creating metrics and identifying best practices. Please see the recent article on this issue included in Exhibit 13. It is Novant and CLMC's position that patient safety is intimately intertwined with quality of care. So patient safety initiatives will be part of the quality of care initiatives at CMLC [sic].

Cost Effective Services

Novant Health, Inc. is a national header in cost-effective approaches for health care services. It is anticipated that these processes and approach to cost-effectiveness will be carried forward at CLMC. In 2008 Novant is ranked 4th nationally among the 'Top 100 Integrated Healthcare Networks based on an analysis conducted by Verispan, a health informatics company. Please see the recent article on this issue included in Exhibit 13. According to 'Modern Heahthcare' the best performing integrated healthcare systems continue to improve efficiency and have bottom lines to show it including improved occupancy, well-integrated information systems, and ... strong margins.'"

FMC and Novant adequately demonstrate the project is a cost effective approach and that medically underserved groups will have access to the proposed services. The applicants also adequately demonstrate their ability to encourage quality health care services. Further, the applicants adequately demonstrated that their projected volumes for the proposed satellite campus incorporate the basic principles in meeting the needs of the patients to be served. See Criteria (3) and (13c) for additional discussion. Therefore, the application is consistent with Policy GEN-3.

In summary, the application is consistent with Policy AC-5 and Policy GEN-3, and therefore is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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(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.

CA

Forsyth Memorial Hospital, Inc. and Novant Health, Inc. (**Novant**) own and operate Forsyth Medical Center (**FMC**), a hospital located in Winston-Salem in Forsyth County, which is currently licensed for 751 acute care beds, 30 operating rooms (ORs)[2] and 8 gastrointestinal (GI) endoscopy rooms. Novant also owns Medical Park Hospital (**MPH**), which is located across the street from FMC. MPH is currently licensed for 22 acute care beds and 13 ORs. Development of the following previously approved projects will change the number of acute care beds, ORs and GI endoscopy rooms at FMC and the number of ORs at MPH.

- **Project I.D. #G-7412-05** – The certificate of need issued March 6, 2007 authorizes FMC to develop two additional shared ORs by converting two existing GI endoscopy rooms.
- **Project I.D. #G-7416-05** – The certificate of need issued March 6, 2007 authorizes Hawthorne Surgical Center (HSC) to develop two additional dedicated outpatient ORs by relocating and converting two of FMC's existing GI endoscopy rooms. Novant is the ultimate parent of HSC, which is located on FMC's campus. Effective January 1, 2008, HSC is licensed as part of FMC.
- **Project I.D. #G-7604-06** – The certificate of need issued July 24, 2007 authorizes FMC to develop 39 additional acute care beds and relocate 11 existing acute care beds to develop a 50-bed satellite campus in Kernersville. In addition, FMC is also authorized to relocate three existing ORs from FMC and one existing OR from MPH to Kernersville. The FMC-Kernersville campus will be licensed as part of FMC.

Thus, upon completion of the previously approved projects listed above, FMC will be licensed for 790 acute care beds [751 + 39 = 790], 35 ORs [30 + 2 + 2 + 1 = 35] and 4 GI endoscopy rooms [8 –

[2] The 30 ORs includes the 4 dedicated outpatient ORs at Hawthorne Surgical Center which are now licensed as part of FMC.

(2 + 2) = 4]. Further, MPH will be licensed for 22 acute care beds and 12 ORs [13 – 1 = 12].

In this application, FMC and Novant propose to develop a 50-bed satellite campus in Clemmons (**FMC-Clemmons**) by relocating 40 existing acute care beds from FMC and 10 existing acute care beds and 5 existing operating rooms from MPH. The applicants also propose to develop one new GI endoscopy room in Clemmons. The applicants state FMC-Clemmons will be licensed as part of FMC. Thus, upon completion of the project under review and the previously approved projects, FMC would be licensed for a total of 800 acute care beds [751 + 39 + 10 = 800], 40 ORs [30 + 2 + 2 + 1 + 5 = 40] and 5 GI endoscopy rooms [8 – (2 + 2) + 1 = 5]. Further, MPH would be licensed for 12 acute care beds [22 – 10 = 12] and 7 ORs [13 – (1 + 5) = 7].

Based on the applicants' representations in Section II.1, pages 24-28, the design schematics in Exhibit 16, and the list of equipment to be acquired provided in Exhibit 17, the applicants propose to offer the following services at FMC-Clemmons:

- 46 general medical/surgical acute care beds (36 existing general medical/surgical acute care beds to be relocated from FMC-Winston-Salem and 10 from MPH)
- 4 intensive care unit (ICU) beds (4 existing general medical/surgical acute care beds to be relocated from FMC-Winston-Salem)
- 6 unlicensed observation beds
- 5 shared operating rooms (ORs) (5 existing shared ORs to be relocated from MPH)
- 1 new gastrointestinal (GI) endoscopy room
- a new 24 hour Emergency Department (ED), with 12 treatment rooms
- laboratory (lab) services, including phlebotomy, blood bank, pathology, chemistry, hematology coagulation, micro urinalysis and accessioning
- pharmacy
- respiratory therapy
- physical therapy
- speech therapy
- diagnostic imaging, including
  - 1 new CT scanner

- 1 new x-ray unit
- 1 new x-ray/fluoroscopy unit
- 1 new nuclear medicine camera (without coincidence circuitry)
- 1 new mammography unit
- 1 new ultrasound (US) unit
- 2 new electrocardiograph (ECG) units
- 1 new electroencephalograph (EKG) unit

The applicants do not propose to offer obstetric or neonatal services at FMC-Clemmons, and do not propose to develop any non-surgical procedure rooms on the new campus.

POPULATION TO BE SERVED

The following table illustrates patient origin during Federal Fiscal Year (FFY) 2007 (October 1, 2006 – September 31, 2007) for acute care services provided at FMC, as provided by the applicants in Section III.4(a), page 150.

FFY 2007 PATIENT ORIGIN FOR ACUTE CARE SERVICES PROVIDED AT FMC

COUNTY	PERCENTAGE OF TOTAL
Forsyth	58.4%
Stokes	7.6%
Surry	6.4%
Davie	5.5%
Yadkin	5.4%
Davidson	5.3%
Wilkes	2.2%
Guilford	1.7%
All Other	7.5%
Total	100.0%

The following table illustrates the projected patient origin for acute care services to be provided on the FMC-Clemmons campus in the second operating year, as provided by the applicants in Section III.5(c), page 153.

PROJECTED PATIENT ORIGIN FOR FMC-CLEMMONS DURING YEAR TWO

ZIP CODE	COUNTY / CITY	PERCENTAGE OF TOTAL PATIENT DAYS
27012	Forsyth / Clemmons	16.1%
27023	Forsyth / Lewisville	28.9%
27006	Davie / Advance	12.6%
27028 [1]	Davie / Mocksville	32.4%
Other inmigration [2]		10.0%
Total		100.0%

[1] 27028 also includes Zip Code 27014 (Cooleemee), which is a post office box.

[2] In Section III.1, page 120, the applicants state *"Other inmigration is expected to come from surrounding zip codes in Forsyth County and other surrounding counties, such as Iredell and Yadkin."*

In Section III.1(a), page 97, the applicants state that FMC and MPH currently provide approximately 60% of the acute care services provided to residents of the five zip codes in the primary service area. In Section III.5(a), page 152, the applicants state

> *"Novant Health reviewed zip code population in suburban communities and the growth expected from 2007 to 2015, as well as the patient origin of its existing facilities to determine the proposed location of CLMC. ... Once the proposed location was determined, actual utilization of hospital acute inpatient services by residents of the service area was determined by reviewing Solucient data and calculating future need, based on market share and population growth of each zip code in the service area. Projected utilization for CLMC resulted in the patient origin of the proposed facility."*

The applicants adequately identified the population proposed to be served.

Need for Proposed Project

In Section III.1(a), pages 97-110, the applicants state

> *"The CLMC proposed service area represents a growing community of 77,000 people in the western suburbs of Winston Salem, including western Forsyth County and Davie County in total. FMC, MPH, and other NHTR*

facilities and the associated physicians have been the predominant provider of inpatient and surgical care for that population for many years ....

...

In addition, Novant Medical Group physicians in the service area and contiguous to the service area are the preferred providers of primary care services for thousands of residents of the proposed CLMC service area .... The Novant Medical Group network includes four established practices in the CLMC service area with five office locations and 28 physicians and physician extenders .... The NMG practices in the Triad Region, along with these four practices have existing doctor-patient relationships with 42,500 patients of the CLMC service area. When the entire CLMC service area of western Forsyth County and all of Davie County is considered, NMG physicians have earned the privilege of caring for almost 60% of the primary care needs of those residents .... NMG practices are chosen in almost one-half the population of Davie County for their primary care needs. Those NMG practices have expressed their support for the proposed Clemmons Medical Center and expressed an intent to refer clinically appropriate patients to CLMC. See Exhibit 11. ...

...

Consistent with its belief that health care is a local issue, Novant Health and Forsyth Medical Center are committed to meeting the local health care needs in each of the communities it serves. Novant Health has determined that the development of a 50-bed hospital in Clemmons will provide a community alternative for residents of the defined service area and would help to relieve some of the future pressure for additional beds and ED visit capacity at Forsyth Medical Center in Winston Salem.

...

The unmet need for inpatient acute care services in the greater Clemmons area of Forsyth and Davie Counties is substantiated by the rapidly growing population and the

lack of comprehensive inpatient and outpatient services in the defined service area. In addition, the need for the community based hospital services at the community level for the residents of the defined service area is also supported by:

- *the increasing utilization of FMC inpatient facilities in Winston Salem* [sic]
- *the resulting identified need for additional beds at FMC, and*
- *Novant health's commitment to provide locally-accessible quality health care services in the communities it serves.*

...

... [F]*rom 2000 to 2008 the population in these five zip codes grew 17.7% or an average rate of 2.2% annually The proposed service area population is projected to continue growing an additional 9%, or an estimated average rate of 1.8% annually from 2008 to 2013.*

...

There are four hospital facilities providing inpatient hospital care in Forsyth amid Davie Counties: Forsyth Medical Center, Medical Park Hospital, North Carolina Baptist Hospital, and Davie County Hospital, a critical access hospital. ... Davie County Hospital ... is the only existing hospital located in the proposed five zip code service area."

In Section III.1(b), page 136, the applicants state

"Using April 2007-March 2008 emergency visit data from the NHTR internal Trendstar database, CLMC calculated the NHTR market share for each zip code in the defined service area. Relevant data is included in Exhibit 5, Table 37. The following table shows NHTR emergency visits, total defined service area emergency visits, and NHTR market share for zip codes in the defined service area.

Zip Code	*County*	*NH Winston Salem Emergency Visits*	*Total Emergency Visits*	*NH Winston Salem Market Share*
27006	*Davie*	*1,721*	*5,809*	*29.6%*
27012	*Forsyth*	*4,220*	*10,889*	*38.8%*
27023	*Forsyth*	*1,585*	*4,791*	*33.1%*
27028 (Includes 28014 Volume)	*Davie*	*2,133*	*12,007*	*28.8%* [sic][*]
[Total		9,659	33,496	28.8%]

[* On page 136, the applicants state that Novant's current ED market share for Zip Code area 27028 (including 27014) is 28.8%. However, 28.8% is Novant's current ED market share for the entire primary service area (9,659 / 33,496 = 0.288). Novant's current ED market share for Zip Code area 27028 (including 28014) is 17.8% (2,133 / 12, 007 = .178).]

Further, in Section III.1(a), pages 110-116, the applicants state

> *"Currently nearly 30% of all residents from the five zip code service area seek emergency services at Forsyth Medical Center which is as much as 29 minutes away depending on location within the proposed service area. When traffic on I-40 is heavy, or during rush hours, driving time will be even greater. ...* [T]*he proposed location for CLMC provides decreased travel time for all residents of Clemmons and Lewisville. The proposed CLMC is closer for all residents of Advance, except those living in the very southern part of the zip code which are closer to the DCH Critical Access Hospital ....*
>
> ...
>
> *Furthermore, according to a recent American College of Emergency Physicians (ACEP) report, The National Report Card on the State of Emergency Medicine, North Carolina earned a 'C-overall for its support of emergency care.' In comparison with other states, North Carolina ranked 37th in the number of emergency departments per million population. One recommendation ACEP made to North Carolina is to build more emergency medicine facilities[3]. The proposed CLMC addresses this issue as it will include a new emergency department and will provide increased accessibility to emergency medicine facilities for residents of a growing market located in western Forsyth and Davie Counties.*

[3] The applicants provide a copy of the report in Exhibit 5.

The proposed location will provide quicker and more ready access to emergency services for many residents in the Mocksville zip code area ... and will provide a more accessible and closer emergency option for all residents in the Advance, Clemmons and Lewisville Townships. The result: improved access to health care services for residents of the proposed service area. ...

...

CLMC analyzed zip code level Solucient data to establish the current inpatient volume from the proposed CLMC zip code service area utilizing Novant Health Triad Region (NHTR) Winston Salem facilities in Forsyth and Davie Counties. As previously discussed, the proposed CLMC will be a satellite hospital under the FMC hospital license. Cardiac surgery and other tertiary level services will not be provided. Therefore, to determine the potential medical/surgical patient days to be included in the analysis the following exclusions were made from the total Solucient patient days from the five zip code service area.

Solucient Database Exclusions

Medical Surgical Exclusions
Mental Health and Drug Abuse DRGs (424-433 and 521-523)
Rehab (462)
Normal Newborns (391)
Delivery DRGs (370-375)
NICU (385-390)
Diag Cardiac Cath (124, 125)
DRGs with FY 2005 Relative Weight = 2.0

... Residents in the Forsyth County zip codes choose FMC and MPH consistently over 70% of the time for all acuity-adjusted, non-obstetric care. And in Davie County residents have consistently chosen FMC and MPH about 50% of the time for all inpatient days related to acuity adjusted, non obstetric care during the last three calendar years. Clearly FMC, MPH, and the affiliated physicians (on the FMC and MPH medical staffs or part of Novant Medical Group) have established and [sic] *enduring relationships with the residents of the proposed CLMC service area ....*

...

Significantly, the applicant is not proposing a market share shift from other facilities in order to meet the required utilization targets at CLMC. Rather, the applicant is able to demonstrate more than sufficient utilization at CLMC based on the patients already served by FMC and MPH and the average annual population growth in the CLMC service area. ...

...

Historic utilization at FMC has continually increased during the last several years, even as FMC has reached inpatient capacity levels in excess of 90% during the week and during flu season. MPH has experienced ups and downs in utilization during the same time frame, as it functions as a small surgical specialty hospital and thus the relocation of even one or two surgeons can have a marked impact. ...

...

In late 2004 FMC opened a new expanded Emergency Department. ... FMC outgrew the ED renovations and expansions, almost before the expansions could be completed. FMC opened a new and expanded ED in November 2004 and visits increased by 13%, or more than 10,000 visits, in the first year of operation. ...

...

The existing high utilization at the FMC ED and projected growth in emergency visits in Forsyth County and the surrounding areas is expected to continue. The CDC's National Center for Health Statistics Report reported that in 2006 the ED utilization rate was 39.6 visits per 100 persons nationally, which represented an increase of 31% since 1995. And during the same timeframe, the number of hospital EDs in the U.S. has decreased by 9.1%. Further, emergency room utilization varied by geographic location. In the South, visit rates were even higher, at 41.7 visits per

100 persons: North Carolina emergency room visits per 100 population in 2006 was estimated at 43.4 visits: In addition, the emergency department visit use rate is expected to continue to increase as much as 13 percent growth between 2002 and 2012, related to population increase, uninsured ED utilization, and other variables. The growing ED use rate and the fact that the North Carolina ED use rate is higher than the national norm and the southern states norm [sic] *contributes to growing demand for services in emergency departments in Forsyth and surrounding counties.*

...

... Approval and development of new emergency department capacity at FMC-Kernersville and CLMC will result in a significant and necessary shift in emergency room utilization from the main FMC campus on Hawthorne Road to the two new facilities. As a result, the existing FMC emergency department may not need to be expanded in the near future unless ED utilization grows more rapidly than projected during the next several years. ...

Without the proposed CLMC emergency department, the emergency room at FMC will have to expand. Putting the needed emergency rooms closer to a growing population is a better alternative than expanding the ED at FMC in a Winston-Salem location that is not close to the local population."

...

During the last several years, NHTR Winston Salem has analyzed a variety of options to maximize utilization of its Hawthorne Road assets, including the greater FMC Campus where FMC and MPH currently are located just across the street from each other. ...

The additional demand for beds at FMC reflects the increasing number of patients from all areas of Forsyth and surrounding counties (including residents of the proposed CLMC service area) who seek all levels of health care services. As previously discussed, NHTR Winston

Salem currently has a 60% market share of the proposed CLMC service area.[4] *The development of the proposed CLMC will result in a shift of much of this volume to the proposed 50 bed community hospital. The projected patient shift to the community hospital will open up more capacity at FMC in the future. ...*

...

The impetus driving the proposed relocation of fifty acute care beds from FMC and MPH and five existing licensed operating rooms from MPH to CLMC is to provide high quality patient care services in a local community that has depended on Novant Health Triad Region inpatient facilities and physicians for many years while at the same time, maximizing utilization of existing NHTR Winston Salem resources."

Projected Utilization

Acute Care Beds – The proposed FMC-Clemmons campus would be licensed for 50 acute care beds to include 40 existing acute care beds relocated from FMC and 10 existing acute care beds relocated from MPH. The following table summarizes the applicants' methodology and assumptions used to project utilization of the 50 acute care beds at FMC-Clemmons, which are provided in Section III.1(b), pages 120-124, and Exhibit 5, Tables 6-18.

[4] In Section III.1(a), page 112, and Exhibit 5, Table 7, the applicants provide data which shows that, during 2007, Novant's market share for acute care services (inpatient only) provided to residents of the primary service area was 59.6%.

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ACUTE CARE BEDS

STEP	DESCRIPTION	CY 2012	CY 2013	CY 2014	CY 2015
1	Projected population of the 5 zip code areas in the proposed primary service area for FMC-Clemmons	82,696	84,138	85,606	87,100
2	Average acute care use rate per 1,000 population (not adjusted for acuity) for the 5 zip code areas in the proposed primary service area for FMC-Clemmons during 2005-2007, which is based on Thomson data	95.1	95.1	95.1	95.1
3	Project acute care discharges (use rate x population / 1,000) (Step 1 x Step 2 / 1,000)	7,865	8,002	8,141	8,283
4	Novant's historical market share for the 5 zip code areas in the proposed primary service area for FMC-Clemmons, which is based on Thomson data	60%	60%	60%	60%
5	Project total acute care discharges at Novant facilities (Step 3 x Step 4)	4,717	4,801	4,885	4,970
			YEAR 1 4/1/12-3/31/13	**YEAR 2 4/1/13-3/31/14**	**YEAR 3 4/1/14-3/31/15**
6	Adjust projected CY acute care discharges at Novant facilities (Step 5) to first three operating years of FMC-Clemmons		4,737	4,820	4,904
7	% projected to shift from Novant facilities to FMC-Clemmons, which is based on the historical % of total discharges which are acuity adjusted discharges (acuity adjusted discharges include DRGs with a weight less than 2.0 and exclude all DRGs for mental health and drug abuse, rehab, normal newborn, obstetrical, neonatal intensive care and cardiac cath) (Novant's historical acuity adjusted discharges as a % of total discharges from the service area were 65.5% in FFY 2005, 70.6% in FFY 2006 and 70.7% in FFY 2007)		55%	60%	65%
8	Project acute care discharges to shift to FMC-Clemmons (Step 6 x Step 7)		2,605	2,892	3,188
9	Projected average length of stay (ALOS) is based on the actual ALOS for acuity adjusted discharges and patient days from all hospitals serving the 5 zip code areas in the proposed primary service area during 2006 (4.28) and 2007 (4.48) (The average of the two is 4.38)		4.39	4.39	4.39
10	Projected patient days (Step 8 x Step 9)		11,438	12,696	13,994
11	Average daily census (ADC) (Step 10 / 365)		31.3	34.8	38.3
12	Number of acute care beds		50	50	50
13	Percent occupancy (Step 11 / Step 12)		62.7%	69.6%	76.7%

ACUTE CARE BEDS

STEP	DESCRIPTION	CY 2012	CY 2013	CY 2014	CY 2015
1	Projected population of the 5 zip code areas in the proposed primary service area for FMC-Clemmons	82,696	84,138	85,606	87,100
2	Average acute care use rate per 1,000 population (not adjusted for acuity) for the 5 zip code areas in the proposed primary service area for FMC-Clemmons during 2005-2007, which is based on Thomson data	95.1	95.1	95.1	95.1
3	Project acute care discharges (use rate x population / 1,000) (Step 1 x Step 2 / 1,000)	7,865	8,002	8,141	8,283
4	Novant's historical market share for the 5 zip code areas in the proposed primary service area for FMC-Clemmons, which is based on Thomson data	60%	60%	60%	60%
5	Project total acute care discharges at Novant facilities (Step 3 x Step 4)	4,717	4,801	4,885	4,970
			YEAR 1 4/1/12-3/31/13	**YEAR 2 4/1/13-3/31/14**	**YEAR 3 4/1/14-3/31/15**
6	Adjust projected CY acute care discharges at Novant facilities (Step 5) to first three operating years of FMC-Clemmons		4,737	4,820	4,904
7	% projected to shift from Novant facilities to FMC-Clemmons, which is based on the historical % of total discharges which are acuity adjusted discharges (acuity adjusted discharges include DRGs with a weight less than 2.0 and exclude all DRGs for mental health and drug abuse, rehab, normal newborn, obstetrical, neonatal intensive care and cardiac cath) (Novant's historical acuity adjusted discharges as a % of total discharges from the service area were 65.5% in FFY 2005, 70.6% in FFY 2006 and 70.7% in FFY 2007)		55%	60%	65%
8	Project acute care discharges to shift to FMC-Clemmons (Step 6 x Step 7)		2,605	2,892	3,188
9	Projected average length of stay (ALOS) is based on the actual ALOS for acuity adjusted discharges and patient days from all hospitals serving the 5 zip code areas in the proposed primary service area during 2006 (4.28) and 2007 (4.48) (The average of the two is 4.38)		4.39	4.39	4.39
10	Projected patient days (Step 8 x Step 9)		11,438	12,696	13,994
11	Average daily census (ADC) (Step 10 / 365)		31.3	34.8	38.3
12	Number of acute care beds		50	50	50
13	Percent occupancy (Step 11 / Step 12)		62.7%	69.6%	76.7%

ACUTE CARE BEDS

STEP	DESCRIPTION	CY 2012	CY 2013	CY 2014	CY 2015
1	Projected population of the 5 zip code areas in the proposed primary service area for FMC-Clemmons	82,696	84,138	85,606	87,100
2	Average acute care use rate per 1,000 population (not adjusted for acuity) for the 5 zip code areas in the proposed primary service area for FMC-Clemmons during 2005-2007, which is based on Thomson data	95.1	95.1	95.1	95.1
3	Project acute care discharges (use rate x population / 1,000) (Step 1 x Step 2 / 1,000)	7,865	8,002	8,141	8,283
4	Novant's historical market share for the 5 zip code areas in the proposed primary service area for FMC-Clemmons, which is based on Thomson data	60%	60%	60%	60%
5	Project total acute care discharges at Novant facilities (Step 3 x Step 4)	4,717	4,801	4,885	4,970
			YEAR 1 4/1/12-3/31/13	**YEAR 2 4/1/13-3/31/14**	**YEAR 3 4/1/14-3/31/15**
6	Adjust projected CY acute care discharges at Novant facilities (Step 5) to first three operating years of FMC-Clemmons		4,737	4,820	4,904
7	% projected to shift from Novant facilities to FMC-Clemmons, which is based on the historical % of total discharges which are acuity adjusted discharges (acuity adjusted discharges include DRGs with a weight less than 2.0 and exclude all DRGs for mental health and drug abuse, rehab, normal newborn, obstetrical, neonatal intensive care and cardiac cath) (Novant's historical acuity adjusted discharges as a % of total discharges from the service area were 65.5% in FFY 2005, 70.6% in FFY 2006 and 70.7% in FFY 2007)		55%	60%	65%
8	Project acute care discharges to shift to FMC-Clemmons (Step 6 x Step 7)		2,605	2,892	3,188
9	Projected average length of stay (ALOS) is based on the actual ALOS for acuity adjusted discharges and patient days from all hospitals serving the 5 zip code areas in the proposed primary service area during 2006 (4.28) and 2007 (4.48) (The average of the two is 4.38)		4.39	4.39	4.39
10	Projected patient days (Step 8 x Step 9)		11,438	12,696	13,994
11	Average daily census (ADC) (Step 10 / 365)		31.3	34.8	38.3
12	Number of acute care beds		50	50	50
13	Percent occupancy (Step 11 / Step 12)		62.7%	69.6%	76.7%

As shown in the above table, in Year Three, the applicants project that the proposed FMC-Clemmons campus will provide 13,994 acute days of care in 50 beds, which is an ADC of 38.3 patients and an occupancy rate of 76.7%. Projected utilization of the acute care beds is based on reasonable assumptions, including but not limited to: 1) an acute care use rate per 1,000 population of 95.1 (the average of the actual use rates during 2005-2007) which is held constant; 2) Novant's historical 60% market share of acute care discharges for the service area which is held constant; 3) the percentage of acute care discharges to be shifted to FMC-Clemmons (55-65%) which is less than the actual percentage of acuity adjusted acute care discharges from all hospitals serving the primary service area during 2005-2007; and 4) an ALOS of 4.39 days per patient discharge which is approximately the average ALOS for acuity adjusted discharges from all hospitals serving the primary service area during 2006 and 2007.

The applicants also provide an Impact Analysis in Section III.8(c), pages 159-161, and Exhibit 5, regarding the impact of FMC-Clemmons on utilization of acute care beds at FMC-Winston-Salem, FMC-Kernersville and MPH following the proposed relocation of 50 acute care beds. The applicants provided adjusted utilization projections at each campus to account for the patients expected to shift to FMC-Clemmons. The following table illustrates projected utilization of the acute care beds at FMC and MPH through the third operating year of the project, as presented in Section III.8(c), page 160, and Exhibit 5, Table 54.

Acute Care Beds	FMC				MPH
	WINSTON-SALEM CAMPUS	KERNERSVILLE CAMPUS	CLEMMONS CAMPUS	TOTAL	
2008					
Patient Days	210,148			210,148	5,762
ADC	576			576	16
# of Beds	751			751	22
% Occupancy	76.7%			76.7%	71.8%
YEAR ONE (4/1/12 - 3/31/13)					
Patient Days	203,237	14,703	11,438	229,378	3,437
ADC	557	40	31	628	9
# of Beds	700	50	50	800	12
% Occupancy	79.5%	80.6%	62.7%	78.6%	78.5%
YEAR TWO (4/1/13 - 3/31/14)					
Patient Days	204,422	15,186	12,696	232,304	3,179
ADC	560	42	35	636	9
# of Beds	700	50	50	800	12
% Occupancy	80.0%	83.2%	69.6%	79.6%	72.6%
YEAR THREE (4/1/14 - 3/31/15)					
Patient Days	205,568	15,684	13,994	235,246	2,921
ADC	563	43	38	645	8
# of Beds	700	50	50	800	12
% Occupancy	80.5%	85.9%	76.7%	80.6%	66.7%

As shown in the above table, in Exhibit 5, Table 54, the applicants provide projected utilization for each of Novant's Forsyth County hospitals using the following methodology:

- First, the applicants projected utilization at FMC and MPH through the third operating year assuming neither the FMC-Kernersville nor the FMC-Clemmons projects will be developed. In this step, the applicants assume patient days at FMC and MPH will increase at the same rate the population of the service area is projected to increase, which is 1.1% per year.
- Second, projected utilization at FMC-Winston-Salem and MPH was adjusted to reflect development of FMC-Kernersville during 2009. For FMC-Kernersville, the applicants assume patient days will increase 3.3% per year, which is based on the assumptions regarding the number of patients to be shifted from FMC and MPH plus projected market share increases

described in the previously approved certificate of need application.

- Third, projected utilization at FMC-Winston-Salem and MPH was adjusted to reflect development of FMC-Clemmons.

Further, the applicants provide an Impact Analysis in Exhibit 5, regarding the impact the development of FMC-Clemmons will have on utilization of the acute care beds at North Carolina Baptist Hospital and DCH. On page 1 of the Impact Analysis in Exhibit 5, the applicants state *"The proposed project is based upon market volume shift from the service area which currently is provided at FMC and MPH to CLMC. No increase in market share is projected, therefore, no market volume shift is assumed from either NCBH or DCH."* On page 4 of the Impact Analysis in Exhibit 5, the applicants state *"that there are and will continue to be more than enough patients in the area to support the continued high utilization of the existing area hospitals and the proposed 50 bed community hospital in Clemmons. All health care providers are well positioned to benefit from the growth in the greater Clemmons area."*

To critique the applicants' Impact Analysis, the following table was prepared by the analyst to compare acute care discharges projected by FMC-Clemmons for residents of Davie County, the Zip Code areas for Clemmons (27012) and Lewisville (27023) in Forsyth County and Zip Code area 27055 in Yadkin County, to the total number of acute care discharges projected in the FMC-Clemmons and DCH applications, including inmigration.

Step		2012	2013	2014	2015
	Projected Acute Care Utilization by Residents of the Primary Service Area				
1	Projected Population of Davie County + 2 Zip Codes in Forsyth County, which is the primary service area for FMC-Clemmons. (See page 120 of the FMC-Clemmons application for projected population data.)	82,696	84,138	85,606	87,100
2	Projected Population of 1 Zip Code in Yadkin County, which is included in DCH's primary service area but not FMC-Clemmons' primary service area. (from page 53 of the previously approved DCH application)	13,577	13,591	13,604	13,618
3	Total Projected Population (Step 1 + Step 2)	96,273	97,729	99,210	100,718
4	Acute Care Use Rate per 1,000 Population (not adjusted for acuity) (from page 121 of the FMC-Clemmons application)	95.1	95.1	95.1	95.1
5	Projected Acute Care Discharges (Use Rate x Population / 1,000) (Step 3 x Step 4 / 1,000)	9,156	9,294	9,435	9,578
6	Projected Acuity Adjusted Acute Care Discharges (65% of total acute care discharges) (See page 121 of the FMC-Clemmons application for table showing actual acuity adjusted acute care discharges as a % of total acute care discharges during 2005-2007) (Step 5 x 65%)	5,951	6,041	6,133	6,226
	Projected Acute Care Utilization at FMC-Clemmons and DCH				
7	Projected Acute Care Discharges at FMC-Clemmons (includes 10% inmigration from Yadkin and Iredell counties plus other zip codes in Forsyth County) (from page 123 of the FMC-Clemmons application) (not adjusted to calendar years)		2,606	2,892	3,188
8	Projected Acute Care Discharges at DCH (includes 8.51% inmigration from other counties) (from the findings for the previously approved DCH application)	2,512	2,607	2,706	2,809
9	Total Projected Acute Care Discharges at FMC-Clemmons and DCH (Step 7 + Step 8)	2,512	5,213	5,598	5,997
10	% of Total Acuity Adjusted Acute Care Discharges for the Service Area	42.2%	86.3%	91.3%	96.3%

It should be noted that Step 6 includes only the projected number of acute care discharges of residents of the primary service areas and does not include projected acute care discharges resulting from inmigration at either FMC-Clemmons or DCH. In contrast, Step 9 includes all discharges at FMC-Clemmons and DCH, including those resulting from inmigration, which is 10% of total discharges at FMC-Clemmons and 8.51% at DCH. Thus, 18.51% of the projected acute care discharges shown in Step 9 will not be residents of the primary service areas. If the population of the counties representing discharges from inmigration were included in Step 3, the projected acuity adjusted acute care discharges in Step 6

Step		2012	2013	2014	2015
	Projected Acute Care Utilization by Residents of the Primary Service Area				
1	Projected Population of Davie County + 2 Zip Codes in Forsyth County, which is the primary service area for FMC-Clemmons. (See page 120 of the FMC-Clemmons application for projected population data.)	82,696	84,138	85,606	87,100
2	Projected Population of 1 Zip Code in Yadkin County, which is included in DCH's primary service area but not FMC-Clemmons' primary service area. (from page 53 of the previously approved DCH application)	13,577	13,591	13,604	13,618
3	Total Projected Population (Step 1 + Step 2)	96,273	97,729	99,210	100,718
4	Acute Care Use Rate per 1,000 Population (not adjusted for acuity) (from page 121 of the FMC-Clemmons application)	95.1	95.1	95.1	95.1
5	Projected Acute Care Discharges (Use Rate x Population / 1,000) (Step 3 x Step 4 / 1,000)	9,156	9,294	9,435	9,578
6	Projected Acuity Adjusted Acute Care Discharges (65% of total acute care discharges) (See page 121 of the FMC-Clemmons application for table showing actual acuity adjusted acute care discharges as a % of total acute care discharges during 2005-2007) (Step 5 x 65%)	5,951	6,041	6,133	6,226
	Projected Acute Care Utilization at FMC-Clemmons and DCH				
7	Projected Acute Care Discharges at FMC-Clemmons (includes 10% inmigration from Yadkin and Iredell counties plus other zip codes in Forsyth County) (from page 123 of the FMC-Clemmons application) (not adjusted to calendar years)		2,606	2,892	3,188
8	Projected Acute Care Discharges at DCH (includes 8.51% inmigration from other counties) (from the findings for the previously approved DCH application)	2,512	2,607	2,706	2,809
9	Total Projected Acute Care Discharges at FMC-Clemmons and DCH (Step 7 + Step 8)	2,512	5,213	5,598	5,997
10	% of Total Acuity Adjusted Acute Care Discharges for the Service Area	42.2%	86.3%	91.3%	96.3%

It should be noted that Step 6 includes only the projected number of acute care discharges of residents of the primary service areas and does not include projected acute care discharges resulting from inmigration at either FMC-Clemmons or DCH. In contrast, Step 9 includes all discharges at FMC-Clemmons and DCH, including those resulting from inmigration, which is 10% of total discharges at FMC-Clemmons and 8.51% at DCH. Thus, 18.51% of the projected acute care discharges shown in Step 9 will not be residents of the primary service areas. If the population of the counties representing discharges from inmigration were included in Step 3, the projected acuity adjusted acute care discharges in Step 6

would be greater. As shown in the above table, FMC-Clemmons and DCH together propose to serve approximately 5,997 acute care discharges (including inmigration) in CY 2015, which is only 96.3% of the total acuity adjusted discharges from the proposed primary service area that were projected by FMC-Clemmons, plus the acuity adjusted discharges from Zip Code area 27055 [5,997 / 6,226 = .963]. If inmigration discharges were included in Step 6, the two facilities would be projecting to serve an even smaller percentage of the population in need. Consequently, based on data provided by FMC-Clemmons, the analyst concluded that the number of potential patients in the primary service area is sufficient to justify the need for the 50 proposed acute care beds at FMC-Clemmons, in addition to the 48 previously approved acute care beds at DCH.

In summary, the applicants adequately demonstrate that the acute care beds at the proposed FMC-Clemmons are needed by the population proposed to be served in the service area.

Intensive Care Unit Beds – Of the 50 licensed acute care beds at FMC-Clemmons, the applicants propose that 4 will be developed as intensive care unit (ICU) beds. In Section III.1(b), page 124, the applicants state

> *"Projected ICU beds were determined using total projected inpatient days and FFY 2007 ICU utilization data from North Carolina hospitals. CLMC reviewed historical ICU utilization for all hospitals in North Carolina reporting ICU utilization. This data is included in Exhibit 5, Tables 14 and 15. ICU patient days as a percent of Total Acute Inpatient Patient Days (less neonatal days) for all North Carolina hospital* [sic] *reporting ICU data averaged 13.1% in FFY 2007, well over the percentage used to project CLMC ICU days. The range for ICU days as a percent of total days for all North Carolina hospitals is 30% at the high end and 3.4% 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 11.0%.*
>
> *Based upon the total North Carolina ICU database, CLMC ICU days were projected assuming that 8.4% of total patient days would be ICU days. This 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 5, Table 14 and 15."

The following table summarizes the applicants' methodology and assumptions used to project utilization of the four ICU beds at FMC-Clemmons, which are provided in Section III.1(b), pages 124-125, and Exhibit 5, Tables 14-15.

INTENSIVE CARE UNIT	YEAR 1	YEAR 2	YEAR 3
Total acute care patient days	11,438	12,696	13,994
ICU patient days (8.4% of total acute care patient days)	965	1,071	1,181
ADC (ICU patient days / 365)	2.6	2.9	3.2
# of ICU beds	4	4	4
% occupancy (ADC / # of ICU beds)	65.0%	72.5%	80.0%

As shown in the above table, the applicants project the ICU will provide 1,181 days of care in 4 beds, which is an ADC of 3.2 patients and an occupancy rate of 80%. Projected utilization of the ICU beds is based on reasonable assumptions, including but not limited to, the ratio (8.4%) of ICU days (excluding neonatal ICU days) to total acute care days which is based on grouping ratios for all hospitals in the State and taking the average of the ratios in the lower 50%. The applicants adequately demonstrate the need the patients proposed to be served have for four ICU beds at FMC-Clemmons.

Unlicensed Observation Beds – The applicants propose to develop six unlicensed observation beds at FMC-Clemmons. In Section III.1(b), page 125, the applicants state

"CLMC reviewed historical utilization of observation beds and days for all hospitals in North Carolina reporting observation days in the 2008 Hospital Licensure Renewal Application. This data is included in Exhibit 5, Table 16. Utilization of observation days was varied across hospital sizes and services. However, at hospitals with designated observation units, the mean ratio of acute inpatient days to observation days was 1:14.3, the median ratio was 1:10.3, and the data was bi-modal with modes at 1:9.8 and 1:9.0 acute care days. CLMC used 9.8 acute care days to one observation day to project future observation bed need at CLMC.

Furthermore, the FFY 2007 observation day utilization data from BCH, TMC, PHM and PHH reflect [sic] *ratio of 9.0 acute care days to one observation day. The average of these four facilities is a reasonable assumption consistent with previously approved CON applications. However, CLCM utilized the more conservative ratio, 9.8 acute care days per 1 observation day based upon the review of 2008 LRAs to project observation bed need at CLMC."*

The following table summarizes the applicants' methodology and assumptions used to project utilization of the six unlicensed observation beds at FMC-Clemmons, which are provided in Section III.1(b), page 125, and Exhibit 5, Tables 6 and 16.

UNLICENSED OBSERVATION BEDS	YEAR 1	YEAR 2	YEAR 3
Total acute care patient days	11,438	12,696	13,994
Projected observation days [ratio of 1 observation day for every 9.8 acute care days, which is 10.2% (1 / 9.8 = 0.102)]	1,167	1,295	1,428
ADC (observation days / 365)	3.2	3.5	3.9
# of unlicensed observation beds	6	6	6
% occupancy (ADC / # of beds)	53.3%	58.3%	65.0%

As shown in the above table, the applicants project the unlicensed observation beds will provide 1,428 days of care in 6 beds, which is an ADC of 3.9 and an occupancy rate of 65%. Projected utilization of the unlicensed observation beds is based on reasonable assumptions, including but not limited to, the ratio (10.2%) of observation days to total acute care days which is based on the higher of the two most frequent ratios (i.e., modes) for all hospitals in North Carolina with a dedicated observation unit. The applicants adequately demonstrate the need the patients proposed to be served have for six unlicensed observation beds at FMC-Clemmons.

Operating Rooms – The applicants propose to relocate five existing shared ORs from MPH to FMC-Clemmons. The applicants assumptions and methodology used to project utilization of the five shared ORs at FMC-Clemmons are provided in Section III.1(b), pages 126-129, and are summarized as follows.

Furthermore, the FFY 2007 observation day utilization data from BCH, TMC, PHM and PHH reflect [sic] *ratio of 9.0 acute care days to one observation day. The average of these four facilities is a reasonable assumption consistent with previously approved CON applications. However, CLCM utilized the more conservative ratio, 9.8 acute care days per 1 observation day based upon the review of 2008 LRAs to project observation bed need at CLMC."*

The following table summarizes the applicants' methodology and assumptions used to project utilization of the six unlicensed observation beds at FMC-Clemmons, which are provided in Section III.1(b), page 125, and Exhibit 5, Tables 6 and 16.

UNLICENSED OBSERVATION BEDS	YEAR 1	YEAR 2	YEAR 3
Total acute care patient days	11,438	12,696	13,994
Projected observation days [ratio of 1 observation day for every 9.8 acute care days, which is 10.2% (1 / 9.8 = 0.102)]	1,167	1,295	1,428
ADC (observation days / 365)	3.2	3.5	3.9
# of unlicensed observation beds	6	6	6
% occupancy (ADC / # of beds)	53.3%	58.3%	65.0%

As shown in the above table, the applicants project the unlicensed observation beds will provide 1,428 days of care in 6 beds, which is an ADC of 3.9 and an occupancy rate of 65%. Projected utilization of the unlicensed observation beds is based on reasonable assumptions, including but not limited to, the ratio (10.2%) of observation days to total acute care days which is based on the higher of the two most frequent ratios (i.e., modes) for all hospitals in North Carolina with a dedicated observation unit. The applicants adequately demonstrate the need the patients proposed to be served have for six unlicensed observation beds at FMC-Clemmons.

Operating Rooms – The applicants propose to relocate five existing shared ORs from MPH to FMC-Clemmons. The applicants assumptions and methodology used to project utilization of the five shared ORs at FMC-Clemmons are provided in Section III.1(b), pages 126-129, and are summarized as follows.

- On page 127, the applicants state *"CLMC projected surgical utilization for the first three years of operation using the following methodology:*

Projected Inpatient Surgical Cases = (Defined Service Area Population x Inpatient Surgical Use Rate x Market Share) + 'Other Inmigration'

AND

Projected Outpatient Surgical Cases = (Defined Service Area Population x Outpatient Surgical Use Rate x Market Share) + 'Other Inmigration'"

- On page 126, the applicants state *"Inpatient and outpatient cases from Forsyth and Davie County were aggregated from the 2008 Hospital Licensure Renewal Applications and the 2008 Freestanding Ambulatory Surgery Center Annual Licensure Renewal Applications. County population estimates for 2007 were obtained from the North Carolina Office of State Demographics. Inpatient and outpatient surgical use rates for 2007 were calculated for Forsyth and Davie Counties, respectively."* The following table illustrates the inpatient and outpatient surgical use rates, as provided by the applicants on page 126, and Exhibit 5, Table 20.

COUNTY	INPATIENT SURGICAL USE RATE PER 1,000 POPULATION	OUTPATIENT SURGICAL USE RATE PER 1,000 POPULATION
Forsyth	32.98	67.54
Davie	32.50	77.73

- On page 126, the applicants state *"The county specific surgical use rate for each zip code was used to determine total inpatient and outpatient surgery in the defined service area for the first three years of proposed project."*

- On page 126, the applicants state "*Using FFY 2007 inpatient and outpatient surgical case data from 2008 Hospital Licensure Renewal Application, CLMC calculated the Novant surgical market share for each county."* The following table illustrates Novant's current market share for inpatient and outpatient surgical services in Forsyth and Davie counties, as

provided by the applicants on page 127, and Exhibit 5, Tables 22 and 23.

COUNTY	NOVANT'S CURRENT MARKET SHARE FOR SURGICAL SERVICES		
	INPATIENT	OUTPATIENT	TOTAL
Forsyth	67.1%	57.7%	60.8%
Davie	57.6%	55.2%	55.9%
Total	66.1%	57.4%	60.2%

- On page 127, the applicants state they assume that 59% of the inpatient surgical cases currently being performed on residents of the service area at FMC and MPH would shift to FMC-Clemmons. The applicants assume that 85% of the outpatient surgical cases currently performed on residents of the service area at FMC and MPH would shift to FMC-Clemmons. The applicants also assume *"that the proposed market shift from FMC and MPH in Winston Salem will occur gradually over the first three years of CLMC operation."* The following table illustrates the projected shift from FMC and MPH, as provided by the applicants on page 127, and Exhibit 5, Table 19.

	PROJECTED SHIFT FROM FMC AND MPH		
	YEAR 1	YEAR 2	YEAR 3
Inpatient	80% of 59% (47.2%)	90% of 59% (53.1%)	100% of 59% (59%)
Outpatient	80% of 85% (68%)	90% of 85% (76.5%)	100% of 85% (85%)

On page 129, the applicants state *"The following factors were considered important to the determination of the percent of market volume projected to shift from the zip code service area.*

- *Surgical scheduling for all NHTR surgical facilities is centralized and surgical administration works with physicians and patients to maximize utilization of surgical resources.* [sic]
- *CLMC is closer to all areas of each of the five zip codes than existing NHTR Winston Salem facilities as reflected in Exhibit 5. Table 1 and Map 5;*
- *There currently are four NMG-Forsyth employed practices in the defined service area: Medical Associates of Davie/Mocksville - 27028 & Medical Associates of Davie/Hillsdale - 27006 (7 MDs, 5 extenders); Clemmons*

Family Practice/Clemmons - 27012 (3 MDs, 2 extenders), Family Medical Associates of Lewisville/Lewisville - 27023 (5 MDs); and West Forsyth Family Medicine/Clemmons - 27012 (1 MD, 2 extenders); a total of 28 medical providers with established practices and satisfied patients;

- *These established physician practices and other nearby NMG practices combined have existing doctor-patient relationships with 45,200 patients that reside in the CLMC 5-Zip Code service area for the most recent 12-month period (June 1, 2007 – May 31, 2008). NMG patient visits during that same time period for the these residents of Clemmons, Lewisville, Davie County were over 150,000;*
- *Additional physician offices with easier access will be developed in the future on the CLMC campus;*
- *Congestion and traffic on I-40 into Winston Salem will increase;*
- *CLMC offers a choice for surgical services closer to home;*
- *The proposed location of CLMC adjacent to I-40 and the Harper Rd. interchange, just two miles from the Davie Counts border, 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 existing surgical facilities, therefore 100% of the demand for services in the five zip codes will not shift to CLMC;*
- *Based upon an analysis of both acuity-adjusted inpatient surgery as a percent of total surgery at FMC and MPH and as a percent of total surgery for the service area at FMC and MPH, 65% to 70% of total surgery performed at FMC and MPH is appropriate for the proposed surgical services program at CLMC."*

The following table illustrates projected utilization of the five shared ORs at FMC-Clemmons, as provided by the applicants in Section III.1(b), page 128, and Exhibit 5, Table 19.

Faculty Associates (Washington D.C), Maine General Health (Augusta, ME), Advocate Health Partners (Mt Prospect, IL), University of Mississippi Medical Center, Holston Medical Group (Kingsport, TN), Healthcare Partners Medical Group (Torrence, CA), Sierra Health Services & Southwest Medical Associates (Las Vegas), UMass Memorial Healthcare (Worcester, MA). See the article in Exhibit 13. This reflects Novant's focus on continuing to improve key processes of patient care delivery in the future and this initiative will be undertaken at CLMC when it opens.

Novant Health continues to invest major capital in the installation of an electronic medical record (EMR) at six locations within the next two years and eventually with the remaining 256 Novant Health locations. Novant's commitment to the EMR conversion represents a mindset for capturing essential medical and patients [sic] *information to allow providers speedier access to patient information and to give nurses and physicians more decision making tools. The EMR will also serve to decrease harmful errors caused by handwritten notes and will significantly improve access to medical information from almost any location. See the article in Exhibit 13.*

Novant Health is one of the first health systems in the nation to invest in the Microsoft Amalga system, which pulls together patient medical information from multiple sources, such as imaging, lab, pharmacy and surgery and presents it all in one single view for physicians. Novant believes this system will reduce the administrative burden (of gathering this information from (disparate sources) on physicians, so that they can better spend their time and expertise on patient care management and decision making. See the article in Exhibit 13. The EMR, Amalga, and ePrescribing initiative illustrate Novant and CLMC's commitment to the improvement of patient care, including clinical ancillary services such as lab, imaging, and pharmacy, through the simplification and error-proofing of key processes of care.

Furthermore, in May 2007 Novant Health, Inc. announced its participation with a group of the nation's leading

OPERATING ROOMS	YEAR 1	YEAR 2	YEAR 3
Projected # of Inpatient Cases (Population by County x Use Rate per 1,000 x County x Market Share for each County x Projected Shift from FMC and MPH)	885	1,012	1,144
Projected # of Outpatient Cases (Population by County x Use Rate per 1,000 x County x Market Share for each County x Projected Shift from FMC and MPH)	2,578	2,951	3,336
Inpatient Hours (# of cases x 3 hrs / case)	2,655	3,036	3,432
Outpatient Hours (# of cases x 1.5 hrs / case)	3,867	4,427	5,004
Total Hours	6,522	7,463	8,436
Total Hours / 1,872 hrs per OR per year	3.5	4.0	4.5

The applicants adequately demonstrate that projected utilization of the five shared ORs at FMC-Clemmons is based on reasonable and supported assumptions. Therefore, the applicants adequately demonstrate the need the patients proposed to be served have for five shared ORs at FMC-Clemmons.

The applicant provides an Impact Analysis in Section III.8(c), page 161, and Exhibit 5, regarding utilization of ORs at FMC-Winston-Salem, FMC-Kernersville and MPH following the proposed relocation. The applicants adjusted their utilization projections to account for the patients expected to shift from MPH and FMC to FMC-Clemmons. The following table illustrates the number of ORs at FMC and MPH upon completion of this project and all previously approved projects.

TYPE OF OR	FMC		MPH	
	EXISTING & APPROVED (1) (2)	THIS PROPOSAL	EXISTING & APPROVED (2)	THIS PROPOSAL
Open Heart	3	3	0	0
Dedicated C-section	2	2	0	0
Dedicated Outpatient	8	8	0	0
Shared	22	27	12	7
TOTAL	**35**	**40**	**12**	**7**

(1) Effective January 1, 2008, the four dedicated outpatient ORs at Hawthorne Surgical Center (HSC) were added to FMC's license. Novant is the ultimate parent of HSC, which is located on FMC's campus.

(2) Includes changes resulting from the following approved projects:

- Project I.D. #G-7412-05 – The certificate of need issued March 6, 2007 authorizes FMC to develop two additional shared ORs by converting two existing GI endoscopy rooms.
- Project I.D. #G-7412-05 – The certificate of need issued March 6, 2007 authorizes HSC to develop two additional shared ORs by relocating and converting two of FMC's existing GI endoscopy rooms.
- Project I.D. #G-7604-06 – The certificate of need issued July 24, 2007 authorizes FMC to relocate three existing ORs from FMC and one existing OR from MPH to Kernersville.

The following table illustrates the number of inpatient surgical cases (excluding open heart cases and C-sections) and outpatient surgical cases projected to be performed during the first three operating years at FMC and MPH. In Exhibit 5, the applicants state projected utilization of the ORs at FMC and MPH is based on FFY 2007 surgical use rates for residents of Forsyth and Davie counties which is calculated from patient origin data in the 2008 license renewal applications submitted by all hospitals and ambulatory surgical facilities, historical Novant market share and projected population by zip code. Projected utilization was adjusted to account for the patients currently utilizing the ORs at FMC-Winston-Salem and MPH who reside in the proposed service area (primary and inmigration) and are expected to shift to FMC-Clemmons.

	FMC				MPH
	WINSTON-SALEM CAMPUS (includes HSC)	KERNERSVILLE CAMPUS	CLEMMONS CAMPUS	TOTAL	
4/1/07 - 3/31/08					
Inpatient Cases	9,791			9,791	1,170
Outpatient Cases	6,320			6,320	10,508
Inpatient Hours (# of cases x 3 hrs / case)	29,373			29,373	3,510
Outpatient Hours (# of cases x 1.5 hrs / case)	9,480			9,480	15,762
Total Hours	38,853			38,853	19,272
Total Hours / 1,872 hrs per OR per year	20.8			20.8	10.3
Year One (4/1/12 - 3/31/13)					
Inpatient Cases	9,510	1,156	885	11,551	587
Outpatient Cases	13,183	2,596	2,578	18,357	8,464
Inpatient Hours (# of cases x 3 hrs / case)	28,530	3,468	2,655	34,653	1,761
Outpatient Hours (# of cases x 1.5 hrs / case)	19,775	3,894	3,867	27,536	12,696
Total Hours	48,305	7,362	6,522	62,189	14,457
Total Hours / 1,872 hrs per OR per year	25.8	3.9	3.5	33.2	7.7
Year Two (4/1/13 - 3/31/14)					
Inpatient Cases	9,530	1,180	1,012	11,722	554
Outpatient Cases	13,203	2,648	2,951	18,802	8,329
Inpatient Hours (# of cases x 3 hrs / case)	28,590	3,540	3,036	35,166	1,662
Outpatient Hours (# of cases x 1.5 hrs / case)	19,805	3,972	4,427	28,203	12,494
Total Hours	48,395	7,512	7,463	63,369	14,156
Total Hours / 1,872 hrs per OR per year	25.9	4.0	4.0	33.9	7.6
Year Three (4/1/14 - 3/31/15)					
Inpatient Cases	9,577	1,204	1,144	11,925	487
Outpatient Cases	13,219	2,701	3,336	19,256	8,100
Inpatient Hours (# of cases x 3 hrs / case)	28,731	3,612	3,432	35,775	1,461
Outpatient Hours (# of cases x 1.5 hrs / case)	19,829	4,052	5,004	28,884	12,150
Total Hours	48,560	7,664	8,436	64,659	13,611
Total Hours / 1,872 hrs per OR per year	25.9	4.1	4.5	34.5	7.3

The applicants adequately demonstrate that projected utilization of all the ORs at Novant's Forsyth County facilities is based on reasonable and supported assumptions regarding inpatient and outpatient surgical use rates per 1,000 population, projected population and Novant's historical market share which was held constant.

Further, the applicants provide an Impact Analysis in Exhibit 5, regarding the impact the development of FMC-Clemmons will have on utilization of the ORs at North Carolina Baptist Hospital and DCH. On page 1 of the Impact Analysis in Exhibit 5, the

applicants state *"The proposed project is based upon market volume shift from the service area which currently is provided at FMC and MPH to CLMC. No increase in market share is projected, therefore, no market volume shift is assumed from either NCBH or DCH."* On page 4 of the Impact Analysis is Exhibit 5, the applicants state they believe *"that there are and will continue to be more than enough patients in the area to support the continued high utilization of the existing area hospitals and the proposed 50 bed community hospital in Clemmons. All health care providers are well positioned to benefit from the growth in the greater Clemmons area."*

To critique the applicants' Impact Analysis, the following table was prepared by the analyst to compare surgical utilization projected by FMC-Clemmons for residents of the proposed primary service areas, to the total number of surgical cases projected in the FMC-Clemmons and DCH applications.

Step		2012	2013	2014	2015
	Projected OR Utilization by Residents of the Primary Service Area				
1	Projected Population of Davie County + 2 Zip Codes in Forsyth County, which is the primary service area for FMC-Clemmons. (See page 120 of the FMC-Clemmons application for projected population data.)	82,696	84,138	85,606	87,100
2	Projected Population of 1 Zip Code in Yadkin County, which is included in DCH's primary service area but not FMC-Clemmons' primary service area. (from page 53 of the previously approved DCH application)	13,577	13,591	13,604	13,618
3	Total Projected Population (Step 1 + Step 2)	96,273	97,729	99,210	100,718
4	Inpatient Surgical Use Rate per 1,000 Population (average of Forsyth & Davie counties) (from page 126 of the FMC-Clemmons application)	32.74	32.74	32.74	32.74
5	Outpatient Surgical Use Rate per 1,000 Population (average of Forsyth & Davie counties) (from page 126 of the FMC-Clemmons application)	72.63	72.63	72.63	72.63
6	Total Projected Inpatient Cases (Step 3 x Step 4 / 1,000)	3,152	3,200	3,248	3,298
7	Total Projected Outpatient Cases (Step 3 x Step 5 / 1,000)	6,992	7,098	7,206	7,315
8	Total Surgical Cases (Step 6 + Step 7)	10,144	10,298	10,454	10,613
	Projected OR Utilization at FMC-Clemmons and DCH				
9	FMC-Clemmons (from page 128 of the FMC-Clemmons application)		3,463	3,963	4,480
10	DCH (from page 28 of the findings for the previously approved DCH application)	2,622	2,714	2,799	2,892
11	Total (Step 9 + Step 10)	2,622	6,177	6,762	7,372
12	% of Total Surgical Cases for Service Area (Step 11 / Step 8)	25.8%	60.0%	64.7%	69.5%
	# of ORs Projected to be Utilized by Residents of the Service Area				
13	Projected Inpatient Hours (# of cases x 3 hrs per case) (Step 6 x 3)	9,456	9,599	9,744	9,893
14	Projected Outpatient Hours (# of cases x 1.5 hrs per case) (Step 7 x 1.5)	10,488	10,647	10,808	10,973
15	Total Hours (Step 13 + Step 14)	19,944	20,246	20,553	20,865
16	Total Hours / 1,872 hours per OR per year	11	11	11	11
	# of ORs Proposed at FMC-Clemmons and DCH				
17	FMC-Clemmons	5	5	5	5
18	DCH	2	2	2	2
19	Total	7	7	7	7

As shown in the above table, FMC-Clemmons and DCH together propose to perform approximately 7,372 surgical cases (including

inmigration cases) in CY 2015, which is only 70% of the surgical cases from the proposed primary service area that were projected by FMC-Clemmons, plus the surgical cases from Zip Code area 27055 [7,372 / 10,613 = 0.695]. Consequently, based on data provided by FMC-Clemmons, the analyst concluded that the number of potential patients in the primary service area is sufficient to justify the need for the five proposed ORs at FMC-Clemmons, in addition to the two previously approved ORs at DCH.

GI Endoscopy Room – The applicants propose to develop one additional GI endoscopy room at FMC-Clemmons. The applicants assumptions and methodology used to project utilization of the proposed GI endoscopy room at FMC-Clemmons are provided in Section III.1(b), pages 129-132, and are summarized as follows.

- On page 131, the applicants state *"CLMC projected GI endoscopy cases for the first three years of operation using the following methodology:*

  Projected GI Endoscopy Cases = (Defined Service Area Population x GI Endoscopy Use Rate x Market Share) + 'Other Inmigration'

- On page 129, the applicants state *"GI endoscopy cases from Forsyth and Davie County were aggregated from the 2008 Hospital Licensure Renewal Applications and the 2008 Freestanding Ambulatory Surgery Center Annual Licensure Renewal Applications. County population estimates for 2008 were obtained from the North Carolina Office of State Demographics. The GI endoscopy use rate per 1,000 population for 2007 was calculated for Forsyth and Davie Counties, respectively."* The following table illustrates the GI endoscopy use rates, as provided by the applicants on page 130, and Exhibit 5, Table 29.

COUNTY	GI ENDOSCOPY USE RATE PER 1,000 POPULATION
Forsyth	59.15
Davie	59.52

- On page 130, the applicants state *"The county specific GI endoscopy use rate was used to determine total GI endoscopy*

cases by zip code in the defined service area for the first three years of the proposed project."

- On page 130, the applicants state "*Using 2007 GI endoscopy case data from the hospital* [and ambulatory surgical facility] *licensure renewal applications, CLMC calculated the Novant market share for both Forsyth and Davie County."* The following table illustrates Novant's current market share for GI endoscopy services in Forsyth and Davie counties, as provided by the applicants on page 130, and Exhibit 5, Tables 29-31.

COUNTY	NOVANT'S CURRENT MARKET SHARE FOR GI ENDOSCOPY SERVICES
Forsyth	22.1%
Davie	17.0%

- On page 130, the applicants state *"CLMC GI endoscopy projections reflect an increase in market share .... Currently the only GI endoscopy procedure room in the service area is located in Mocksville. Projected GI endoscopy volume in the service area can justify 4.4 additional GI endoscopy rooms in the future based* [sic] *population growth and upon 1,500 procedures annually per room."* The applicants assume a 15% increase in Novant's market share in both Forsyth and Davie counties. Thus, by the third operating year, the applicants assume that Novant's market share for Forsyth County will increase to 37.1% [22.1% + 15% = 37.1%] and the market share for Davie County will increase to 32% [17% + 15% = 32%]. However, the applicants do not state why they assume Novant's market share for GI endoscopy services in Forsyth and Davie counties would increase 15% as a result of this project and do not provide any discussion to support the reasonableness of this assumption.

- On page 131, the applicants state "*CLMC also assumed that the proposed market shift, 85% of total volume currently at FMC, will occur gradually over the first three years of CLMC operation, realizing 80% of projected market share in Project Year 1, 90% in Project Year 2, and 100% in Project Year 3."*

- On pages 131-132, the applicants state *"CLMC reviewed 2008 Hospital Licensure Renewal Application GI endoscopy data, included in Exhibit 5, Table 29, to determine that 6.1% of*

endoscopy cases in GI endoscopy rooms are for bronchoscopy and other non-GI endoscopy procedures and that 1.29 GI endoscopy procedures are performed per endoscopy case at existing Novant Health community hospitals. Projected GI endoscopy cases were adjusted to delete non-GI endoscopy procedures and were then multiplied by [sic] *average 1.29 procedures per case to determine projected GI endoscopy procedures."*

However, the application contains inconsistent and unreconcilable information regarding the number of procedures projected to be performed in the GI endoscopy room at FMC-Clemmons. The following table illustrates projected utilization of the GI endoscopy room at FMC-Clemmons, as provided by the applicants in Exhibit 5, Table 29.

	FMC-CLEMMONS # OF GI ENDOSCOPY CASES AND PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM, AS PROVIDED BY THE APPLICANTS IN TABLE 29	
	TOTAL GI ENDOSCOPY CASES	TOTAL GI ENDOSCOPY PROCEDURES (1.29 procedures per case)
Year One	1,201	1,546
Year Two	1,375	1,770
Year Three	1,554	2,000

In contrast, in Exhibit 5, Table 32, the applicants provide different projections as illustrated in the following table. The applicants state that Table 32 includes all procedures (GI endoscopy and non-GI endoscopy) projected to be performed in the proposed GI endoscopy room.

	FMC-CLEMMONS TOTAL # OF PROCEDURES (INCLUDING NON-GI ENDOSCOPY PROCEDURES) PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM AS PROVIDED BY THE APPLICANTS IN TABLE 32
Year One	1,546
Year Two	1,770
Year Three	2,000

As shown in the two tables above, the number of GI endoscopy procedures provided by the applicants in Exhibit 5, Table 29 is the same as the total number of procedures (GI endoscopy and non-GI

endoscopy) provided in Exhibit 5, Table 32. However, in Section II.8, page 63, the applicants state that 6% of all procedures are projected to be non-GI endoscopy procedures. Thus, based on the 6% assumption and numbers in Table 32, the number of GI endoscopy procedures would be only 1,453 in Year One, 1,664 in Year Two and 1,880 in Year Three. The inconsistent projections cannot be reconciled.

Further, the applicants provided inconsistent and unreconcilable; information regarding the number of GI endoscopy procedures projected to be performed at FMC-Winston-Salem. The following table illustrates the number of GI and non-GI endoscopy procedures projected to be performed in the four existing GI endoscopy rooms at FMC-Winston-Salem, as provided by the applicants in Table 33.

	FMC-WINSTON-SALEM TOTAL # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE FOUR EXISTING GI ENDOSCOPY ROOMS AS PROVIDED BY THE APPLICANTS IN TABLE 33		
	GI ENDOSCOPY PROCEDURES	NON-GI ENDOSCOPY PROCEDURES	TOTAL PROCEDURES
Year One	14,185	986	15,171
Year Two	14,339	997	15,336
Year Three	14,494	1,008	15,502

However, in Exhibit 5, Table 30, the applicants provide different projections for FMC-Winston-Salem, as illustrated in the following table. (See also Section II.8, page 68, of the application.)

	FMC-WINSTON-SALEM # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE EXISTING GI ENDOSCOPY ROOMS, AS PROVIDED BY THE APPLICANTS IN TABLE 30
Year One	13,624
Year Two	13,566
Year Three	13,502

The applicants do not state whether the projected procedures in Table 30 include only the GI endoscopy procedures or all types of procedures projected to be performed in the four existing GI endoscopy rooms on the FMC-Winston-Salem campus. Regardless, the projections provided by the applicants in Table 30

are not consistent with any of the projections provided in Table 33 and cannot be reconciled.

In addition, the application contains inconsistent and unreconcilable information regarding the number of patients to be served in the existing GI endoscopy rooms at FMC-Winston-Salem. In Section II.8, page 64, and Exhibit 5, Table 30, the applicants provide the number of GI endoscopy patients projected to be served in the existing GI endoscopy rooms at FMC-Winston-Salem in each of the first three operating years, as illustrated in the following table.

FMC-WINSTON-SALEM	YEAR ONE	YEAR TWO	YEAR THREE
Projected GI endoscopy patients	7,171	7,140	7,106

However, in Exhibit 5, Table 33, the applicants provide different projections for the number of GI endoscopy patients to be served, as illustrated in the following table.

FMC-WINSTON-SALEM	YEAR ONE	YEAR TWO	YEAR THREE
Projected GI endoscopy patients	7,466	7,547	7,629
Projected non-GI endoscopy patients	519	524	530
Total	7,985	8,071	8,159

As shown in the two tables above, the patient projections provided by the applicants in Tables 30 and 33 are not consistent and cannot be reconciled.

Moreover, the applicants failed to demonstrate that GI endoscopy procedures are not and will not be performed in the ORs at MPH, as required by 10A NCAC 14C .3903(d). MPH is owned by Novant (a co-applicant) and is located in Forsyth County, which is one of the counties included in the proposed service area.

Further, the applicants' GI endoscopy service area also includes Yadkin and Iredell counties because a percentage of the patients to be served in the new facility reside in these counties. Novant is a minority owner of Davis Regional Medical Center (Davis) and Lake Norman Regional Medical Center (Lake Norman), which makes them related entities as defined in 10A NCAC 14C .3901(5). Both of these facilities are located in Iredell County. According to Davis' 2008 Hospital License Renewal Application, during FFY 2007, 31 GI endoscopy procedures were performed at Davis but not in one of the two existing GI endoscopy rooms. The

applicants do not demonstrate that GI endoscopy procedures were not performed in the six shared ORs at Davis or the seven shared ORs at Lake Norman in the last 12 months and will not be performed in those rooms in the future as required by 10A NCAC 14C .3903(d).

In summary, the applicants did not adequately demonstrate the need the population proposed to be served have for one new GI endoscopy room at FMC-Clemmons. Therefore, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons.

Emergency Department – The applicants propose to develop a new ED at the proposed FMC-Clemmons campus with 12 new treatment rooms. The applicants assumptions and methodology used to project utilization of the proposed ED at FMC-Clemmons are provided in Section III.1(b), pages 135-141, and are summarized as follows.

- On page 138, the applicants state *"CLMC projected emergency department visits for the first three years of operation using the following methodology:*

  Projected Emergency Department Visits = (Defined Service Area Population x North Carolina Hospital Emergency Department Visit Use Rate x Market Share) + 'Other Inmigration'"

- On page 135, the applicants state *"CLMC used the North Carolina Emergency Department Visit Use Rate for community hospitals defined by the American Hospital Association (AHA) to project emergency department visits."* In Exhibit 5, Table 38, the applicants provide supporting documentation which shows that the North Carolina ED use rate in 2006 was 434 per 1,000 population. On page 135, the applicants state that they held the ED use rate constant through the third operating year of the project.

- On pages 135-136, the applicants state *"The projected North Carolina Emergency Department Visit Use Rate was used to determine total emergency department visits and NHTR Winston Salem market share by zip code in the defined service area for the first three years of the proposed project ...* [u]*sing April 2007*

– March 2008 emergency visit data from the NHTR internal Trendstar database."

- On page 136, the applicants state that they assume 85% of the residents of the five zip codes in the primary service area currently utilizing the FMC ED in Winston-Salem will shift to the new ED at FMC-Clemmons. On page 138, the applicants state that they assume the shift would *"occur gradually over the first three years of operation, realizing 70% of projected market share in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3."*

- On page 136, the applicants state they assume their market share will increase 30% in the Clemmons (27012) and Advance (27006) zip code areas. On page 137, the applicants state *"The following factors were considered important to the determination the projected CLMC market share of emergency visits from each zip code:*

  - *The new hospital will bring a new emergency service to a growing population;*
  - *As a community hospital patients will avoid the confusion and wait times associated with larger trauma centers and busy urban emergency departments.*
  - *CLMC is closer to areas of each of the five zip codes than existing NHTR Winston Salem facilities as reflected in Exhibit 5, Table 1 and Map 7 resulting in shorter travel time for emergency services;*
  - *The proposed location of CLMC adjacent to I-40 at the Harper Rd. interchange will result in ease of access for the existing population in the defined service area;*
  - *Some patients will choose to seek emergency care at other NHRT Winston Salem hospitals, and the protocols for emergency care defined by FMC with area ambulance providers will result in bypassing CLMC emergency department less than 5% of the time, therefore 100% of the demand for services in the five zip codes will not shift to CLMC."*

- On page 137, the applicants state *"Furthermore, ... according to a recent American College of Emergency Physicians (ACEP) report, The national Report card on the State of Emergency*

Medicine, North Carolina earned a 'C-overall for its support of emergency care.'"

- On page 139, the applicants state they assume 1,333 ED visits per treatment room based on the guidelines of the American College of Emergency Physicians. See Exhibit 5, Table 40.

The following table illustrates projected utilization of the ED at FMC-Clemmons during the first three operating years, as provided by the applicants in Section III.1(b), page 139, and Exhibit 5, Table 36.

EMERGENCY DEPARTMENT	YEAR ONE	YEAR TWO	YEAR THREE
Projected # of ED Visits [(Population by County x NC ED Use Rate per 1,000 Population x Market Share) + Other Inmigration]	11,020	13,616	16,300
# of ED Treatment Rooms	12	12	12
Average # of ED Visits per Treatment Room	918.3	1,134.6	1,358.3

As shown in the above table, the applicants project 16,300 ED visits at FMC-Clemmons during the third operating year, which is an average of 1,358.3 visits per treatment room. The applicants adequately demonstrate that the projected number of ED visits at FMC-Clemmons is based on reasonable assumptions.

The applicant provides an Impact Analysis in Section III.1(b), pages 139-141, and Exhibit 5, Table 43, on all existing EDs in Forsyth, Davie and Yadkin counties, regardless of provider. The following table illustrates the existing EDs located in Forsyth, Davie and Yadkin counties, as reported by the applicants in Exhibit 5, Table 43, or the hospitals in their 2008 Hospital License Renewal Applications.

HOSPITAL	# OF EXISTING ED TREATMENT ROOMS	# OF PREVIOUSLY APPROVED ADDITIONAL ED TREATMENT ROOMS	TOTAL # OF ED TREATMENT ROOMS
Forsyth Medical Center			
Winston-Salem campus	59	0	59
Kernersville campus	0	14	14
Total	59	14	73
North Carolina Baptist Hospital	47	31	78
Davie County Hospital	9	7	16
Hoots Memorial Hospital [1]	4	0	4
Total	119	52	171

[1] FMC-Clemmons states that Hoots Memorial Hospital has 18 ED treatment rooms. However, according to its 2008 Hospital License Renewal Application, Hoots Memorial Hospital has only 4 ED treatment rooms.

On page 139, the applicants provide data that shows total ED visits for all providers increased an average of 6.9% per year between 2003 and 2007 in Forsyth, Davie and Yadkin counties. On page 140, the applicants provide data that shows total ED visits for all providers increased an average of 4.6% per year between 2003 and 2007 in Forsyth, Davie, Yadkin, Davidson, Stokes, Surry, Guilford and Wilkes counties. The following table illustrates projected ED utilization in Forsyth, Davie and Yadkin counties in 2015 (Year Three) based on FMC-Clemmons' 6.9% and 4.6% growth rates, respectively. Further, the table illustrates the number of ED treatment rooms needed in Forsyth, Davie and Yadkin counties assuming 1,350 ED visits per treatment room per year.

	PROJECTED ED UTILIZATION IN FORSYTH, DAVIE & YADKIN COUNTIES IN 2015 (YEAR THREE)	
	4.6% GROWTH RATE	6.9% GROWTH RATE
Projected # of ED Visits in 2015 (Year Three)	294,504	349,955
# of ED Treatment Rooms Needed assuming 1,350 Visits per Treatment Room per Year	218	259
# of Existing and Approved ED Treatment Rooms [1]	171	171
Deficit	47	88

[1] Includes FMC, North Carolina Baptist Hospital, Davie County Hospital and Hoots Memorial Hospital.

As shown in the above table, using the applicants' assumptions of a 4.6% growth rate and 1,350 ED visits per treatment room per year, there would be a deficit of 47 ED treatment rooms in Forsyth,

Davie and Yadkin counties in 2015. Further, using the applicants' assumptions of a 6.9% growth rate and 1,350 ED visits per treatment room per year, there would be a deficit of 88 ED treatment rooms in the same counties in 2015.

The analyst also analyzed the need for ED treatment rooms in Forsyth, Davie and Yadkin counties in 2015 using the applicants' projected growth rates, but assuming 1,500 ED visits per treatment room per year rather than 1,350, as illustrated in the following table.

	PROJECTED ED UTILIZATION IN FORSYTH, DAVIE & YADKIN COUNTIES IN 2015 (YEAR THREE)	
	4.6% GROWTH RATE	**6.9% GROWTH RATE**
Projected # of ED Visits in 2015 (Year Three)	294,504	349,955
# of ED Treatment Rooms Needed assuming 1,500 Visits per Treatment Room per Year	196	233
# of Existing and Approved ED Treatment Rooms	171	171
Deficit	25	62

As shown in the above table, assuming a growth rate of 4.6% per year and 1,500 ED visits per treatment room per year, there would be a deficit of 25 ED treatment rooms in Forsyth, Davie and Yadkin counties in 2015. However, assuming a growth rate of 6.9% and 1,500 ED visits per treatment room per year, there would be a deficit of 62 ED treatment rooms in the same counties in 2015. Based on the two previous tables, the applicants demonstrate the need for at least 12 new ED treatment rooms in the proposed primary service area by 2015.

To critique the applicants' Impact Analysis, the following table was prepared by the analyst to compare ED utilization projected by FMC-Clemmons for residents of Davie County, the Zip Code areas for Clemmons (27012) and Lewisville (27023) in Forsyth County and Zip Code area 27055 in Yadkin County, to ED visits projected in the FMC-Clemmons and DCH applications.

Step		2012	2013	2014	2015
	Projected ED Utilization by Residents of the Primary Service Area				
1	Projected Population of Davie County + 2 Zip Codes in Forsyth County, which is the primary service area for FMC-Clemmons. (See page 120 of the FMC-Clemmons application for projected population data.)	82,696	84,138	85,606	87,100
2	Projected Population of 1 Zip Code in Yadkin County, which is included in DCH's primary service area but not FMC-Clemmons' primary service area. (from page 53 of the previously approved DCH application)	13,577	13,591	13,604	13,618
3	Total Projected Population (Step 1 + Step 2)	96,273	97,729	99,210	100,718
4	ED Use Rate per 1,000 Population (from page 135 of the FMC-Clemmons application)	434	434	434	434
5	Projected ED Visits (Population x Use Rate / 1,000) (Step 3 x Step 4 / 1,000)	41,782	42,414	43,057	43,712
6	# of ED treatment rooms needed in the primary service area at 1,500 visits per treatment room per year (Step 5 / 1,500)	27.9	28.3	28.7	29.1
7	# of existing and approved ED treatment rooms in the primary service area [DCH (16)]	16	16	16	16
8	Deficit of ED Treatment Rooms in Primary Service Area (Step 6 – Step 7)	11.9	12.3	12.7	13.1
	Projected Utilization of the EDs at FMC-Clemmons and DCH				
9	FMC-Clemmons projected ED visits (from page 139 of the FMC-Clemmons application)		11,020	13,616	16,300
10	DCH projected ED visits (from page 71 of the previously approved DCH application)	16,915	18,042	19,255	20,545
11	Total (Step 9 + Step 10)	16,915	29,062	32,871	36,845
12	% of Total ED visits for service area (Step 11 / Step 5)	40.5%	68.5%	76.3%	84.3%

As shown in the above table, FMC-Clemmons and DCH together propose to provide 36,845 ED visits in CY 2015, which is approximately 84% of the ED visits from the primary service area that were projected by FMC-Clemmons plus the ED visits from Zip Code area 27055 [36,845 / 43,712 = 0.843]. Further, as shown in the above table, in CY 2015, assuming 1,500 ED visits per treatment room, the residents of the primary service area are projected to utilize 29.1 ED treatment rooms. With the proposed project there will be 28 ED treatment rooms located in the primary service area (DCH with 16 and FMC-Clemmons with 12). Consequently, based on data provided by FMC-Clemmons, the analyst concluded that the number of potential patients in the primary service area is sufficient to justify the need for the 12

proposed ED treatment rooms at FMC-Clemmons, in addition to the 16 previously approved at DCH.

The applicants adequately demonstrate the need for an ED with 12 treatment rooms at FMC-Clemmons.

Respiratory, Physical and Speech Therapy Services – In Section II.1, pages 26-27, the applicants state

> *"The CLMC Respiratory Therapy staff will provide therapeutic and diagnostic RT services to CLMC inpatients, outpatients, and ED patients as requested or ordered by physician. The qualifications of the RT staff at CLMC will include registration by registered by [sic] the National Board of Respiratory Care and current certification in Basic Life Support (CPR), ACLS, and PALS. Respiratory Therapists are also part of the hospital's Code Blue resuscitation team.*
>
> *The CLMC RT staff will be qualified and equipped to provide the following types of services at the proposed 50-bed community hospital in Clemmons:*
>
> - *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 outline in the Respiratory Care Protocol and department policy/procedures*
> - *Assistance with bronchoscopes*
> - *Performance of femoral ABG sticks and decompression of tension pneumothorax*
> - *Sep 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*

...

The CLMC 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*
- *MBS/FEE evaluations per physicians' orders*
- *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 CLMC 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* [sic] *P.T. Plan*
- *Review P.T. Plan of Care with family"*

In addition, in Exhibit 2, the applicants provide FMC's Clinical Improvement Plan – Annual Appraisal for 2008, which states

> *"Criteria for referrals to support services are utilized as needs are identified. Referrals are made for resources that will be needed during the stay and at the time of discharge to promote maintaining and sustaining the health of the people of our region."* (Emphasis in original.)

Exhibit 2 also includes a copy of FMC's Hospital Plan for Care Delivery 2008, which states

> *"The care planning process addresses continuity of care after discharge. Arrangements for any services are made to meet identified needs. Multidisciplinary patient and family education is part of the discharge planning process. Patient education is based on the biopsychosocial needs of the patient identified on admission or as part of ongoing reassessment. Consideration is given to the patient or caretaker's ability, culture, readiness to learn, any barriers to learning and the length of the patient's stay. The effectiveness of the discharge planning process is measured to ensure that the patient's health care needs are met following discharge from the hospital."*

The applicants adequately demonstrate the need to provide respiratory, speech and physical therapy services to both inpatients and outpatients at FMC-Clemmons as part of their plan of care.

Other Ancillary Services – In Section III.1(b), page 142, the applicants state *"ancillary projections reflect total procedures, scans or individual tests completed by department or services, not total patients. In most cases a patient receives services from more than one department or has more than one test or procedure at one visit."* On page 144, the applicants provide projected utilization for ancillary services for the first three operating years of the FMC-Clemmons, as illustrated in the following table. The table also illustrates the applicants' assumptions regarding projected utilization.

ANCILLARY SERVICE	PROJECTED # OF SCANS, TESTS, ETC.			ASSUMPTIONS
	YEAR ONE	YEAR TWO	YEAR THREE	
CT Scanner				
Inpatient	2,536	2,581	2,626	# of inpatient CT scans = 53.5% of acute care discharges
Outpatient & ED	5,763	7,067	8,415	# of outpatient CT scans = 23.4% of outpatient & ER visits
Total	8,299	9,647	11,041	
Nuclear Medicine				
Inpatient	840	855	870	# of inpatient NM scans = 17.7% of acute care discharges
Outpatient & ED	1,183	1,450	1,727	# of outpatient NM scans = 4.8% of outpatient & ER visits
Total	2,023	2,305	2,597	
Mammograms				
Inpatient	0	0	0	
Outpatient & ED	1,982	2,431	2,894	# of outpatient mammograms = 8% of outpatient & ER visits
Total	1,982	2,431	2,894	
X-Ray				
Inpatient	5,897	5,999	6,104	# of inpatient x-rays = 124.5% of acute care discharges
Outpatient & ED	9,841	12,068	14,370	# of outpatient x-rays = 39.9% of outpatient & ER visits
Total	15,738	18,067	20,474	
Ultrasound				
Inpatient	900	916	932	# of inpatient ultrasounds = 19% of acute care discharges
Outpatient & ED	2,220	2,722	3,241	#of outpatient ultrasounds = 9% of outpatient & ER visits
Total	3,120	3,638	4,173	
Pharmacy				
Inpatient	375,531	382,080	388,746	# of inpatient pharmacy units = 79.3% of acute care discharges
Outpatient & ED	74,983	91,946	109,487	#of outpatient pharmacy units = 3% of outpatient & ER visits
Total	450,514	474,025	498,233	
Laboratory				
Inpatient	82,335	83,771	85,233	# of inpatient lab tests = 17.4% of acute care discharges
Outpatient & ED	33,545	41,134	48,981	#of outpatient lab tests = 1.4% of outpatient & ER visits
Total	115,880	124,905	134,214	

Regarding both the inpatient, outpatient and ED assumptions in the above table, on pages 142-143, the applicants state

> *"Ancillary utilization projections were calculated based upon existing ancillary utilization patterns at existing Novant Health community hospitals: Thomasville Medical Center (TMC), Brunswick Community Hospital (BCH), Presbyterian Hospital Matthews (PHM) and Presbyterian Hospital Huntersville (PHH). CLMC assumes that projected ancillary utilization at CLMC will imitate current ancillary utilization patterns at TMC, BCH, PHM and PHH. ...*
>
> *Relevant data was acquired from Hospital Licensure Renewal Applications from FFY 2003 to 2007 as available for PHH, PHM, TMC and most recently BCH. BCH was acquired by Novant Health in 2006 and FFY 2006 was the*

first full year of operation by Novant. This data is included in Exhibit 5 Tables 48 and 50. Data was averaged to determine the relationship between ancillary volumes and inpatient, outpatient and ED volumes. Inpatient ancillary volumes for CLMC were projected using total average data across the facilities and the years. High and low values were deleted from the average. The resulting average was used to calculate ancillary services at CLMC."

In addition, in a footnote on page 143, the applicants state

"Ratios for laboratory, pharmacy and ultrasound were calculated based upon historical utilization at FMC and MPH. The resulting projections, when compared to the community hospital ratios used in the PHMH application, were very high. Therefore, CLMC utilized the ratios used in the PHMH application to project future laboratory, pharmacy and ultrasound volumes in this application."

See also Exhibit 5, Tables 48 and 50.

The applicants adequately demonstrate that projected utilization of ancillary services by inpatients and ED patients is based on reasonable and supported assumptions. See discussion above regarding utilization of inpatient and ED services.

With regard to outpatient utilization (excluding ED utilization), the applicants project a combined total of outpatient visits (i.e., encounters) for CT scanner, nuclear medicine, mammograms, x-ray, ultrasound, pharmacy, laboratory, respiratory therapy, physical therapy and speech therapy services to be provided at MPH-Clemmons during the first three operating years, as illustrated in the following table, which excludes ED visits or encounters. [Note: the number of outpatient visits is not the sum of the numbers of procedures, laboratory tests and pharmacy units listed for "Outpatient & ED" because the numbers in the previous table include ED visits with other outpatient visits and a patient could have more than one procedure or test during a single visit or encounter.]

OPERATING YEAR	TOTAL # OF OUTPATIENT VISITS OR ENCOUNTERS
4/1/12 – 3/31/13 (projected) (Year One)	11,067
4/1/13 – 3/31/14 (projected) (Year Two)	13,678
4/1/14 – 3/31/15 (projected) (Year Three)	16,379

Source: Exhibit 5, Table 44.

As shown in the above table, in Year Three, the applicants project a total of 16,379 outpatient visits or encounters at the proposed FMC-Clemmons, excluding emergency department visits. The applicants provide the assumptions and methodology used to project the above numbers of outpatient visits or encounters in Section III.1, pages 132-135, which are summarized as follows.

- On page 134, the applicants state

  "Projected Hospital Outpatient Visits = (Defined [Primary] *Service Area Population x North Carolina Hospital Outpatient Visit Use Rate x Market Share) + 'Other Inmigration'"*

- On page 132, the applicants state that the American Hospital Association's 2006 North Carolina hospital outpatient visit use rate (194.1 per 100 population) includes emergency visits, but not outpatient surgeries. The applicants adjusted the rate to exclude emergency visits (43.4 per 100 population). The applicants state that the adjusted rate is 150.1 outpatient visits per 100 population. However, the rate is actually 150.7 outpatient visits per 100 population (194.1 – 43.4 = 150.7), which means projected outpatient visits would be greater if the applicants had used the slightly higher rate.

- On pages 132-133, the applicants calculated Novant's current market share of total hospital outpatient visits by residents of the proposed primary service area as follows: the total number of outpatient visits at Novant's Forsyth County facilities by residents of the proposed primary service area (17,441) was divided by the total estimated number of hospital outpatient visits for this same area (112,322) (See Section III.1(b), page 133, and Exhibit 5, Tables 44 & 45). Thus, Novant's current market share of the estimated outpatient visits in the proposed primary service area is 15.5% [17,441 / 112,322 = 0.155].

- On page 133, the applicants state they assume 75% of the residents of the proposed primary service area currently using FMC or MPH for outpatient visits will shift to the proposed FMC-Clemmons. On page 134, the applicants state they *"assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3."* Regarding the projected shift from FMC and MPH, on pages 133-134, the applicants state

  - *"The new hospital will be a community hospital and will have a full range of outpatient services including imaging, laboratory, pharmacy, physical therapy, etc., in addition to surgical services. ...*
  - *CLMC will treat a variety of patients as inpatients, emergency patients and patients referred from local physicians with asthma, strokes, orthopedic injuries and other diagnosis which require outpatient therapy services such as physical therapy, speech therapy, occupational therapy, respiratory therapy; utilization of these outpatient* [sic] *are included in these outpatient projections.*
  - *Much of FMC's outpatient imaging volume is referred to other NHTR/Excel Imaging and MedQuest freestanding imaging facilities in Winston-Salem, such as Maplewood Imaging Center, Salem MRI Center, The Breast Clinic, and Piedmont Imaging; therefore, this volume was not included in the calculation of current hospital outpatient visit market share.*
  - *CLMC is closer to areas of each of the five zip codes than existing NHTR Winston Salem facilities as reflected in Exhibit 5, Table 1 and Map 7;*
  - *New physician offices with easier access will be developed in the future on and near the CLMC campus;*
  - *Congestion and traffic on I-40 into Winston Salem will increase;*
  - *CLMC offers a choice for outpatient services closer to home;*

  ...

  - *Some patients will continue to seek care at other NHTR Winston Salem hospitals, therefore 100% of the demand*

for services in the five zip codes will not shift to CLMC."

The applicants adequately demonstrate that the projected number of outpatient visits or encounters at FMC-Clemmons is based on reasonable assumptions regarding Novant's current market share for outpatient services which is held constant and the percentage of patients currently receiving outpatient services at Novant facilities that are expected to shift to FMC-Clemmons.

Further, on pages 134-135, the applicants state

"The need for additional ancillary and outpatient services at CLMC is substantiated by the existing utilization of services at FMC. ... [I]*npatient and emergency department utilization at FMC are at an all time high. Over the last several years, inpatient demands have resulted in FMC shifting outpatient services to other providers. ... This shift has been the result of direct efforts of FMC to provide outpatient services in settings less complex than a tertiary care hospital. ... In addition, certain elective outpatient services are subject to getting delayed or re-scheduled if a higher acuity or emergent need intervenes. ... Thus, the proposed hospital in Clemmons will provide another location for needed outpatient services in the community setting and away from the higher intensity tertiary campus at FMC."*

The following table illustrates historical utilization at FMC, as provided by the applicants on page 135, which the applicants state is from FMC's license renewal applications.

	FFY 2004	FFY 2005	FFY 2006	FFY 2007	CAGR
Inpatient Days	200,063	206,071	207,044	210,427	1.7%
Emergency Visits	77,533	86,118	89,941	97,685	8.0%
Outpatient Visits	27,190	29,596	26,876	23,321	-4.5%

As shown in the above table, although the number of outpatient visits has declined at FMC between FFY 2004 and FFY 2007, the numbers of inpatients and ED patients have increased. The decline in the number of outpatient visits at FMC is the result of shifting outpatients from FMC to other Novant facilities which do not serve inpatients or ED patients to accommodate the increased number of inpatients and ED patients at FMC.

To critique the applicants' Impact Analysis, the following table was prepared by the analyst to compare outpatient utilization projected by FMC-Clemmons for residents of Davie County, the Zip Code areas for Clemmons (27012) and Lewisville (27023) in Forsyth County and Zip Code area 27055 in Yadkin County, to the total number of outpatient visits projected in the FMC-Clemmons and DCH applications, including inmigration.

Step		2012	2013	2014	2015
	Projected OP Utilization by Residents of the Primary Service Area				
1	Projected Population of Davie County + 2 Zip Codes in Forsyth County, which is the primary service area for FMC-Clemmons. (See page 120 of the FMC-Clemmons application for projected population data.)	82,696	84,138	85,606	87,100
2	Projected Population of 1 Zip Code in Yadkin County, which is included in DCH's primary service area but not FMC-Clemmons' primary service area. (from page 53 of the previously approved DCH application)	13,577	13,591	13,604	13,618
3	Total Projected Population (Step 1 + Step 2)	96,273	97,729	99,210	100,718
4	OP Use Rate per 100 Population, as calculated by the applicants (from page 132 of the FMC-Clemmons application)	150.1	150.1	150.1	150.1
5	Projected OP Visits (Population x Use Rate / 100) (Step 3 x Step 4 / 100)	144,506	146,691	148,914	151,178
	Projected OP Utilization at FMC-Clemmons and the previously approved DCH				
6	FMC-Clemmons (from page 134 of the FMC-Clemmons application)		11,067	13,678	16,379
7	DCH [1]	NA	NA	NA	NA

[1] DCH provided the projected number of outpatient procedures rather than the projected number of outpatient visits.

As shown in the above table, even though DCH did not provide the estimated number of outpatient visits or encounters, FMC-Clemmons proposes to provide only 10.8% of all projected outpatient visits or encounters in the proposed primary service area in CY 2015 [16,379 / 151,178 = 10.8%]. Consequently, based on data provided by FMC-Clemmons, the analyst concluded that the number of potential outpatients in the primary service area is sufficient to justify the need for the proposed outpatient services to

be provided at FMC-Clemmons, in addition to the outpatient services previously approved to be provided at DCH.

The applicants adequately demonstrate the need to provide the proposed outpatient services at FMC-Clemmons, including CT services. However, the applicants did not adequately demonstrate the need to acquire a new CT scanner as opposed to relocating an existing CT scanner to meet the need for CT services or utilizing an existing mobile unit. Specifically, the applicants did not adequately demonstrate conformance to the required rules for acquisition of a CT scanner in 10A NCAC 14C .2302 and 10A NCAC 14C.2303. See 10A NCAC 14C .2302 and 10A NCAC 14C .2303 for discussion. Therefore, the applicants did not adequately demonstrate the need to acquire a new CT scanner.

In summary, the applicants adequately identify the population proposed to be served and adequately demonstrate the need for the proposed services, with the exception of an additional GI endoscopy room and a new CT scanner. Therefore, the application is conforming to this criterion subject to the following conditions.

1. **Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall not acquire a new CT scanner for the Clemmons campus of Forsyth Medical Center, but instead may contract for an existing mobile CT scanner or relocate one of Novant Health, Inc.'s existing CT scanners currently located in the CT service area to the Clemmons campus.**

2. **Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall not develop a gastrointestinal endoscopy room at the Clemmons campus of Forsyth Medical Center.**

(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.

The applicants propose to relocate 40 existing acute care beds from FMC in Winston-Salem to Clemmons. Additionally, the applicants propose to relocate 10 existing acute care beds and five existing ORs from MPH to the FMC-Clemmons campus.

Proposed Relocation of Acute Care Beds from FMC

The applicants assume that the FMC-Kernersville campus will open in 2009 and some acute care patients will shift from the Winston-Salem campus to the Kernersville campus at that time. Also, the applicants assume that the FMC-Clemmons campus will open in April 2012 and that additional acute care patients are projected to shift from the Winston-Salem campus to the Clemmons campus when it opens. In addition, some acute care patients are projected to shift from MPH to FMC-Winston-Salem. See Section III.8(c), page 160, and Exhibit 5, Table 54. The following table illustrates projected utilization of acute care beds at FMC-Winston-Salem after completion of these projects, as provided by the applicants in Section III.8(c), page 160, and Exhibit 5, Table 54.

FMC-Winston-Salem	Acute Care Patient Days	ADC	# of Beds	% Occupancy
2008 (actual)	210,148	576	751	76.7%
2009 (projected)	209,424	574	751	76.4%
2010 (projected)	211,980	581	740	78.5%
2011 (projected)	210,318	576	740	77.9%
2012 (projected)	211,756	580	740	78.4%
2013 (projected)	203,237	557	700	79.5%
2014 (projected)	204,422	560	700	80.0%
2015 (projected)	205,568	563	700	80.5%

Before adjusting projected utilization at FMC-Winston-Salem to reflect the patients expected to shift to FMC-Kernersville and FMC-Clemmons and from MPH, the applicants assume that acute care patient days will increase 1.1% per year at FMC, which is the same rate the population of the primary service area is projected to increase annually. Thus, in the third operating year, the applicants project that the occupancy rate for the 700 acute care beds on the FMC-Winston-Salem campus would be 80.5%. In Section III.8(c), page 160, the applicants state *"The net result of the proposed project is continued utilization of FMC at 80% occupancy. FMC has a demonstrated history of successfully providing inpatient care at these occupancy rates."* [Note: in a previous review, FMC was

conditionally approved to develop 13 additional acute care beds on the Winston-Salem campus for a total of 713 beds in 2015. That approval is under appeal. Assuming an ADC of 563 acute care patients, the occupancy rate for 713 acute care beds would be 79% (563 / 713 = 0.7896).] The applicants adequately demonstrate the availability of a sufficient number of acute care beds at FMC-Winston-Salem to meet the needs of the patients to be served.

Proposed Relocation of Acute Care Beds from MPH

The following table illustrates projected utilization of acute care beds at MPH after relocation of 10 acute care beds to Clemmons, as provided by the applicants in Section III.8(c), page 160, and Exhibit 5, Table 54.

MPH	ACUTE CARE PATIENT DAYS	ADC	# OF BEDS	% OCCUPANCY
2008 (actual)	5,762	15.8	22	71.8%
2009 (projected)	5,831	16.0	22	72.6%
2010 (projected)	5,893	16.1	22	73.4%
2011 (projected)	5,957	16.3	22	74.1%
2012 (projected)	6,020	16.5	22	75.0%
2013 (projected)	3,437	9.4	12	78.5%
2014 (projected)	3,179	8.7	12	72.6%
2015 (projected)	2,921	8.0	12	67.0%

For years prior to 2013, the applicants assume that acute care patient days will increase 1.1% per year at MPH, which is the same rate the population of the primary service area is projected to increase annually. Beginning in 2013, the number of acute care patient days at MPH decreases each year through the third operating year to reflect a gradual shift of patients to FMC-Clemmons and FMC-Winston-Salem over that three year period. Thus, in the third operating year, the applicants project that the occupancy rate for the 12 acute care beds remaining at MPH would be 67%. The applicants adequately demonstrate the availability of a sufficient number of acute care beds at MPH to meet the needs of the patients to be served.

Proposed Relocation of Operating Rooms from MPH

The applicants assume that some of the patients currently utilizing the ORs at MPH will shift to FMC-Clemmons and FMC-Winston-Salem. See Section III.8(c), page 161, and Exhibit 5, Table 25. The following table illustrates projected utilization of ORs at MPH after

the relocation of five ORs to FMC-Clemmons, as provided by the applicants in Section III.8(c), page 161, and Exhibit 5, Table 25.

MPH	# OF INPATIENT CASES	# OF OUTPATIENT CASES	# OF INPATIENT HOURS (3.0 PER CASE)	#OF OUTPATIENT HOURS (1.5 PER CASE)	TOTAL HOURS	TOTAL HOURS / 1,872	# OF LICENSED ORS (1)
2008 (actual)	1,170	10,508	3,510	15,762.0	19,272.0	10.3	13
2009 (projected)	1,184	10,651	3,552	15,976.5	19,528.5	10.4	13
2010 (projected)	1,197	10,779	3,591	16,168.5	19,759.5	10.6	12
2011 (projected)	1,209	10,898	3,627	16,347.0	19,974.0	10.7	12
2012 (projected)	1,221	11,019	3,663	16,528.5	20,191.5	10.8	12
2013 (projected)	587	8,464	1,761	12,696.0	14,457.0	7.7	7
2014 (projected)	554	8,329	1,662	12,493.5	14,155.5	7.6	7
2015 (projected)	487	8,100	1,461	12,150.0	13,611.0	7.3	7

(1) Pursuant to the certificate of need issued for Project I.D. #G-7604-06, one of MPH's ORs will be relocated to FMC-Kernersville. The applicants project that the FMC-Kernersville campus will open during 2009.

The applicants adequately demonstrate the availability of a sufficient number of ORs at MPH to meet the needs of the patients to be served.

In summary, the application is conforming to 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.

CA

In Section II.5, pages 33-40, the applicants discuss the alternatives considered prior to submission of this application including: 1) maintaining the status quo; 2) expanding acute, surgical and emergency services at FMC; 3) renovating MPH; 4) constructing a replacement MPH at its current location; 5) developing a medical plaza in western Forsyth County, which would provide outpatient imaging and surgery services; and 6) relocating existing acute care beds and ORs from FMC and MPH to western Forsyth County. On page 39, the applicants state

"After thoroughly considering all the above options, the applicant determined that the preferred option is the relocation of existing beds and operating rooms at FMC and MPH to a new location in the western Forsyth/Davie County market area in order to create a 50-bed community hospital with ORs, an ED, an ICU, and the full compliment

the relocation of five ORs to FMC-Clemmons, as provided by the applicants in Section III.8(c), page 161, and Exhibit 5, Table 25.

MPH	# OF INPATIENT CASES	# OF OUTPATIENT CASES	# OF INPATIENT HOURS (3.0 PER CASE)	#OF OUTPATIENT HOURS (1.5 PER CASE)	TOTAL HOURS	TOTAL HOURS / 1,872	# OF LICENSED ORS (1)
2008 (actual)	1,170	10,508	3,510	15,762.0	19,272.0	10.3	13
2009 (projected)	1,184	10,651	3,552	15,976.5	19,528.5	10.4	13
2010 (projected)	1,197	10,779	3,591	16,168.5	19,759.5	10.6	12
2011 (projected)	1,209	10,898	3,627	16,347.0	19,974.0	10.7	12
2012 (projected)	1,221	11,019	3,663	16,528.5	20,191.5	10.8	12
2013 (projected)	587	8,464	1,761	12,696.0	14,457.0	7.7	7
2014 (projected)	554	8,329	1,662	12,493.5	14,155.5	7.6	7
2015 (projected)	487	8,100	1,461	12,150.0	13,611.0	7.3	7

(1) Pursuant to the certificate of need issued for Project I.D. #G-7604-06, one of MPH's ORs will be relocated to FMC-Kernersville. The applicants project that the FMC-Kernersville campus will open during 2009.

The applicants adequately demonstrate the availability of a sufficient number of ORs at MPH to meet the needs of the patients to be served.

In summary, the application is conforming to 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.

CA

In Section II.5, pages 33-40, the applicants discuss the alternatives considered prior to submission of this application including: 1) maintaining the status quo; 2) expanding acute, surgical and emergency services at FMC; 3) renovating MPH; 4) constructing a replacement MPH at its current location; 5) developing a medical plaza in western Forsyth County, which would provide outpatient imaging and surgery services; and 6) relocating existing acute care beds and ORs from FMC and MPH to western Forsyth County. On page 39, the applicants state

"After thoroughly considering all the above options, the applicant determined that the preferred option is the relocation of existing beds and operating rooms at FMC and MPH to a new location in the western Forsyth/Davie County market area in order to create a 50-bed community hospital with ORs, an ED, an ICU, and the full compliment

> [sic] *of ancillary services (radiology, lab, pathology, pharmacy). This full-continuum* [sic] *of services will best meet the needs of the existing patient base from the western Forsyth/Davie County market that FMC and affiliated NHTR facilities and physicians have the privilege to serve. Novant Health Triad Region facilities (including FMC and MPH) and physicians, both primary care and specialty, are the market leaders in serving this population. In addition, it has the benefit of de-compressing* [sic] *the increasing complex and busy Winston-Salem campuses for existing NHTR facilities such as Forsyth Medical Center, Medical Park Hospital, and Hawthorne Surgery Center. Moreover, there is overwhelming evidence that the 35+-year* [sic] *old MPH facility requires a significant infusion of capital, in order for it to continue to be able* [sic] *the same 'high touch, high tech' care for which it has become known over the past three decades."*

In addition, regarding developing a medical plaza in western Forsyth County, on page 37, the applicants state

> *"An ambulatory medical plaza would allow some of these services to be provided in a setting away from the more distant and congested Winston-Salem campuses and offices and closer to where the patients live. However, given the growth in the population and the durability of the existing NHTR doctor-patient relationships in the western Forsyth/Davie County region, there was concern that the ambulatory medical plaza capacity might be quickly over-whelmed with the demand for services. Thus, while this appeared, at first glance, to be an attractive option, it may have proved to be an extra step requiring the expenditure of additional time and capital on the way to the inevitable construction of a 50-bed community hospital."*

Further, the application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a), (20), the Criteria and Standards for Intensive Care Services promulgated in 10A NCAC 14C .1200, the Criteria and Standards for Computed Tomography promulgated in 10A NCAC 14C .2300, the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities promulgated in 10A NCAC 14C

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Further, the application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a), (20), the Criteria and Standards for Intensive Care Services promulgated in 10A NCAC 14C .1200, the Criteria and Standards for Computed Tomography promulgated in 10A NCAC 14C .2300, the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities promulgated in 10A NCAC 14C

.3900, and the Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The applicants adequately demonstrate that the proposed project, as conditioned, is their most effective alternative subject to the conditions in Criterion (3) and the following conditions.

1. **Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall materially comply with all representations made in their certificate of need application, except as specifically amended by the conditions of approval.**

2. **Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall develop and operate no more than 46 licensed general acute care beds, 4 licensed intensive care unit beds, 6 unlicensed observation beds and 5 licensed shared operating rooms in Clemmons.**

3. **Upon completion of the project, Novant Health, Inc. shall take the steps necessary to amend the license of Medical Park Hospital to delicense 10 acute care beds at Medical Park Hospital for a total of no more than 12 acute care beds at Medical Park Hospital.**

4. **Upon completion of the project, Novant Health, Inc. shall take the steps necessary to amend the license of Medical Park Hospital to delicense five shared operating rooms at Medical Park Hospital for a total of no more than seven operating rooms at Medical Park Hospital.**

5. **Upon completion of the project, Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center shall take the steps necessary to amend the license of Forsyth Medical Center to delicense 40 acute care beds on the Winston-Salem campus for a total of no more than 700 acute care beds on the Winston-Salem campus following completion of this project and Project I.D. #G-7604-06 (relocate 11 acute care beds from the Winston-Salem campus to Kernersville).**

6. **Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall not acquire, as part of this project, any equipment that is not included in the proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

7. **Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

(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

In Section VIII.1, page 223, the applicants project that the total capital cost of the project will be $100,591,669, as illustrated below.

Site Costs		
Purchase Price of the Land	$1,852,000	
Site Preparation Costs	$3,982,938	
Roads	$2,196,049	
Subtotal Site Costs		**$8,030,987**
Construction Costs		**$63,572,119**
Miscellaneous Costs		
Financing Costs *		
Fixed & Movable Equipment	$15,137,567	
Information Technology	$4,500,000	
Furniture	$1,100,000	
Consultant Fees	$3,510,753	
Interest during Construction	$2,823,214	
Contingency	$1,917,029	
Subtotal Miscellaneous Costs		**$29,988,563**
Total Capital Cost		**$100,591,669**

* In a footnote, on page 223, the applicants state *"Any interest expense associated with future bond financing is included as an expense line item in the Clemmons Medical Center's Pro Forma Income Statements included with this CON application."* In the pro formas, the applicants project $3,991,424 for interest expense in Year One, $3,919,252 in Year Two and $3,844,140 in Year Three.

In Section IX, page 235, the applicants also project that start up expenses will be $1,700,000. In Section VIII.3, page 224, and Section IX, page 235, the applicants state that the capital and working capital needs of the project will be financed with the accumulated reserves of Novant. The audited financial statements for Novant are provided in Exhibit 9. As of December 31, 2007, Novant had $321,913,000 in cash and cash equivalents, $112,624,000 in short-term investments, $3,448,599,000 in total assets and $1,655,127,000 in total net assets (total assets less total liabilities). Exhibit 9 also contains a letter signed by the Chief Financial Officer for Novant, which states

> *"This letter will serve to confirm that Novant Health will be funding the capital cost ($100,591,669) and the working capital needs of Clemmons Medical Center out of accumulated reserves. In the alternative Novant also reserves the right to seek tax exempt bond funding for all or part of this project as discussed in Section VI of our CON application."*

The applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project.

In the projected revenue and expense statement, the applicants project that revenues will exceed operating costs at FMC-Clemmons in the second and third operating years. The assumptions used by the applicants in preparation of the pro formas are reasonable, including projected utilization, costs and charges. See the pro forma section for the pro formas and assumptions. See Criterion (3) for discussion of utilization projections. Therefore, the applicants adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Consequently, the application is conforming 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.

CA

The applicants adequately demonstrate the need for all of the services they propose to provide in Clemmons, with the exception of the acquisition of a new CT scanner and the development of a new GI endoscopy room. See Criterion (3) for discussion and conditions. Therefore, the applicants adequately demonstrate that the proposal, as conditioned, would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion subject to the conditions in Criterion (3) regarding the CT scanner and the GI endoscopy room.

(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

In Section VII.2, pages 205-208, the applicants provide the projected staffing for the proposed FMC-Clemmons campus, which will be licensed as part of FMC, as illustrated in the following table.

DEPARTMENT / UNIT	# OF FULL-TIME EQUIVALENTS (FTEs)		
	YEAR 1	YEAR 2	YEAR 3
Administration	8.0	8.0	8.0
Human Resources	2.5	2.5	2.5
Guest Services	1.0	1.0	1.0
Nursing Administration	14.2	14.2	14.2
Intensive Care Unit	10.5	11.6	12.6
2nd Floor Med/Surg Unit	34.9	38.7	42.7
3rd Floor Med/Surg Unit	22.6	25.1	27.6
3rd Floor Observation Unit	6.3	7.0	7.7
Emergency Department	17.9	22.1	26.4
Pharmacy	10.6	11.2	11.8
Respiratory/EKG	4.7	4.7	5.1
Surgical Services	42.3	46.2	50.2
GI Endoscopy Unit	3.0	3.6	5.0
Outpatient Care Unit	5.0	5.0	5.0
Radiology	37.8	43.2	49.4
Patient Access	21.0	21.0	21.0
Medical Records	7.0	8.7	10.5
Environmental Services	24.0	25.6	27.5
Food & Nutrition	16.9	18.9	20.6
Laboratory	17.0	18.4	19.9
Plant Operations	8.5	8.5	8.5
Transcription	4.0	4.0	4.0
Public Safety	13.0	13.0	13.0
Rehab Department (PT/ST)	1.9	2.1	2.2
Total	**334.6**	**364.3**	**396.4**

As shown in the above table, the applicants propose to employ a total of 334.6 FTE staff positions in Year One, 364.3 FTE staff positions in Year Two and 396.4 FTE staff positions in Year Three. In Section VII.3(b), page 210, the applicants state *"It is anticipated that Clemmons Medical Center staff will be new hires, except for those existing Novant Health Triad Region personnel who may choose to apply for the Clemmons Medical Center positions when the jobs are posted. ... Any applicants whose positions are eliminated due to the partial relocation of MPH ORs and beds and FMC beds to Clemmons will be accorded high priority for positions at Clemmons Medical Center."* In Section VII.3(c), pages 210-211, the applicants state that they will recruit the additional staff by posting job openings in area newspapers, trade journals and the web. The applicants also participate in job fairs. Exhibit 9 contains a letter signed by the Senior Vice President, Financial Planning and Analysis for Novant, which states that Novant will provide the following corporate services for the proposed FMC-Clemmons campus: 1) information technology; 2) human resources; 3) finance; 4) managed care contracting; and 5) billing. In Section IV.5, pages 175-176, and Section V.3(c), page 184, the applicants identify the physicians who will provide professional coverage and medical direction for the proposed FMC-Clemmons campus for the following services: 1) Emergency Department; 2) Intensive Care Unit; 3) surgery; 4) GI endoscopy; 5) anesthesiology; 6) radiology; 7) pathology; and 8) hospitalists. In Exhibit 11, the applicants provide letters from these physicians stating their intent to serve as medical director and their curriculum vitae. The applicants demonstrate the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to 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

In Section VII.6, pages 215-217, Section IV.5(a), pages 175-176, Section II.1, pages 24-28, and Exhibit 14, the applicants describe the ancillary and support services that will be available at the new

facility. Exhibit 10 contains a copy of the transfer agreement between the new facility and FMC. Exhibit 11 contains letters from area physicians supporting the proposed project. The applicants adequately demonstrated that the necessary ancillary and support services will be available for the new facility in Clemmons and that the services will be coordinated with the existing health care system. Therefore, the application is conforming to 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

NA

(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

The applicants propose to construct a new facility with 206,638 square feet that will have 50 general acute care beds. In Section XI.7, pages 262-263, the applicants state that applicable energy savings features will be incorporated into the construction plans. In Exhibit 16, the applicants provide a letter signed by an architect licensed in North Carolina, which certifies that the cost of construction and site prep for the proposed new facility in Clemmons is $67,555,057. The architect's certified cost of construction and site prep is consistent with the applicants' projected cost of construction and site prep in Section VIII.1, page 223. The applicants adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. The application is conforming 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

The following table illustrates the current payor mix for all services provided at FMC during CY 2007, as reported in Section VI.10, page 197.

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS
Self Pay / Indigent / Charity Care	13.48%
Medicare & Medicare Managed Care	29.88%
Medicaid & Medicaid Managed Care	17.59%
Commercial Insurance / Managed Care	36.28%
Other (Workers Comp. & other gov't)	2.77%
TOTAL	100.00%

The applicants demonstrated that medically underserved populations currently have adequate access to the services provided at FMC. Therefore, the application 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;

C

In Section VI.8, page 196, the applicants state that there have been no civil rights access complaints filed against FMC or Novant Health Triad Region during the previous five years.

(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

The following table compares the actual CY 2007 payor mix for all services provided at FMC with the projected payor mix for only those services to be provided at FMC-Clemmons facility during Year Two (4/1/13 – 3/31/14), as reported in Section VI.10, page 197, and Section VI.12, page 200, respectively.

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS	
	CY 2007 (ACTUAL)	FY 2014 (PROJECTED) YEAR TWO
Self Pay / Indigent / Charity Care	13.48%	7.47%
Medicare & Medicare Managed Care	29.88%	44.16%
Medicaid & Medicaid Managed Care	17.59%	8.96%
Commercial Insurance / Managed Care	36.28%	37.26%
Other (Workers Comp. & other gov't)	2.77%	2.15%
TOTAL	100.00%	100.00%

As shown in the above table, the applicants project a significantly different payor mix for FMC-Clemmons compared to the actual payor mix for FMC during CY 2007. Regarding the projected payor mix for the proposed new facility in Clemmons, in Section VI.12, page 203, the applicants state

> *"Although Clemmons Medical Center (CLMC) will be licensed under the existing acute care hospital license of Forsyth Medical Center, we anticipate that the Clemmons Medical Center payor mix will be different than that of Forsyth Medical Center. FMC is a tertiary hospital and offers services that will not be offered at CLMC such as open heart surgery and neonatal intensive care services. Clemmons Medical Center is proposed as a 50-bed community hospital, with volume projections based on DRGs with an acuity weight of less than 2.0. Thus, based on location, as well as scope and acuity of services, it is anticipated that the Clemmons Medical Center payor mix will be distinct from the Forsyth Medical Center payor mix."*

Further, in the assumptions following the pro formas, the applicants state

> *"Payer mix for the proposed facility was based on the payer mix experience at Forsyth Medical Center for both inpatient, outpatient, and ED for patients living in the Clemmons area."*

The applicants demonstrated that medically underserved populations would have adequate access to the proposed

services. Therefore, the application is conforming to 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

See Section VI.7, page 195 and Exhibits 9 and 10, for documentation of the range of means by which patients would have access to the services to be provided at FMC-Clemmons. The information provided 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

See Section V.1, pages 178-180, and Exhibit 10 for documentation that FMC currently accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. The information provided is reasonable and credible and supports a finding of conformity with 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.

CA

The applicants adequately demonstrate that the proposal, as conditioned, would have a positive impact upon the cost effectiveness, quality and access to the proposed services. See Criteria (1), (3), (3a), (5), (7), (8), (12), (13) and (20). Therefore, the application is conforming to this criterion subject to the conditions in Criterion (3) regarding the CT scanner and the GI endoscopy room.

(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.

C

FMC and MPH are accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. 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 on either hospital. 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.

CA

The applicants propose to relocate four general medical/surgical beds from Winston-Salem and convert them to four ICU beds at the proposed new facility in Clemmons. Thus, the proposal results in the development of expanded intensive care services. The application is conforming, as conditioned, to all applicable

Criteria and Standards for Intensive Care Services promulgated in 10A NCAC 14C .1200. The specific criteria are discussed below.

The applicants also propose to acquire an additional CT scanner. The application is conforming, as conditioned, to all applicable Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300. The specific criteria are discussed below.

The applicants propose to develop one additional GI endoscopy room. The application is conforming, as conditioned, with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3900. The specific criteria are discussed below.

Further, while the proposal will not increase the total number of licensed ORs in Forsyth County, the applicants propose to relocate existing ORs from one licensed facility (MPH) to another licensed facility (FMC). The application is conforming, as conditioned, with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

SECTION .2100 CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT

.2102(a) This rule states *"An applicant proposing to establish a new ambulatory surgical facility, to increase the number of 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 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) ther [sic] *specialty area identified by the applicant."*

-C- FMC-Clemmons states in Section II.8, page 45, that *"It is anticipated that surgical services in all of the referenced specialties above will be provided at CLMC and in addition that urological surgery will be provided. As reflected in the FMC 2008 Annual Licensure Renewal Application form on page 8, all of the referenced surgical services, as well as others, currently are provided at FMC."*

.2102(b) This rule states *"An applicant proposing to establish a new ambulatory surgical facility, to increase the number of operating rooms except relocations of existing operating rooms between existing licensed facilities within the same 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 licensed 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 licensed 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 licensed 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 licensed facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule; (5) a detailed 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- FMC-Clemmons proposes to relocate existing ORs between existing licensed facilities within the same service area.

.2102(c)(1) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: (1) the number and type of existing and approved operating rooms in each licensed 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- In Section II.8, page 46, the applicants provide the number and type of existing and approved ORs at FMC and MPH, as illustrated in the following table.

TYPE OF OR	FMC		MPH	
	EXISTING [1]	APPROVED [2]	EXISTING	APPROVED [2]
Open Heart	3	3	0	0
Dedicated C-section	2	2	0	0
Dedicated Outpatient	6	8	0	0
Shared	19	22	13	12
TOTAL	**30**	**35**	**13**	**12**

[1] Effective January 1, 2008, the four dedicated outpatient ORs at Hawthorne Surgical Center (HSC) were added to FMC's license. HSC is located on FMC's campus.

[2] Development of the following approved projects will change the number of ORs at FMC and MPH:

- Project I.D. #G-7412-05 – The certificate of need issued March 6, 2007 authorizes FMC to develop two additional shared ORs by converting two existing GI endoscopy rooms.
- Project I.D. #G-7412-05 – The certificate of need issued March 6, 2007 authorizes HSC to develop two additional shared ORs by converting two existing GI endoscopy rooms.
- Project I.D. #G-7604-06 – The certificate of need issued July 24, 2007 authorizes FMC to relocate three existing ORs from FMC and one existing OR from MPH to the FMC-Kernersville campus, which will be licensed as part of FMC.

.2102(c)(2) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (2) the number and type of operating rooms to be located in each affected licensed 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- In Section II.8, page 46, the applicants provide the number of type of ORs to be located at FMC and MPH upon completion of this project and all previously approved projects, as illustrated in the following table.

TYPE OF OR	FMC		MPH	
	EXISTING & APPROVED	THIS PROPOSAL	EXISTING & APPROVED	THIS PROPOSAL
Open Heart	3	3	0	0
Dedicated C-section	2	2	0	0
Dedicated Outpatient	8	8	0	0
Shared	22	27	12	7
TOTAL	**35**	**40**	**12**	**7**

.2102(c)(3) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information:...*

(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 licensed facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule."

-C- In Section II.8, page 47, and Exhibit 5, Table 28, the applicants provide the number of inpatient surgical cases (excluding open heart cases and C-sections) and outpatient surgical cases performed between May 2007 and April 2008 at FMC, HSC (which was separately licensed until January 1, 2008) and MPH, as illustrated in the following table.

FACILITY	INPATIENT [1]	OUTPATIENT	TOTAL
FMC	9,729	6,327	**16,056**
HSC	0	6,455	**6,455**
MPH	1,156	10,563	**11,719**
TOTAL	**10,885**	**23,345**	**34,230**

[1] Excludes inpatient surgical cases performed at FMC in the three open heart ORs and two dedicated C-section ORs.

.2102(c)(4) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (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 licensed facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule."*

-C- In Section II.8, page 48, and Exhibit 5, Table 25, the applicants provide the number of inpatient surgical cases (excluding open heart cases and C-sections) and outpatient surgical cases projected to be performed during the first three operating years at FMC and MPH, as illustrated in the following table.

	FMC				MPH
	Winston-Salem Campus (includes HSC)	Kernersville Campus	Clemmons Campus	Total	
Year One 4/1/12 - 3/31/13					
Inpatient [1]	9,510	1,156	885	11,551	587
Outpatient	13,183	2,596	2,578	18,357	8,464
Year Two 4/1/13 - 3/31/14					
Inpatient [1]	9,530	1,180	1,012	11,722	554
Outpatient	13,203	2,648	2,951	18,802	8,329
Year Three 4/1/14 - 3/31/15					
Inpatient [1]	9,577	1,204	1,144	11,925	487
Outpatient	13,219	2,701	3,336	19,256	8,100

[1] Excludes inpatient surgical cases performed at FMC's Winston-Salem campus in the three open heart ORs and two dedicated C-section ORs.

.2102(c)(5) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (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- The applicants provide a detailed description of and documentation to support the assumptions and methodology used to develop the projections required by this rule in Section III.1, pages 126-129, and Exhibit 5, Tables 19-28. See Criterion (3) for additional discussion.

.2102(c)(6) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (6) the hours of operation of the facility to be expanded."*

-C- In Section II.8, pages 48-49, the applicants provide the hours of operation for each existing, approved and proposed FMC campus.

.2102(c)(7) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ...*

	FMC				MPH
	WINSTON-SALEM CAMPUS (includes HSC)	KERNERSVILLE CAMPUS	CLEMMONS CAMPUS	TOTAL	
YEAR ONE 4/1/12 - 3/31/13					
Inpatient [1]	9,510	1,156	885	11,551	587
Outpatient	13,183	2,596	2,578	18,357	8,464
YEAR TWO 4/1/13 - 3/31/14					
Inpatient [1]	9,530	1,180	1,012	11,722	554
Outpatient	13,203	2,648	2,951	18,802	8,329
YEAR THREE 4/1/14 - 3/31/15					
Inpatient [1]	9,577	1,204	1,144	11,925	487
Outpatient	13,219	2,701	3,336	19,256	8,100

[1] Excludes inpatient surgical cases performed at FMC's Winston-Salem campus in the three open heart ORs and two dedicated C-section ORs.

.2102(c)(5) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (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- The applicants provide a detailed description of and documentation to support the assumptions and methodology used to develop the projections required by this rule in Section III.1, pages 126-129, and Exhibit 5, Tables 19-28. See Criterion (3) for additional discussion.

.2102(c)(6) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (6) the hours of operation of the facility to be expanded."*

-C- In Section II.8, pages 48-49, the applicants provide the hours of operation for each existing, approved and proposed FMC campus.

.2102(c)(7) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ...*

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected licensed facility during the preceding 12 months and a list of all services and items included in the reimbursement."

-CA- In Section II.8, pages 49-50, the applicants provide the average reimbursement received per procedure for the 20 surgical procedures most commonly performed at FMC during CY 2008 and a list of all services and items included in the reimbursement. However, the applicants did not provide the same information for MPH. Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall provide the Certificate of Need Section with the average reimbursement received per procedure for the 20 surgical procedures most commonly performed at Medical Park Hospital during CY 2008 and a list of all services and items included in the reimbursement.

.2102(c)(8) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (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."*

-C- In Section II.8, pages 51-52, the applicants provide the projected average reimbursement to be received per procedure for the 20 surgical procedures the applicants project will be performed most often at FMC-Clemmons and a list of all services and items included in the reimbursement.

.2102(c)(9) This rule states *"An applicant proposing to relocate existing operating rooms between existing licensed facilities within the same service area shall provide the following information: ... (9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge."*

-C- In Section II.8, pages 52-53, the applicants identify the providers of pre-operative services and procedures, which are not included in the facility's charge.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

.2103(a) This rule states *"In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year."*

-C- In Section II.8, page 53, the applicants state they assumed the ORs at FMC-Clemmons would be available for use 5 days per week and 52 weeks a year.

.2103(b)(1) This rule states *"A proposal to establish a new ambulatory surgical facility, to increase the number of operating rooms (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 not be approved unless: (1) the applicant reasonably demonstrates the need for the number of proposed operating rooms in the facility, which is the subject of this review, 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, II, or III 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, approved and proposed operating rooms, excluding one operating room for Level I, II or III trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms. The number of rooms needed is the positive difference rounded to the next highest number for fractions of 0.50 or greater; or (2) the applicant demonstrates 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."*

-C- In Section II.8, pages 52-53, the applicants identify the providers of pre-operative services and procedures, which are not included in the facility's charge.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

.2103(a) This rule states *"In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year."*

-C- In Section II.8, page 53, the applicants state they assumed the ORs at FMC-Clemmons would be available for use 5 days per week and 52 weeks a year.

.2103(b)(1) This rule states *"A proposal to establish a new ambulatory surgical facility, to increase the number of operating rooms (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 not be approved unless: (1) the applicant reasonably demonstrates the need for the number of proposed operating rooms in the facility, which is the subject of this review, 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, II, or III 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, approved and proposed operating rooms, excluding one operating room for Level I, II or III trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms. The number of rooms needed is the positive difference rounded to the next highest number for fractions of 0.50 or greater; or (2) the applicant demonstrates 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."*

-NA- The applicants do not propose to increase the number of ORs in the service area, but instead to relocate five existing ORs from MPH, an existing licensed hospital, to FMC-Clemmons, which will be licensed as part of FMC, an existing licensed hospital. Therefore, the rule is not applicable to this review.

.2103(c) This rule states *"A proposal to establish a new ambulatory surgical facility, to increase the number of operating rooms (excluding dedicated C-section operating rooms) except relocations of existing operating rooms between existing licensed facilities within the same 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 not be approved unless the applicant reasonably demonstrates the need for the number of proposed operating rooms in addition to the rooms in its 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 its facilities, 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 C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all its facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing, approved and proposed operating rooms, excluding one operating room for Level I, II or III 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 its licensed facilities in the service area. A need is demonstrated if the difference is a positive number greater than or equal to 0.50."*

-NA- The applicants propose to relocate five existing ORs from MPH, an existing licensed hospital, to FMC-Clemmons, which will be licensed as part of FMC, an existing licensed hospital. Therefore, the rule is not applicable to this review.

.2103(d) This rule states *"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- The applicants do not propose to develop a dedicated C-section OR. Therefore, the rule is not applicable to this review.

.2103(e) This rule states *"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 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."*

-NA- The applicants do not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program. Therefore, the rule is not applicable to this review.

.2103(f) This rule states *"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 reasonably demonstrate the need for the conversion 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 for*

the conversion 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- The applicants do not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program. Therefore, the rule is not applicable to this review.

.2103(g) This rule states *"The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule."*

-NA- The applicants were not required to provide any projections pursuant to this rule. Therefore, the rule is not applicable to this review. However, see Criterion (3) for projected utilization and the applicants' assumptions and methodology used.

10A NCAC 14C .2104 SUPPORT SERVICES

.2104(a) This rule states *"An applicant proposing to establish a new ambulatory surgical facility, increase the number of operating rooms, convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or add a specialty to a specialty ambulatory surgical program shall provide written policies and procedures demonstrating that the facility will have patient referral, transfer, and followup procedures."*

-C- Exhibit 19 contains copies of written policies and procedures which demonstrate that FMC has patient referral, transfer and follow-up procedures, which will also apply to the proposed FMC-Clemmons campus.

.2104(b) This rule states *"The applicant shall provide documentation showing the proximity of the proposed facility to the following services:*

(1) emergency services;
(2) support services;
(3) ancillary services; and
(4) public transportation."

-C- In Section II.8, pages 56-57, the applicants provide documentation regarding the proximity of the proposed FMC-Clemmons campus to the services listed in this rule.

10A NCAC 14C .2105 STAFFING AND STAFF TRAINING

.2105(a) This rule states *"An applicant proposing to establish a new ambulatory surgical facility, to increase the number of 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 identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas:*

(1) administration;
(2) pre-operative;
(3) post-operative;
(4) operating room; and
(5) other."

-CA- In response to this rule, in Section II.8, page 57, the applicants state *"The staffing table in Section VII of this application identifies the necessary staffing for the surgical services program at CLMC for the first three years of operation."* The following table illustrates proposed staffing for Surgical Services at FMC-Clemmons, as reported by the applicants in Section VII.2, page 207.

SURGICAL SERVICES POSITION	# OF FTE STAFF POSITIONS		
	YEAR 1	YEAR 2	YEAR 3
Nurse Manager	1.0	1.0	1.0
Assistant Nurse Manager	1.0	1.0	1.0
Administrative Specialist II	1.0	1.0	1.0
Clinical Coordinator	1.0	1.0	1.0
Data Specialist	1.0	1.0	1.0
Registered Nurse	23.3	25.7	28.3
Surgical Tech	4.0	4.4	4.9
Sterile Reprocessing Tech Cert	3.0	3.3	3.6
Transportation Aide	1.0	1.1	1.2
Surgical Partner	3.0	3.3	3.6
CRNA	3.0	3.3	3.6
Total	42.3	46.1	50.2

As shown in the above table, it is possible to determine the number of FTE administrative staff positions, but not the

number of FTE positions to be utilized in each of the following areas: pre-operative, post-operative, operating room and other. Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall provide the Certificate of Need Section a breakdown of the total number of surgical services staff, which was provided, that will be utilized in each of the following areas: 1) pre-operative; 2) post-operative; 3) operating room; and 4) other.

.2105(b) This rule states *"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- In Section II.8, page 58, the applicants identify the number of physicians by specialty currently utilizing the ORs at FMC in Winston-Salem and the projected number of physicians by specialty expected to utilize the ORs at FMC-Clemmons.

.2105(c) This rule states *"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 ambulatory surgical service area in which the facility is, or will be, located or will have written referral procedures with a physician who is an active member in good standing at a general acute care hospital in the ambulatory surgical service area."*

-C- In Section II.8, pages 58-59, the applicants state that all of the physicians utilizing the ORs at FMC-Clemmons will be members of FMC's Medical Staff.

10A NCAC 14C .2106 FACILITY

.2106(a) This rule states *"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- The applicants do not propose to develop a licensed ambulatory surgical facility.

.2106(b) This rule states *"An applicant proposing a licensed ambulatory surgical facility 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."*

-NA- The applicants do not propose to develop a licensed ambulatory surgical facility.

.2106(c) This rule states *"An applicant proposing to establish a new ambulatory surgical facility, to increase the number of 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 document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies."*

-C- Exhibit 19 contains a July 1, 2008 letter signed by the Senior Director, Design and Construction for Novant, which states that the physical environment of FMC-Clemmons will conform to the requirements of federal, state and local regulatory bodies.

.2106(d) This rule states *"The applicant 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- Exhibits 16 and 19 contain floor plans of the first floor of the proposed FMC-Clemmons which identifies all of the areas listed in this rule.

.2106(e) This rule states *"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- The applicants do not propose to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or add a specialty to a specialty ambulatory surgical program.

SECTION .3900 CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILTIES

10A NCAC 14C .3902 INFORMATION REQUIRED OF APPLICANT

.3902(a)(1) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: (1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906."*

-C- Pursuant to 10A NCAC 14C .3901(6), *"'Service area' means the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients."* In response to the above rule, in Section II.8, page 61, the applicants state *"The service area for the proposed project is defined as five zip codes in Forsyth and Davie Counties."* In Section III.1, page 120, the applicants also state that 10% of the patients served at FMC-Clemmons are projected to reside in *"surrounding zip codes in Forsyth County and other surrounding counties, such as Iredell and Yadkin."* Thus, the applicants describe the proposed service area as including Forsyth, Davie, Iredell and Yadkin counties.

.3902(a)(2)(A) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: (A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located."*

-C- In Section II.8, pages 61-62, the applicants state that FMC is currently licensed for 6 GI endoscopy rooms but will be converting 2 of those to 2 dedicated OP ORs pursuant to the certificate of need issued for Project I.D. #G-7416-05. According to its 2008 license, FMC, which now includes HSC, is currently licensed for 8 GI endoscopy rooms, not 6. The

following projects were previously approved for FMC and HSC and are not yet complete:

- Project I.D. #G-7412-05 (convert 2 existing GI endoscopy rooms at FMC to 2 shared ORs); and
- Project I.D. # G-7416-05 (relocate 2 existing GI endoscopy rooms from FMC to HSC and convert them to 2 dedicated OP ORs).

Thus, upon completion of both of those projects, FMC will be licensed for 4 GI endoscopy rooms. In this application, the applicants propose to develop one additional GI endoscopy room on the FMC-Clemmons campus, for a total of 5 GI endoscopy rooms upon completion of this project, Project I.D. #G-7412-05 and Project I.D. #G-7416-05.

.3902(a)(2)(B) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area."*

-C- In response to this rule, in Section II.8, page 62, the applicants state *"Not applicable. Neither FMC nor Novant has a controlling interest in any other GI Endoscopy Room located in Forsyth or Davie County."* However, the applicants' proposed service area also includes Yadkin and Iredell counties. See discussion in 10A NCAC 14C .3902(a)(1). Novant, a co-applicant, is one of the owners of Davis Regional Medical Center (Davis) and Lake Norman Regional Medical Center (Lake Norman), both of which are located in Iredell County. According to their 2008 Hospital License Renewal Applications, Davis is licensed for 2 GI endoscopy rooms and Lake Norman is licensed for 3 GI endoscopy rooms.

.3902(a)(2)(C) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an*

existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months."

-C- In Exhibit 5, Table 33, the applicants provide a list of the procedures, identified by ICD-9-CM code, performed in the GI endoscopy rooms at FMC during CY 2007.

.3902(a)(2)(D) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project."*

-CA- FMC-Winston-Salem – In Section II.8, page 63, the applicants state *"Please see Exhibit 5, Table 34 for projected GI Endoscopy procedures at FMC in the four existing GI Endoscopy rooms."* However, Exhibit 5, Table 34 does not contain projected utilization for the four existing GI endoscopy rooms at FMC-Winston-Salem. Instead, the information required by this rule is provided in Exhibit 5, Table 33, for FMC-Winston-Salem. The following table illustrates the number of procedures projected to be performed in the four existing GI endoscopy rooms at FMC-Winston-Salem, as provided by the applicants in Table 33 where the procedures are identified by ICD-9-CM code.

existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months."

-C- In Exhibit 5, Table 33, the applicants provide a list of the procedures, identified by ICD-9-CM code, performed in the GI endoscopy rooms at FMC during CY 2007.

.3902(a)(2)(D) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project."*

-CA- FMC-Winston-Salem – In Section II.8, page 63, the applicants state *"Please see Exhibit 5, Table 34 for projected GI Endoscopy procedures at FMC in the four existing GI Endoscopy rooms."* However, Exhibit 5, Table 34 does not contain projected utilization for the four existing GI endoscopy rooms at FMC-Winston-Salem. Instead, the information required by this rule is provided in Exhibit 5, Table 33, for FMC-Winston-Salem. The following table illustrates the number of procedures projected to be performed in the four existing GI endoscopy rooms at FMC-Winston-Salem, as provided by the applicants in Table 33 where the procedures are identified by ICD-9-CM code.

	FMC-Winston-Salem Total # of Procedures Projected to be Performed in the Four Existing GI Endoscopy Rooms as Provided by the Applicants in Table 33		
	GI Endoscopy Procedures	Non-GI Endoscopy Procedures	Total Procedures
Year One	14,185	986	15,171
Year Two	14,339	997	15,336
Year Three	14,494	1,008	15,502

In comparison, the following table illustrates the number of GI endoscopy procedures projected to be performed at FMC-Winston-Salem during the first three operating years, as provided by the applicants in Section II.8, page 68, and Exhibit 5, Table 30.

	FMC-Winston-Salem # of GI Endoscopy Procedures Projected to be Performed in the Four Existing GI Endoscopy Rooms, as Provided by the Applicants in Section II.8, page 68, and Table 30
Year One	13,624
Year Two	13,566
Year Three	13,502

As shown in the two tables above, the number of GI endoscopy procedures reported in Table 33 is not the same as the number reported in Table 30.

FMC-Clemmons – In Section II.8, page 62, the applicants state *"Please see Exhibit 5, Table 32 for projected GI Endoscopy procedures at CLMC in the one new GI Endoscopy room."* The following table illustrates the number of GI endoscopy procedures projected to be performed at FMC-Clemmons during the first three operating years, as provided by the applicants in Exhibit 5, Table 29.

	FMC-CLEMMONS # OF GI ENDOSCOPY CASES AND PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM, AS PROVIDED BY THE APPLICANTS IN TABLE 29	
	GI ENDOSCOPY CASES	GI ENDOSCOPY PROCEDURES (1.29 procedures per case)
Year One	1,201	1,546
Year Two	1,375	1,770
Year Three	1,554	2,000

In comparison, the following table illustrates the total number of procedures (GI and non-GI endoscopy) projected to be performed in the proposed GI endoscopy room at FMC-Clemmons, as provided by the applicants in Table 32 where the procedures are identified by ICD-9-CM code.

	FMC-CLEMMONS TOTAL # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM (including GI Endoscopy and Non-GI Endoscopy Procedures) AS PROVIDED BY THE APPLICANTS IN TABLE 32
Year One	1,546
Year Two	1,770
Year Three	2,000

As shown in the two tables above, the number of GI endoscopy procedures provided by the applicants in Exhibit 5, Table 29 is the same as the total number of procedures (GI endoscopy and non-GI endoscopy) provided in Exhibit 5, Table 32. However, in Section II.8, page 63, the applicants state that 6% of all procedures are projected to be non-GI endoscopy procedures. Thus, based on the 6% assumption and numbers in Table 32, the number of GI endoscopy procedures would be only 1,453 in Year One, 1,664 in Year Two and 1,880 in Year Three. The inconsistent projections cannot be reconciled.

In summary, the applicants provided inconsistent projections in response to this rule. Therefore, the correct number of GI endoscopy procedures to be performed at either FMC-Winston-Salem or FMC-Clemmons is not known. Consequently, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for additional discussion and condition.

	FMC-CLEMMONS # OF GI ENDOSCOPY CASES AND PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM, AS PROVIDED BY THE APPLICANTS IN TABLE 29	
	GI ENDOSCOPY CASES	GI ENDOSCOPY PROCEDURES (1.29 procedures per case)
Year One	1,201	1,546
Year Two	1,375	1,770
Year Three	1,554	2,000

In comparison, the following table illustrates the total number of procedures (GI and non-GI endoscopy) projected to be performed in the proposed GI endoscopy room at FMC-Clemmons, as provided by the applicants in Table 32 where the procedures are identified by ICD-9-CM code.

	FMC-CLEMMONS TOTAL # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM (including GI Endoscopy and Non-GI Endoscopy Procedures) AS PROVIDED BY THE APPLICANTS IN TABLE 32
Year One	1,546
Year Two	1,770
Year Three	2,000

As shown in the two tables above, the number of GI endoscopy procedures provided by the applicants in Exhibit 5, Table 29 is the same as the total number of procedures (GI endoscopy and non-GI endoscopy) provided in Exhibit 5, Table 32. However, in Section II.8, page 63, the applicants state that 6% of all procedures are projected to be non-GI endoscopy procedures. Thus, based on the 6% assumption and numbers in Table 32, the number of GI endoscopy procedures would be only 1,453 in Year One, 1,664 in Year Two and 1,880 in Year Three. The inconsistent projections cannot be reconciled.

In summary, the applicants provided inconsistent projections in response to this rule. Therefore, the correct number of GI endoscopy procedures to be performed at either FMC-Winston-Salem or FMC-Clemmons is not known. Consequently, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for additional discussion and condition.

.3902(a)(2)(E) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months."*

-CA- In Section II.8, page 63, the applicants state *"Please see Exhibit 5, Table 33 for GI Endoscopy procedures, including those other than GI Endoscopy procedures performed in the four* [sic] *existing GI Endoscopy rooms at FMC in calendar year 2007."* Exhibit 5, Table 33, consists of a list of all procedures, identified by ICD-9-CM code, performed in the GI endoscopy rooms at FMC during CY 2007. However, the table does not identify which of the listed procedures are not GI endoscopy procedures. Therefore, it is not possible to determine the number of procedures which are not GI endoscopy procedures. Consequently, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for additional discussion and condition.

.3902(a)(2)(F) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project."*

-CA- FMC-Winston-Salem – In Section II.8, page 63, the applicants state *"Please see Exhibit 5, Table 34 for projected GI Endoscopy procedures at FMC in the four existing GI Endoscopy rooms."* However, Exhibit 5, Table 34 does not contain projected utilization for the existing GI endoscopy rooms at FMC-Winston-Salem. The information required by this rule is provided in Exhibit 5, Table 33, for FMC-Winston-Salem. The following table illustrates the total number of

procedures projected to be performed in the four existing GI endoscopy rooms at FMC-Winston-Salem, as provided by the applicants in Table 33 where the procedures are identified by ICD-9-CM code.

	FMC-Winston-Salem Total # of Procedures Projected to be Performed in the Four Existing GI Endoscopy Rooms as Provided by the Applicants in Table 33		
	GI Endoscopy Procedures	Non-GI Endoscopy Procedures	Total Procedures
Year One	14,185	986	15,171
Year Two	14,339	997	15,336
Year Three	14,494	1,008	15,502

In comparison, the following table illustrates the number of GI endoscopy procedures projected to be performed at FMC-Winston-Salem during the first three operating years, as provided by the applicants in Section II.8, page 68, and Exhibit 5, Table 30.

	FMC-Winston-Salem # of GI Endoscopy Procedures Projected to be Performed in the Four Existing GI Endoscopy Rooms, as Provided by the Applicants in Section II.8, page 68, and Table 30
Year One	13,624
Year Two	13,566
Year Three	13,502

As shown in the two tables above, the number of GI endoscopy procedures reported in Table 33 is not the same as the number of procedures reported in Table 30.

FMC-Clemmons – In Section II.8, page 62, the applicants state *"Please see Exhibit 5, Table 32 for projected GI Endoscopy procedures at CLMC in the one new GI Endoscopy room."* The following table illustrates the number of GI endoscopy procedures projected to be performed at FMC-Clemmons during the first three operating years, as provided by the applicants in Exhibit 5, Table 29.

	FMC-CLEMMONS # OF GI ENDOSCOPY CASES AND PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM, AS PROVIDED BY THE APPLICANTS IN TABLE 29	
	GI ENDOSCOPY CASES	GI ENDOSCOPY PROCEDURES (1.29 procedures per case)
Year One	1,201	1,546
Year Two	1,375	1,770
Year Three	1,554	2,000

In comparison, the following table illustrates the total number of procedures projected to be performed in the proposed GI endoscopy room at FMC-Clemmons, as provided by the applicants in Table 32 where the procedures are identified by ICD-9-CM code.

	FMC-CLEMMONS TOTAL # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM (including GI Endoscopy and Non-GI Endoscopy Procedures) AS PROVIDED BY THE APPLICANTS IN TABLE 32
Year One	1,546
Year Two	1,770
Year Three	2,000

As shown in the two tables above, the number of GI endoscopy procedures provided by the applicants in Exhibit 5, Table 29 is the same as the total number of procedures (GI endoscopy and non-GI endoscopy) provided in Exhibit 5, Table 32. However, in Section II.8, page 63, the applicants state that 6% of all procedures are projected to be non-GI endoscopy procedures. Thus, based on the 6% assumption and numbers in Table 32, the number of GI endoscopy procedures would be only 1,453 in Year One, 1,664 in Year Two and 1,880 in Year Three. The inconsistent projections cannot be reconciled.

In summary, the applicants provided inconsistent projections in response to this rule. Therefore, the correct number of non-GI endoscopy procedures to be performed at either FMC-Winston-Salem or FMC-Clemmons is not known. Consequently, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for additional discussion and condition.

.3902(a)(2)(G) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months."*

-C- In Exhibit 5, Table 33, the applicants report that a total of 7,044 patients were served in FMC's existing GI endoscopy rooms during CY 2007.

.3902(a)(2)(H) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: ... (H) the number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project.*

-CA- FMC-Clemmons – In Section II.8, page 64, and Exhibit 5, Table 29, the applicants provide the number of patients projected to be served in the proposed GI endoscopy room at FMC-Clemmons in each of the first three operating years, as illustrated in the following table.

FMC-CLEMMONS	YEAR ONE	YEAR TWO	YEAR THREE
Projected GI endoscopy patients	1,201	1,375	1,554
Projected non-GI endoscopy patients	78	89	101
Total Patients	1,279	1,464	1,655

FMC-Winston-Salem – In Section II.8, page 64, and Exhibit 5, Table 30, the applicants provide the number of GI endoscopy patients projected to be served in the existing GI endoscopy rooms at FMC-Winston-Salem in each of the first three operating years, as illustrated in the following table.

FMC-WINSTON-SALEM SECTION II.8, PAGE 64, AND TABLE 30	YEAR ONE	YEAR TWO	YEAR THREE
Projected GI endoscopy patients	7,171	7,140	7,106

In comparison, the following table illustrates the number of GI endoscopy and non-GI endoscopy patients projected to be served in the existing GI endoscopy rooms at FMC-Winston-Salem, as provided by the applicants in Exhibit 5, Table 33.

FMC-WINSTON-SALEM EXHIBIT 5, TABLE 33	YEAR ONE	YEAR TWO	YEAR THREE
Projected GI endoscopy patients	7,466	7,547	7,629
Projected non-GI endoscopy patients	519	524	530
Total Patients	7,985	8,071	8,159

As shown in the two tables above, the number of GI endoscopy patients projected to be served at FMC-Winston-Salem as reported in Table 30 is not the same as the number reported in Table 33.

In summary, the applicants provided inconsistent projections in response to this rule. Therefore, the correct number of patients to be served at FMC-Winston-Salem is not known. Consequently, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for additional discussion and condition.

.3902(a)(3)(A) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (3) with regard to services provided in the applicant's operating rooms identify: (A) the number of existing operating rooms in the facility.*

-C- In Section II.8, page 64, the applicants provide the number of existing ORs at FMC.

.3902(a)(3)(B) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (3) with regard to services provided in the applicant's operating rooms identify: ... (B) the number of procedures by type performed in the operating rooms in the last 12 months."*

-C- In Section II.8, page 64, the applicants state *"Please see Exhibit 5, Table 35 for historical surgical procedures by type in the last 12 months, May 2008 through April 2007. For the purposes of this rule, procedures by type is defined as surgical procedure codes."* Table 35 in Exhibit 5 is a 9 page list of surgical procedures, identified by ICD-9-CM code, performed between January 1, 2008 and May 31, 2008. In Exhibit 5, Table 25, the applicants provide the total number of inpatient surgical cases (9,791) and outpatient surgical cases (6,320) performed in the existing ORs at FMC between April 1, 2007 and May 31, 2008, which is 12 months.

.3902(a)(3)(C) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (3) with regard to services provided in the applicant's operating rooms identify: ... (C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project."*

-C- In Exhibit 5, Tables 34 and 35, the applicants provide the number of procedures, identified by ICD-9-CM code, projected to be performed in the ORs in each of the first three operating years.

.3902(a)(4) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located."*

-C- In Section II.8, page 65, the applicants provide the hours of operation of the existing GI endoscopy rooms at FMC-Winston-Salem and the proposed GI endoscopy room at FMC-Clemmons.

.3902(a)(5) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an*

existing licensed health service facility shall provide the following information: ... (5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months."

-C- In Section II.8, page 65, the applicants provide the average charge for each of the 10 GI endoscopy procedures most commonly performed at FMC during 2008.

.3902(a)(6) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility."*

-C- In Section II.8, page 66, the applicants provide the projected average charge for each of the 10 GI endoscopy procedures which the applicants project will be performed most often during the first three operating years.

.3902(a)(7) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge."*

-C- In Sections X.1 and X.2, pages 236-250, the applicants provide a list of all services and items included in each charge and a description of the bases on which these costs are included in the charge.

.3902(a)(8) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges."*

-C- In Sections X.1 and X.2, pages 236-250, the applicants identify all services and items that are not included in the facility's charges.

.3902(a)(9) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the ten GI endoscopy procedures most commonly performed in the facility during the preceding 12 months."*

-C- In Section II.8, page 67, the applicants provide the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed at FMC during 2008.

.3902(a)(10) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (10) the average reimbursement projected to be received for each of the ten GI endoscopy procedures which the applicant projects will be performed most frequently in the facility."*

-C- In Section II.8, page 67, the applicants provide the average reimbursement projected to be received for each of the 10 GI endoscopy procedures the applicants state will be performed most frequently during the first three operating years.

.3902(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:*

(1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.

(2) a written commitment to participate in and comply with conditions of participation in the Medicare and

Medicaid programs within three months after licensure of the facility;

(3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;

(4) a written description of patient selection criteria including referral arrangements for high-risk patients;

(5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;

(6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the rationale for its change in practice pattern."

-NA- The applicants do not propose to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures.

10A NCAC 14C .3903 PERFORMANCE STANDARDS

.3903(a) This rule states *"In providing projections for operating rooms, as required in this rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding ten days for holidays."*

-C- In Section II.8, page 68, the applicants state that the FMC-Clemmons GI endoscopy room will operate five days per week, 52 weeks per year, which is 260 days per year.

.3903(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project."*

-CA- FMC-Winston-Salem – In Section II.8, page 63, the applicants state *"Please see Exhibit 5, Table 34 for projected GI Endoscopy procedures at FMC in the four existing GI Endoscopy rooms."* However, Exhibit 5, Table 34 does not contain projected utilization for the existing GI endoscopy rooms at FMC-Winston-Salem. The information required by this rule is provided in Exhibit 5, Table 33, for FMC-Winston-Salem. The following table illustrates the number of procedures projected to be performed in the existing GI endoscopy rooms at FMC-Winston-Salem, as provided by the applicants in Table 33 where the procedures are identified by ICD-9-CM code.

	FMC-WINSTON-SALEM TOTAL # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE FOUR EXISTING GI ENDOSCOPY ROOMS AS PROVIDED BY THE APPLICANTS IN TABLE 33		
	GI ENDOSCOPY PROCEDURES	NON-GI ENDOSCOPY PROCEDURES	TOTAL PROCEDURES
Year One	14,185	986	15,171
Year Two	14,339	997	15,336
Year Three	14,494	1,008	15,502

In comparison, the following table illustrates the number of GI endoscopy procedures projected to be performed at FMC-Winston-Salem during the first three operating years, as provided by the applicants in Section II.8, page 68, and Exhibit 5, Table 30.

	FMC-WINSTON-SALEM # OF GI ENDOSCOPY PROCEDURES PROJECTED TO BE PERFORMED IN THE FOUR EXISTING GI ENDOSCOPY ROOMS, AS PROVIDED BY THE APPLICANTS IN SECTION II.8, PAGE 68, AND TABLE 30
Year One	13,624
Year Two	13,566
Year Three	13,502

As shown in the two tables above, the number of GI endoscopy procedures reported in Table 33 is not the same as the number of procedures reported in Table 30.

FMC-Clemmons – The following table illustrates the number of GI endoscopy procedures projected to be performed at FMC-

Clemmons during the first three operating years, as provided by the applicants in Exhibit 5, Table 29.

	FMC-CLEMMONS # OF GI ENDOSCOPY CASES AND PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM, AS PROVIDED BY THE APPLICANTS IN TABLE 29	
	GI ENDOSCOPY CASES	GI ENDOSCOPY PROCEDURES (1.29 procedures per case)
Year One	1,201	1,546
Year Two	1,375	1,770
Year Three	1,554	2,000

In comparison, the following table illustrates the total number of procedures projected to be performed in the proposed GI endoscopy room at FMC-Clemmons, as provided by the applicants in Table 32 where the procedures are identified by ICD-9-CM code.

	FMC-CLEMMONS TOTAL # OF PROCEDURES PROJECTED TO BE PERFORMED IN THE PROPOSED GI ENDOSCOPY ROOM (including GI Endoscopy and Non-GI Endoscopy Procedures) AS PROVIDED BY THE APPLICANTS IN TABLE 32
Year One	1,546
Year Two	1,770
Year Three	2,000

As shown in the two tables above, the number of GI endoscopy procedures provided by the applicants in Exhibit 5, Table 29 is the same as the total number of procedures (GI endoscopy and non-GI endoscopy) provided in Exhibit 5, Table 32. However, in Section II.8, page 63, the applicants state that 6% of all procedures are projected to be non-GI endoscopy procedures. Thus, based on the 6% assumption and numbers in Table 32, the number of GI endoscopy procedures would be only 1,453 in Year One, 1,664 in Year Two and 1,880 in Year Three. The inconsistent projections cannot be reconciled.

In summary, the applicants provided inconsistent projections in response to this rule. Therefore, the correct number of GI endoscopy procedures to be performed at either FMC-Winston-Salem or FMC-Clemmons is not known. Consequently, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for additional discussion and condition.

.3903(c) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures."*

-C- In Section II.8, page 69, the applicants state *"The proposed GI Endoscopy room at CLMC will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures."*

.3903(d) This rule states *"If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*

(1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or

(2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future."

-CA- In Section II.8, page 69, the applicants state *"FMC does not utilize its existing operating rooms to perform routine endoscopy procedures."* To demonstrate that FMC does not perform GI endoscopy procedures in its ORs, the applicants

refer to FMC's 2008 Hospital License Renewal Application, which shows that FMC did not report performing GI endoscopy procedures in its ORs during FFY 2007. See also, the letter in Exhibit 20 signed by the Vice President, Surgical Services, Novant Health Triad Region, which states that GI endoscopy procedures are not performed and will not be performed in FMC's ORs.

MPH is owned by Novant (a co-applicant) and is located in Forsyth County, which is one of the counties included in the applicants' proposed service area. According to MPH's 2008 Hospital License Renewal Application, during FFY 2007, no GI endoscopy procedures were performed at MPH. However, the applicants failed to demonstrate that GI endoscopy procedures will not be performed in the ORs at MPH in the future.

Further, the applicants' proposed service area also includes Yadkin and Iredell counties. Novant owns a minority interest in Davis Regional Medical Center (Davis) and Lake Norman Regional Medical Center (Lake Norman), both of which are located in Iredell County. According to Davis' 2008 Hospital License Renewal Application, during FFY 2007, 31 GI endoscopy procedures were performed at Davis but not in one of the two existing GI endoscopy rooms. The applicants do not demonstrate that GI endoscopy procedures were not performed in the five shared ORs at Davis in the last 12 months and will not be performed in those rooms in the future. According to Lake Norman's 2008 Hospital License Renewal Application, during FFY 2007, all GI endoscopy procedures performed at Lake Norman were performed in one of the three existing GI endoscopy rooms. However, the applicants do not demonstrate that GI endoscopy procedures will not be performed in one of the seven shared ORs at Lake Norman in the future.

Therefore, the applicants do not demonstrate conformance with the rule and are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for the condition.

.3903(e) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall*

describe all assumptions and the methodology used for each projection in this Rule."

-CA- The applicants describe all assumptions and the methodology used for each projection in this Rule in Section III.1, pages 129-132, and Exhibit 5, Tables 29-35. However, the applicants provide inconsistent projections in response to this Rule. See discussion in 10A NCAC 14C .3903(b) above and Criterion (3). Therefore, the applicants are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for the condition.

10A NCAC 14C .3904 SUPPORT SERVICES

.3904(a) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services."*

-C- Exhibit 20 contains a signed agreement between FMC and Pathologists Diagnostic Services, PLLC for the provision of pathology services to FMC, MPH and Thomasville Medical Center.

.3904(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes."*

-C- Exhibit 20 contains a copy of FMC's existing guidelines for the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes. In Section II.8, page 70, the applicants state *"Since CLMC will be licensed under the existing FMC acute care hospital license, these policies will apply to GI endoscopy services provided at CLMC."*

.3904(c) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases."*

-C- Exhibit 20 contains a copy of FMC's existing policy and procedures for cleaning and monitoring the cleanliness of scopes, other equipment and the procedure room between cases.

.3904(d)(1) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide: (1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county."*

-C- In Section II.8, page 70, the applicants state that the physicians utilizing the proposed GI endoscopy room at FMC-Clemmons will be members of FMC's Medical Staff with practice privileges.

.3904(d)(2) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide: ... (2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges."*

-C- In Section II.8, page 71, the applicants state that the proposed GI endoscopy room will be located in and licensed as part of a hospital. The physicians utilizing the proposed GI endoscopy room will be members of FMC's Medical Staff with practice privileges.

.3904(d)(3) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide: ... (3) documentation of a transfer agreement with a hospital in case of an emergency."*

-C- Exhibit 10 contains a copy of a transfer agreement between the FMC-Winston-Salem campus and the FMC-Clemmons campus.

10A NCAC 14C .3905 STAFFING AND STAFF TRAINING

.3905(a) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas:*

(1) administration;
(2) pre-operative;
(3) post-operative;
(4) procedure rooms;
(5) equipment cleaning, safety, and maintenance; and
(6) other."

-CA- In response to this rule, in Section II.8, page 71, the applicants state *"See the applicant's response to Question VII.2. ... Both the surgical patients and the GI endoscopy patients will share the use of the pre-operative/pre-procedure space and the post-operative/recovery space."* The following table illustrates proposed staffing for GI Endoscopy Services and surgical services at FMC-Clemmons, as reported by the applicants in Section VII.2, page 207.

GI Endoscopy Services Position	# of FTE Staff Positions		
	Year 1	Year 2	Year 3
Registered Nurse	1.5	1.8	2.0
Surgical Tech	1.0	1.3	2.0
Sterile Reprocessing Tech Cert	0.5	0.5	1.0
Total	**3.0**	**3.6**	**5.0**

SURGICAL SERVICES POSITION	# OF FTE STAFF POSITIONS		
	YEAR 1	YEAR 2	YEAR 3
Nurse Manager	1.0	1.0	1.0
Assistant Nurse Manager	1.0	1.0	1.0
Administrative Specialist II	1.0	1.0	1.0
Clinical Coordinator	1.0	1.0	1.0
Data Specialist	1.0	1.0	1.0
Registered Nurse	23.3	25.7	28.3
Surgical Tech	4.0	4.4	4.9
Sterile Reprocessing Tech Cert	3.0	3.3	3.6
Transportation Aide	1.0	1.1	1.2
Surgical Partner	3.0	3.3	3.6
CRNA	3.0	3.3	3.6
Total	42.3	46.1	50.2

As shown in the above tables, it is not possible to determine the number of FTE positions in each of the following areas: administrative, pre-operative, post-operative, procedure room, equipment cleaning, safety and maintenance and other. Therefore, the applicants did not demonstrate conformance with this rule and are conditioned not to develop a GI endoscopy room at FMC-Clemmons. See Criterion (3) for the condition.

.3905(b) This rule states *"The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility."*

-C- In Section II.8, page 72, the applicants identify the number of physicians by specialty and board-certification status that currently utilize the existing GI endoscopy rooms at FMC-Winston-Salem and that are projected to utilize the proposed GI endoscopy room at FMC-Clemmons.

.3905(c) This rule states *"The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility."*

-C- Exhibit 4 contains a copy of FMC's Physician Credentialing Policy, the Bylaws of FMC's Medical Staff and a letter signed by FMC's Executive Vice President of Medical Staff Services, which states that credentialing criteria for privileges at FMC-Clemmons will be the same as those at FMC-Winston-Salem.

.3905(d) This rule states *"If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:*

(1) a Medical director who is a board certified gastroenterologist by American Board of Internal Medicine, colorectal surgeon by American Board of Colon and Rectal Surgery or general surgeon by American Board of Surgery is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;

(2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;

(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;

(4) at least one registered nurse shall be employed per procedure room;

(5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and

(6) a [sic] *least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified."*

-NA- FMC-Clemmons will be licensed as part of FMC, which is accredited by The Joint Commission on Accreditation of Healthcare Organizations.

10A NCAC 14C .3906 FACILITY

.3906(a) This rule states *"An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm 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- The applicants do not propose to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital.

.3906(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project."*

-C- FMC is currently accredited by The Joint Commission on Accreditation of Healthcare Organizations.

.3906(c) This rule states *"If the facility is not accredited at the time the application is submitted, an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall:*

(1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

(2) provide a floor plan of the proposed facility identifying the following areas:

(A) receiving/registering area;

(B) waiting area;

(C) pre-operative area;

(D) procedure room by type; and
(E) recovery area.

(3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and

(4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located."

-NA- FMC-Clemmons will be licensed as part of FMC, which is already accredited.

SECTION .2300 CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

10A NCAC 14C .2302 INFORMATION REQUIRED OF APPLICANT

.2302(a) This rule states *"An applicant proposing to acquire a CT scanner shall use the acute care facility/medical equipment application form."*

-C- The applicants used the acute care facility/medical equipment application form.

.2302(b) This rule states *"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."

-CA- Pursuant to 10A NCAC 14C .2301(4), *"'Computed tomography (CT) service area' means a geographical area defined by the applicant from which the applicant projects to serve patients."* In Section III.1, page 100, the applicants define the proposed service area for FMC-Clemmons as follows:

> *"The proposed CLMC service area consists of two zip codes in Forsyth County and three zip codes in Davie County (one, 27014, is a P.O. Box location in Cooleemee). The service area includes the Township of Clemmons (zip code 27012), the Township of Lewisville (zip code 27023) in Forsyth County, and the Townships*

of Advance (zip code 27006) and Mocksville (zip code 27028) in Davie County."

In addition, in Section III.1, page 120, the applicants state

"While not part of the defined service area, CLMC recognizes that patients from other North Carolina counties may choose to travel across service areas to receive services at CLMC, or may end up having to seek hospital services while in the service area for business or pleasure. As a result, 10% of the total projected utilization in each of the project years has been allocated to the category of 'Other Inmigration.' Other inmigration is expected to come from surrounding zip codes in Forsyth County and other surrounding counties, such as Iredell and Yadkin."

Although the applicants claim the service area for the proposed FMC-Clemmons does not include the rest of Forsyth County or Iredell and Yadkin counties, the applicants state that 1 out of every 10 patients it projects to serve at FMC-Clemmons reside in those areas. Therefore, the rest of Forsyth County and Iredell and Yadkin counties are included in the service area for the proposed FMC-Clemmons.

Moreover, in Section II.8, page 92, the applicants state

"The applicant [sic] *believes that because the scope of services at CLMC which includes an Emergency Department and ICU, it is imperative that patients and physicians at CLMC have on-site access to CT diagnostic services 24 hours per day, 7 days per week. This is the community standard of care and in fact, two Novant hospitals (Forsyth Medical Center and Thomasville Medical Center)* [sic] *CT scanners located both in their emergency departments and in their radiology departments."*

Thus, the applicants project that inpatients and ED patients will use the proposed CT scanner. Because 10% of the patients admitted to an acute care bed (including ICU beds) or seen in the ED are projected to be residents of areas outside the five zip

code areas, the service area for the CT scanner will be the same as the service area for acute care and ED services.

The following table identifies the facilities in which Novant (a co-applicant) or a related entity owns a controlling interest in and is located in the proposed service area for FMC-Clemmons. See Section I.13, pages 16-17. The table also illustrates the number of existing CT scanners operated by these facilities.

FACILITIES IN WHICH NOVANT OR ONE OF ITS SUBSIDIARIES OWNS A CONTROLLING INTEREST IN LOCATED IN THE PROPOSED SERVICE AREA	CITY	COUNTY	# OF EXISTING CT SCANNERS
FMC	Winston-Salem	Forsyth	4
Winston-Salem Health Care	Winston-Salem	Forsyth	1
Piedmont Imaging	Winston-Salem	Forsyth	2
Greystone Imaging Center	Winston-Salem	Forsyth	1
Maplewood Imaging Center	Winston-Salem	Forsyth	2
Kernersville Imaging Center	Kernersville	Forsyth	1
Total			11

In Section II.8, page 85, the applicants provide the number of CT scans performed on the four existing CT scanners at FMC during FFY 2007 for each type of CT scan listed in this rule. However, the applicants failed to provide the number of CT scans performed on the 7 other existing CT scanners located at the other facilities listed in the table above for the previous 12 month period as required by this rule. Therefore, the applicants did not demonstrate conformance with this rule and are conditioned not to acquire a new CT scanner but to either relocate an existing CT scanner to FMC-Clemmons or to contract to use an existing mobile CT scanner. See Criterion (3) for the condition.

.2302(c) This rule states *"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."

-CA- The applicants provided inconsistent information in response to this rule. The following table illustrates the projected number of CT scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule during each of the first three operating years, as reported by the applicants in Section II.8, pages 86, and Exhibit 5, Table 52, page 4.

TYPE OF CT SCAN	YEAR 1	YEAR 2	YEAR 3
head scan without contrast	1,854	2,144	2,444
head scan with contrast	194	229	265
head scan without and with contrast	115	130	146
body scan without contrast	2,034	2,374	2,726
body scan with contrast	3,310	3,858	4,426
body scan without contrast and with contrast	792	911	1,033
biopsy in addition to body scan with or without contrast	0	0	0
abscess drainage in addition to body scan with or without contrast	0	0	0
TOTAL [1]	**8,299**	**9,647**	**11,041**

[1] The totals may not foot due to rounding.

The following table illustrates the projected number of CT scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule during each of the first three operating years, as reported by the applicants in Section II.8, page 87.

TYPE OF CT SCAN	YEAR	YEAR	YEAR
head scan without contrast	1,854	2,144	2,444
head scan with contrast	194	229	266
head scan without and with contrast	115	130	146
body scan without contrast	2,034	2,374	2,726
body scan with contrast	3,310	3,859	4,426
body scan without contrast and with contrast	793	911	1,032
biopsy in addition to body scan with or without contrast	1	1	1
abscess drainage in addition to body scan with or without contrast	0	0	0
TOTAL [1]	**8,299**	**9,647**	**11,041**

[1] The totals may not foot due to rounding.

The following table illustrates the projected number of CT scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule during each of the first three operating years, as reported by the applicants in Exhibit 5, Table 52, page 3.

TYPE OF CT SCAN	YEAR	YEAR	YEAR
head scan without contrast	1,794	2,086	2,387
head scan with contrast	169	197	225
head scan without and with contrast	98	113	130
body scan without contrast	2,093	2,433	2,785
body scan with contrast	3,386	3,936	4,504
body scan without contrast and with contrast	743	863	988
biopsy in addition to body scan with or without contrast	13	15	17
abscess drainage in addition to body scan with or without contrast	3	4	4
TOTAL [1]	**8,299**	**9,647**	**11,040**

[1] The totals may not foot due to rounding.

As shown in the above tables, although the total number of CT scans projected to be performed each year is substantially the same (any differences are due to rounding), the projected numbers of CT scans for each type of CT scan are not consistent. Therefore, the applicants did not demonstrate conformance with the rule and are conditioned not to acquire a new CT scanner but to either relocate an existing CT scanner to FMC-Clemmons or to contract to use an existing mobile CT scanner. See Criterion (3) for the condition.

.2302(d) This rule states *"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*	=	

-CA- In Section II.8, page 88, the applicants provide the number of HECT units performed on the four existing CT scanners at FMC's Winston-Salem campus. However, the applicants failed to provide the historical or projected number of HECT units for the 7 other existing CT scanners located at the other facilities listed in 10A NCAC 14C .2302(c). Further, the applicants provided inconsistent information regarding the projected number of HECT units to be performed on the

proposed CT scanner. See discussion in 10A NCAC 14C .2302(c). Therefore, the applicants did not demonstrate conformance with the rule and are conditioned not to acquire a new CT scanner but to either relocate an existing CT scanner to FMC-Clemmons or to contract to use and existing mobile CT scanner. See Criterion (3) for the condition.

.2302(e) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

.2302(f) This rule states *"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 X.2, page 244, the applicants provide the projected charges for each of the 20 most frequent CT scans to be performed during each of the first three operating years.

.2302(g) This rule states *"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- The applicants have not been utilizing a mobile CT scanner.

.2302(h) This rule *states "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- The applicants do not propose to acquire a mobile CT scanner.

.2302(i) This rule states *"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 7 contains a letter signed by a board-certified radiologist with Forsyth Radiology Associates (FRA), which states that FRA currently provides professional interpretation services for Novant Health Triad Region facilities, including FMC. Further, the radiologist states that he has agreed to serve as medical director for the proposed CT scanner at FMC-Clemmons.

.2302(j) This rule states *"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- Exhibit 7 contains a letter signed by the Director, Radiology Services for FMC, which states that the proposed CT scanner at FMC-Clemmons will be available and staffed for performing CT scans at least 66 hours per week.

10A NCAC 14C .2303 PERFORMANCE STANDARDS

.2303(1) This rule states *"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."*

-C- In Section II.8, page 91, the applicants project that the proposed CT scanner at FMC-Clemmons will perform 11,041 total CT scans or 17,709 total HECT units during the third operating year. The projected number of HECT units exceeds 5,100 regardless of which break-down by type of CT scan is used to calculate HECT units because the total number of CT scans, before conversion to HECT units, is 11,041.

.2303(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate each of the following: ... (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."

-CA- In Section II.8, pages 85 and 93, the applicants state that 24,489 HECT units were performed on the four existing CT scanners at FMC during FFY 2007, which is an average of 6,122.3 HECT units per scanner [24,489 / 4 = 6,122.25]. However, the applicants failed to provide the number of HECT units performed in the previous 12-month period on the 7 other existing CT scanners located at the other facilities listed in 10A NCAC 14C .2302(c). Therefore, the applicants did not demonstrate conformance with this rule and are conditioned not to acquire a new CT scanner but to either relocate an existing CT scanner to FMC-Clemmons or to contract to use an existing mobile CT scanner. See Criterion (3) for the condition.

.2303(3) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate each of the following: ... (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."*

-CA- In Section II.8, pages 85 and 93, the applicants state that 24,489 HECT units were performed on the four existing CT scanners at FMC during FFY 2007, which is an average of 6,122.3 HECT units per scanner [24,489 / 4 = 6,122.25]. In Section II.8, page 93, the applicants state that the four existing CT scanners at FMC are expected to continue performing more than 5,100 HECT units per scanner. However, the applicants failed to provide the number of HECT units projected to be performed on the 7 other existing CT scanners located at the other facilities listed in 10A NCAC 14C .2302(c). Therefore, the applicants did not demonstrate conformance with this rule and are conditioned not to acquire a new CT scanner but to either relocate an existing CT scanner to FMC-Clemmons or to contract to use an existing mobile CT scanner. See Criterion (3) for the condition.

10A NCAC 14C .2304 SUPPORT SERVICES

.2304(a) This rule states *"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."

-NA- FMC-Clemmons will be licensed as part of FMC, which currently provides CT services.

.2304(b) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

10A NCAC 14C .2305 STAFFING AND STAFF TRAINING

.2305(a) This rule states *"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;

(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

(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."

-NA- FMC-Clemmons will be licensed as part of FMC, which currently provides CT services.

.2305(b) This rule states *"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

(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."

-NA- FMC-Clemmons will be licensed as part of FMC, which currently provides CT services.

.2305(c) This rule states *"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- The applicants do not propose to acquire a mobile CT scanner.

SECTION .1200 CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

.1202 INFORMATION REQUIRED OF APPLICANT

.1202(a) This rule states *"An applicant that proposes new or expanded intensive care services shall use the Acute Care Facility/Medical Equipment application form."*

-C- The applicants used the Acute Care Facility/Medical Equipment application form.

.1202(b)(1) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional 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 75, the applicants provide a table illustrating the current and proposed number of ICU beds operated by the applicants at FMC, including the FMC-Kernersville and FMC-Clemmons satellite campuses, as illustrated in the following table.

UNIT	EXISTING AND APPROVED	PROPOSED			
		FMC-WS	FMC-K (1)	FMC-C	TOTAL
Medical/Surgical	58	54	4	4	62
Cardiac	24	24	0	0	24
Cardiovascular Surgery	8	8	0	0	8
Neonatal (2)	42	56	0	0	56
Total	132	142	4	4	150

(1) FMC is authorized to relocate 4 existing medical/surgical ICU beds from Winston-Salem to Kernersville.

(2) FMC is currently licensed for 42 neonatal intensive care unit (NICU) beds. Pursuant to the certificate of need issued for Project I.D. #G-6413-01, FMC is authorized to develop 14 additional NICU beds for a total of 56 NICU beds.

.1202(b)(2)(A) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (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."*

-C- In Section II.8, page 77, the applicants provide the number of inpatient days of care provided to ICU patients (excluding NICU patients) at FMC between 5/1/07 and 4/30/08.

.1202(b)(2)(B) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including: ... (B) the number of patients initially treated at the facility and referred to other facilities for intensive care services."*

-C- In Section II.8, page 77, the applicants provide the number of patients initially treated at FMC and referred to other facilities for intensive care services *"during the past year."*

.1202(b)(2)(C) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including: ... (C) the number of patients initially treated at other facilities and referred to the applicant's facility for intensive care services."*

-C- In Section II.8, page 77, the applicants provide the number of patients initially treated at other facilities and referred to FMC *"during the past year."*

.1202(b)(3) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ...(3) the number of patients from the proposed service area who are projected to require intensive care services by the patients' county of residence in each of the first 12 quarters of operation, including all assumptions and methodologies."*

-CA- In response to this rule, in Section II.8, page 78, and Exhibit 5, Table 18, the applicants provided the number of inpatient days of care to be provided at FMC-Clemmons by the patients' county of residence in each of the first 12 quarters of operation. To project the number of inpatient days of care to be provided in the proposed ICU beds at FMC-Clemmons, the applicants determined the ratio (#) of ICU days (excluding neonatal ICU

days) to total acute care days for each hospital in the State and used the average of the ratios in the lower 50%. See Criterion (3) for discussion regarding reasonableness of projections. However, the rule requires that the applicant provide the number of patients who are projected to require ICU services not the number of inpatient days of care. Further, the applicants provided projections for only the FMC-Clemmons campus rather than projections for all patients in the proposed service area who will need ICU services regardless of provider. Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall provide the Certificate of Need Section with the projected number of patients (except NICU patients) from the proposed service area who are projected to require intensive care services, regardless of provider, by the patients' county of residence in each of the first 12 quarters of operation and the assumptions and methodologies for these on projections.

.1202(b)(4) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (4) 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."*

-CA- FMC currently operates three adult specialized ICUs (i.e., general med/surg, cardiac and cardiovascular surgery). In addition, FMC is approved to relocate four existing general med/surg ICU beds to FMC-Kernersville and is proposing to operate four new general med/surg ICU beds at the proposed FMC-Clemmons. All of these beds will be on the one license issued to FMC. Therefore, projections should be provided for all FMC campuses.

In Section II.8, page 78, and Exhibit 5, Table 18, the applicants provided the number of inpatient days of care to be provided in the four ICU beds at FMC-Clemmons by the patients' county

of residence in each of the first 12 quarters of operation. The applicants provide the assumptions and methodologies used to project the number of inpatient days of care to be provided at FMC-Clemmons in Section III.1, pages 120-125, and Exhibit 5. However, the applicants did not provide the projected number of patients to be served for the four proposed ICU beds at FMC-Clemmons. Further, the applicants did not provide the projected average length of stay for the proposed ICU beds. Therefore, it is not possible to determine the number of ICU patients to be served at FMC-Clemmons.

In Section IV.1(c), page 165, for each of the first 12 quarters of operation, the applicants provided the total number of inpatient days of care to be provided for the total number of ICU beds (except NICU) on all three FMC campuses combined. The applicants assume that utilization will increase 1.0% per year, which is approximately the rate the population of the service area is projected to increase (1.1% per year). The applicants demonstrate that projected utilization of all of FMC's ICU beds combined (excluding the NICU beds) is based on reasonable assumptions. See Criterion (3) for discussion. However, the applicants did not provide the projected number of patients to be served by county broken down by specialized type of ICU (i.e., the adult medical/surgical ICUs, the cardiac ICU and the cardiovascular surgery ICU).

Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall provide the Certificate of Need Section with the breakdown of the total number of patients to be served and inpatient days of care to be provided by county of residence for each of the first twelve calendar quarters of operation by type of intensive care unit (i.e., the general med/surg, cardiac and cardiovascular surgery units).

.1202(b)(5) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (5) data from actual referral sources or correspondence from the proposed referral sources*

documenting their intent to refer patients to the applicant's facility."

-C- In Exhibit 11, the applicants provide letters from physicians that document their intent to refer patients to the proposed new facility in Clemmons for intensive care services.

.1202(b)(6) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (6) documentation which demonstrates the applicant's capability to communicate effectively with emergency transportation agencies."*

-C- In Exhibit 6, the applicants provide a letter signed by the President/Chief Operating Officer for FMC, which states that the emergency department at the proposed FMC-Clemmons campus will have the capability to communicate effectively with emergency transportation agencies.

.1202(b)(7)(A) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (7) documentation of written policies and procedures regarding the provision of care within the intensive care unit, which includes, but is not limited to the following: (A) the admission and discharge of patients; (B) infection control; (C) safety procedures; and (D) scope of service."*

-C- Exhibit 6 contains copies of the applicants' policies and procedures for provision of care in the ICU addressing each item in this rule.

.1202(b)(8) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (8) 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- Exhibits 6 and 16 contain the design schematics for the proposed ICU, which show that the ICU will be operated as a physically and functionally distinct entity in a separate area with controlled access.

.1202(b)(9) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (9) 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 6 contains a letter signed by the Senior Director, Design and Construction for Novant Health, which states that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

.1202(b)(10) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (10) a detailed floor plan of the proposed area drawn to scale."*

-C- See Exhibits 6 and 16 for design schematics of the proposed ICU.

.1202(b)(11) This rule states *"An applicant proposing new or expanded intensive care services shall also submit the following additional information: ... (11) documentation of a means for observation by unit staff of all patients in the unit from at least one vantage point."*

-C- See Exhibits 6 and 16 for design schematics of the proposed ICU.

.1203 PERFORMANCE STANDARDS

.1203(a)(1) This rule states *"The applicant shall demonstrate that the proposed project is capable of meeting the following standards: (a) (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."*

-C- In Section II.8, page 80, the applicants state that FMC currently operates 90 ICU beds, excluding 42 NICU beds. On page 80 and in Exhibit 5, Table 17, the applicants state that 23,308 days of care were provided in the 90 ICU beds between June 1, 2007 and May 31, 2008, which is an occupancy rate of 71% [23,308 / 365 = 63.86; 63.86 / 90 = 0.7095].

.1203(a)(2) This rule states *"The applicant shall demonstrate that the proposed project is capable of meeting the following standards: (a) ... (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."*

-C- In Section II.8, pages 80-82, and Section IV.1, page 165, the applicants provide projected utilization of FMC's ICU beds on all campuses (excluding the NICU beds), as illustrated in the following table.

Campus	# of ICU Beds (excluding NICU)	PROJECTED ICU PATIENT DAYS OF CARE			% OCCUPANCY (YEAR 3)
		YEAR 1	YEAR 2	YEAR 3	
FMC-Winston-Salem	86	22,348	22,455	22,560	71.9%
FMC-Kernersville (relocating)	4	1,176	1,215	1,255	86.0%
FMC-Clemmons (new)	4	965	1,071	1,181	80.9%
Total	94	24,489	24,741	24,996	72.9%

As shown in the above table, during the third operating year, the applicants project that FMC will provide a total of 24,996 days of care in 94 ICU beds (excluding the NICU beds), which is an occupancy rate of 72.9% [24,996 / 365 / 94 = 0.7285]. The applicants adequately demonstrate that the occupancy rate for the existing and proposed ICU beds would be at least 70% during Year Three as required by this rule.

.1203(b) This rule states *"All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided."*

-C- The applicants' assumptions and data supporting the methodology used to project utilization are provided in Section III.1, pages 120-125, and Exhibit 5. The applicants adequately demonstrate that projected utilization of the 94 ICU beds is based on reasonable assumptions. See Criterion (3) for discussion.

.1204 SUPPORT SERVICES

.1204(a) This rule states *"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 ventilatory/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 6 contains a letter signed by the President and Chief Operating Officer for FMC, which states that all of the items listed above will be available at the proposed FMC-Clemmons campus or at FMC's Winston-Salem campus.

.1204(b) This rule states *"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."*

-NA- All of the services listed in this rule will be available at the proposed FMC-Clemmons campus or FMC's Winston-Salem campus.

.1205 STAFFING AND STAFF TRAINING

.1205(1) This rule states *"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."* (Emphasis added.)

-CA- In Section II.8, page 83, the applicants state

> *"Please see Exhibit 6 for a copy of a letter signed by Sallye Liner, the FMC Chief Operating Officer for the required documentation, as it pertains to the qualifications of CLMC RNs with specialized training in the care of critically ill patients, cardiovascular monitoring and life support, at the CLMC ICU. The FMC COO is* [sic] *Registered Nurse, by training and experience and is well-qualified to provide the documentation required by this regulation."*

Exhibit 6 contains a letter signed by the President and Chief Operating Officer for FMC, which states

> *"As Chief Operating Officer of Novant Health, Inc. Triad Region, I am responsible for overseeing the operations of Forsyth Medical Center (FMC). The Intensive Care Unit at FMC falls within my area of responsibility. I will also have matrix management responsibility for the ICU and nursing care at the proposed Clemmons Medical Center.*
>
> *I can attest that the nursing staff for the ICU at Clemmons Medical Center will be required to meet the same professional and clinical qualifications as the current nursing staff at the FMC ICU in Winston-Salem. The nursing care in the ICU at Clemmons Medical Center will be provided by qualified registered nurses with specialized training in the care of critically*

ill patients, cardiovascular monitoring, and life support." (Emphasis added.)

However, the applicants do not state in the application and the letter provided in Exhibit 6 does not state that the nursing care in the ICU will be supervised by a qualified RN with the specialized training required by this rule. Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Novant Health, Inc. shall provide documentation that the nursing care in the ICU will be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring and life support.

.1205(2) This rule states *"The applicant shall demonstrate the ability to meet the following staffing requirements: ... (2) direction of the unit shall be provided by a physician with training, experience and expertise in critical care."*

-C- Exhibits 6 and 11 contain a letter signed by Bary Sigal, M.D. which states that he has agreed to serve as medical director of the proposed ICU. Exhibit 11 contains a copy of his curriculum vitae, which documents that he has training, experience and expertise in critical care.

.1205(3) This rule states *"The applicant shall demonstrate the ability to meet the following staffing requirements: ... (3) assurance from the medical staff that twenty-four hour medical and surgical on-call coverage is available."*

-C- Exhibit 6 contains a letter signed by the Executive Vice President of Medical Staff Services for Novant Health Triad Region, which states that the medical staff will provide twenty-four hour medical and surgical on-call coverage.

.1205(4) This rule states *"The applicant shall demonstrate the ability to meet the following staffing requirements: ... (4) inservice training or continuing education programs shall be provided for the intensive care staff."*

-C- Exhibit 6 contains a letter signed by the President and Chief Operating Officer for FMC, which states

> *"I can confirm that current FMC policies and procedures provide for inservice training and continuing education for ICU staff members at FMC. I will work with Clemmons Medical Center nursing administration to ensure that the inservice training and continuing education programs will apply to and be available for the ICU staff members at Clemmons Medical Center."*

DISCUSSION OF COMPARATIVE ANALYSIS

FMC-Clemmons filed its application for review beginning August 1, 2008. North Carolina Baptist Hospital (**Baptist**) and Davie County Emergency Health Corporation d/b/a Davie County Hospital (**DCH**) also filed an application for review beginning August 1, 2008 in which they propose to develop a replacement hospital offering the following beds or services: 50 general acute care beds, 10 unlicensed observation beds, Surgery, Radiology, Emergency, Laboratory, Pharmacy, Cardiopulmonary and Physical Therapy (Project I.D. #G-8164-08).[5] FMC-Clemmons proposes to develop a satellite campus in Clemmons offering the following beds or services: 50 general acute care beds, 6 unlicensed observation beds, Surgery, Radiology, Emergency, Laboratory, Pharmacy, Respiratory Therapy, Physical Therapy and Speech Therapy. Thus, the proposals are for the same or similar services. Further, the proposed sites are within three to four miles of each other and the applicants propose to serve essentially the same patient population. The following table illustrates the proposed service areas for each proposal.

FMC-CLEMMONS	DCH
Davie County Zip Code Area 27006 Zip Code Area 27028	**Davie County** Zip Code Area 27006 Zip Code Area 27028
Forsyth County Zip Code Area 27012 Zip Code Area 27023 Other "surrounding" zip codes	**Forsyth County** Zip Code Area 27012 Zip Code Area 27023
Yadkin County All Zip Code Areas	**Yadkin County** Zip Code Area 27055
Iredell County All zip code areas	

Pursuant to 10A NCAC 14C .0202(f), *"Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period."* The analyst determined that the approval of the FMC-Clemmons application (Project I.D. #G-8165-08) filed in this review period did not result in the disapproval of the DCH application (Project I.D. #G-8164-08) also filed in this review period. Rather, the DCH application was disapproved for other reasons.

Further, for the sake of argument, even if the DCH application filed in this review period was not a duplication of its previously approved project, the analyst determined that the FMC-Clemmons' project, as conditioned, was needed in addition to DCH's facility proposed to be developed in Bermuda Run in

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[5] Baptist and DCH had filed an application for review beginning April 1, 2008 for essentially the same proposal except the earlier proposal did not include 4 new obstetrical (post partum) beds, 4 new unlicensed labor/delivery/recover beds, 3 new unlicensed bassinets and 1 new dedicated C-section operating room (Project I.D. #G-8078-08). The Agency conditionally approved Project I.D. #G-8078-08, but that decision is currently under appeal.

this review period. Consequently, the approval of the FMC-Clemmons application would not have resulted in the denial of the proposed DCH application. See Criterion (3) for discussion of need.

In summary, the Agency determined that the two applications submitted for review beginning August 1, 2008 are not competitive, and therefore, a comparative analysis was not prepared.