COMMENTS BY RENAL ADVANTAGE, INC. REGARDING PROJECT I.D. NO. F-8747-11 FILED BY DVA HEALTHCARE RENAL CARE, INC. D/B/A NORTH CHARLOTTE DIALYSIS CENTER ADD FOUR STATIONS

Renal Advantage, Inc. ("RAI"), an existing provider of dialysis services in Mecklenburg County, submits the following comments against DVA Healthcare Renal Care, Inc.'s ("DaVita") CON application proposing to add four dialysis stations to its North Charlotte Dialysis Center. This is based on North Charlotte's 88% occupancy and the application of the ESRD Facility Need Methodology. See page 11 of the application. But this does not automatically entitle DaVita to any additional stations. Rather, DaVita must demonstrate the need for the stations. DaVita must also demonstrate that it is not unnecessarily duplicating existing resources. DaVita must also demonstrate that it has provided quality care in the past. The burden is on DaVita to do these things. DaVita cannot meet its burden and its application should be disapproved.

I. DaVita Does Not Demonstrate the Need for More Stations at North Charlotte Dialysis Center.

DaVita states that it now has 74 in-center patients at North Charlotte. It projects 85.9 patients by the end of Year 2. See application, page 12. This is based on the application of the Mecklenburg County Average Annual Change Rate (AACR) of 5.1%. But the mere fact that the facility is located in Mecklenburg County does not mean that it is reasonable to apply the AACR to grow the patient volume at this facility. DaVita states on page 12 of the application that "[t]he North Charlotte Dialysis Center is operating three shifts a day three days a week and two shifts a day three days a week. Having to dialyze on third shift is very inconvenient to many patients." But there is no substantiation for this. There are no letters of support from patients. There is only one letter from the medical director, who does not commit to refer any additional patients. There is no information in the application indicating that patients who are dialyzing during the third shift are complaining about this. Indeed, some patients may actually prefer to dialyze during the third shift due to work commitments or personal reasons. All that DaVita provides is numbers; it does not provide a need methodology, and there is simply no way the Agency can assume that North Charlotte's In addition, this facility has recently growth will track the Mecklenburg County AACR. been approved for a four center expansion. These additional stations were not certified as of the time of the filing of the North Charlotte CON application on September 15, 2011. It would be prudent to see how busy the new stations are before adding any additional stations.

Also not discussed is DaVita's Mint Hill Dialysis Center. DaVita received a CON for this project in 2008 to develop a ten-station center. It still has not been developed, though efforts are apparently being made. *See* attached Declaratory Ruling dated March 30, 2011, attached as Exhibit A. It would be prudent for this already approved capacity to be added before DaVita increases capacity at another center.

Accordingly, the application is non-conforming with Criterion 3 and must be disapproved.

II. DaVita's Proposal Unnecessarily Duplicates Existing Services.

According to the July 2011 Semi Annual Dialysis Report (SDR), Mecklenburg County has a surplus of 15 dialysis stations. ". . . [T]he proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services." N.C. Gen. Stat. § 131E-175(4). Mecklenburg County does not need more stations, regardless of whether the facility need methodology shows a need. Just because a facility *can* expand does not mean it *should* expand. There are some centers in Mecklenburg County, including RAI's Latrobe facility, that have available capacity. Metrolina Nephrology, the practice that provides medical direction for DaVita North Charlotte, serves a variety of dialysis clinics throughout Mecklenburg County so patients would not necessarily have to change doctors in order to take advantage of some of the excess capacity that exists in Mecklenburg County.

Accordingly, the DaVita application is non-conforming with Criterion 6.

III. The Agency Should Carefully Analyze the Application Under Criterion 20.

Criterion 20 requires an applicant already involved in providing health care services to demonstrate that quality care has been provided in the past. DaVita is no stranger to Criterion 20 problems. See, e.g., Findings in Cabarrus County, Davie County and New Hanover County, copies of which are attached as Exhibits B through D. Most importantly, the North Charlotte's sister facility, Charlotte East Dialysis, had an immediate jeopardy situation and was out of compliance with three Medicare Conditions for Coverage based on a survey conducted on October 26, 2010. The facility was not brought back into compliance until December 21, 2010. See Exhibit E. It has been the practice of the CON Section to consider events of this magnitude that occur at the applicant's affiliates in the same county or in adjacent counties within 18 months prior to the decision, especially where there are linkages between the facilities such as ownership, governance and medical direction. The incidents at Charlotte East fit within this 18 month window. The linkages also exist. Accordingly, the North Charlotte application should be denied under Criterion 20.

IV. Conclusion

The DaVita North Charlotte application should be denied.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY)	
RULING BY DVA HEALTHCARE RENAL)	
CARE D/B/A MINT HILL DIALYSIS)	DECLARATORY RULING
CENTER)	
•	j	
Project I.D. No. F-7861-07	Ś	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center ("DVA") has requested a declaratory ruling for Project I.D. No. F-7861-07 ("Project") allowing it to develop and operate the Mint Hill Dialysis Center at a new location. DVA requests this change on the grounds that it does not constitute either (1) a material change in scope or physical location or (2) a failure to materially comply with the representations made by DVA in its certificate of need application for its project or the conditions imposed upon the certificate of need. N.C.G.S. §§ 131E-181(a) and (b). This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. William R. Shenton of Poyner Spruill LLP has requested this ruling on behalf of DVA and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

In September 2008, the CON Section issued a certificate of need for Project I.D. No. F-7861-07 authorizing DVA to relocate six dialysis stations from its Charlotte East Dialysis Center and four dialysis stations from its South Charlotte Dialysis Center to develop a 10-station dialysis facility in Mint Hill, Mecklenburg County, to be known as Mint Hill Dialysis Center.

As a result of the economic downturn, the business park where the primary and secondary sites in DVA's Certificate of Need application were located was not developed, so those sites were no longer available as locations for the facility. DVA identified another site at 9030 Albemarle Road, Charlotte, North Carolina and received a declaratory ruling approving that site. However, after issuance of the declaratory ruling, DVA learned of a restrictive covenant that prohibits any entity with an ownership or similar affiliation with a pharmacy from leasing space in the shopping center on Albemarle Road. That covenant eliminated the Albemarle Road site as a location for DVA's Mint Hill facility, because DVA's parent company DaVita, Inc., has a subsidiary that is a specialized pharmacy.

DVA represents that a new site at 11308 Hawthorne Drive in Mint Hill is available and suitable for development of the dialysis facility as originally configured and designed, and that DVA will operate the same number of dialysis stations as it proposed in its application. The new site has an existing building that once housed a medical practice, and the site is appropriately zoned. DVA's developer will purchase the building and DVA will upfit it with all necessary dialysis-specific renovations. DVA represents that its upfit costs will not exceed 115 percent of the capital expenditure amount shown on its certificate of need. DVA anticipates being able to complete development of the facility and have it ready for certification no later than the first

quarter of 2012. The new site is located at approximately the same distance to support services as the sites identified in the application.

ANALYSIS

The CON law would require a full review of DVA's proposed change if it were to represent a material change in the physical location or scope of the project. N.C.G.S. § 131E-181(a). The proposed change does not constitute a material change in the physical location or the scope of the proposed project. The new site is approximately the same distance to key support services identified in the application as the original sites in DVA's application. DVA will operate the same size facility and offer the same services at the new site as those proposed in the application. Costs for development will not exceed 115% of the amount shown on the certificate of need.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw DVA's certificate of need if DVA fails to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the certificate of need. DVA will not be developing its project in a manner that is materially different from the representations made in its application, nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its certificate of need.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the substitution of 11308 Hawthorne Drive, Mint Hill, North Carolina as the site for DVA's Mint Hill Dialysis Center, Project I.D. No. F-7861-07, will not constitute a material change in the physical location or scope of the project, will not violate N.C.G.S. § 131E-181 and

will	not	constitute	a	failure	to	satisfy	a	condition	of	the	certificate	of	need	in	violation	of
N.C.	G.S.	§ 131E-18	39((b).					•	•						
	T	his the		day o	f_			, 2011.								

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

<u>CERTIFICATE OF SERVICE</u>

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

William R. Shenton Poyner Spruill LLP 301 Fayetteville Street, Suite 1900 Raleigh, NC 27602-1801

I his the day of	, 2011.	
•		
	Jeff Horton Chief Operating Officer	
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ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE:

February 25, 2011

FINDINGS DATE:

March 4, 2011

PROJECT ANALYST:

Tanya S. Rupp

SECTION CHIEF:

Craig R. Smith

PROJECT I.D. NUMBER:

F-8577-10 / Total Renal Care of North Carolina, LLC d/b/a Harrisburg

Dialysis Center / Add five dialysis stations to an existing facility for a

facility total of 20 stations / Cabarrus County

F-8581-10 / Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis / Develop a new twelve-station dialysis facility in

Concord / Cabarrus County

F-8584-10 / Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center / Add six dialysis stations to an existing

facility for a facility total of 27 stations / Cabarrus County

F-8590-10 RAI Care Centers of North Carolina II, LLC d/b/a RAI Care

Centers - Concord / Develop a 23-station dialysis facility in Concord /

Cabarrus County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC All Applications

The 2010 State Medical Facilities Plan (2010 SMFP) and the July 2010 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for additional dialysis stations. According to Section 2(E) of the dialysis station county need methodology,

EXHIBIT

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found on page 333 of the 2010 SMFP, "If a county's December 31, 2010 projected station deficit is ten or greater and the July SDR shows that utilization of each dialysis facility in the county is 80% or greater, the December 31, 2010 county station need determination is the same as the December 31, 2010 projected station deficit. ..." The county need methodology for 2010 results in a need determination for 23 dialysis stations in Cabarrus County. In the July 2010 SDR Table B: ESRD Dialysis Station Need Determinations by Planning Area, a total of 187.4 in-center dialysis patients and 30.4 home patients are projected in Cabarrus County as of December 31, 2010. Four applications were received by the Certificate of Need Section for development of the 23 dialysis stations. The four applicants applied for a total of 46 dialysis stations. Pursuant to the need determination in the 2010 SMFP and the July 2010 SDR, 23 dialysis stations is the limit on the number of dialysis stations that may be approved in this review. A competitive review of these applications began on October 1, 2010. Following is a brief description of the four proposals submitted in this review:

- * F-8577-10 Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center proposes to add five dialysis stations to its existing dialysis facility in Concord in Cabarrus County, in response to the county need methodology. In Section I.8, page 3 of the application, the applicant states the project will require the addition of dialysis machines, chairs, patient TVs, chair side computer terminals and electrical and plumbing work. Harrisburg Dialysis Center currently has 15 certified dialysis stations, including one station for isolation patients; therefore, after completion of this project, Harrisburg Dialysis Center will have a facility total of 20 dialysis stations, including one isolation station.
- F-8581-10 Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis proposes to develop a new 12-station dialysis facility in Concord in Cabarrus County. In Section I.8, page 3, the applicant states the facility will offer incenter hemodialysis, home hemodialysis training, and training in peritoneal dialysis and nocturnal dialysis. The applicant proposes to develop 12 in-center dialysis stations, and the line drawing in Exhibit 25 shows a total of 12 dialysis stations are proposed. The line drawing identifies 10 dialysis stations on the floor, one separate room for patients requiring isolation pursuant to CMS Guidelines¹, and one room labeled for home hemo-dialysis training purposes. Thus, the applicant proposes a total of 12 dialysis stations. The 2010 SMFP defines the need for a maximum of 23 dialysis stations in Cabarrus County. The applicant proposes to develop no more than 12 new dialysis stations in Cabarrus County and therefore is conforming to the need determination in the 2010 SMFP.
- F-8584-10 Total Renal Care of North Carolina, LLC d/b/a/ Copperfield Dialysis Center proposes to add six dialysis stations to its existing dialysis facility in Concord in Cabarrus County, in response to the county need methodology. In Section I.8, page 3 of the application, the applicant states the project will require the addition of dialysis machines, chairs, patient TVs, chair side computer terminals and

¹ See 42 CFR §494.30(a)(1)(i)

electrical and plumbing work. Copperfield Dialysis Center currently has 21 certified dialysis stations, including one station for isolation patients; therefore, after completion of this project, Harrisburg Dialysis Center will have a facility total of 27 dialysis stations, including one isolation station.

** F-8590-10 RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers — Concord ["RAI"] proposes to develop a new 23-station dialysis facility in Concord in Cabarrus County. In Section I.8, page 3, the applicant states the facility will offer in-center hemodialysis on 21 stations, will include one separate room for patients requiring isolation, pursuant to CMS Guidelines, and one additional separate room, to offer home hemodialysis training. The line drawing in Section II.12, page 27, and in Exhibit 23 show a total of 23 dialysis stations are proposed. The line drawing identifies 21 dialysis stations on the floor, one room separate for patients requiring isolation, and one room labeled for home hemodialysis purposes. Thus, the applicant proposes a total of 23 dialysis stations. The 2010 SMFP defines the need for a maximum of 23 dialysis stations in Cabarrus County. The applicant proposes to develop no more than 23 dialysis stations in Cabarrus County and therefore is conforming to the need determination in the 2010 SMFP.

There is one policy in the 2010 SMFP applicable to the review of two of the applications submitted for review. Policy Gen-3, on page 39 of the 2010 SMFP states:

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

All four applications propose dialysis stations in Cabarrus County in response to a need determination in the 2010 SMFP.

F-8577-10 Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis:

Promote Safety and Quality

In Section II, page 21, the applicant states,

² See 42 CFR §494.30(a)(1)(i)

"DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita's Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. ...The program exemplifies DaVita's total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals."

On page 22, the applicant states,

"The Harrisburg Dialysis Center is attended by Dr. Charles Stoddard, admitting Nephrologist who directly oversees the quality of care of the dialysis facility. ... In addition, Dr. Stoddard serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company's Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care and patient outcomes."

In addition, in Exhibit 24 the applicant provides a copy of DaVita, Inc. Health and Safety, Policy and Procedure Manual that address safety in the dialysis facility. In Exhibit 4, the applicant provides a copy of publications and articles about DaVita and its approach to safety and quality in clinical outcomes. Therefore, the applicant adequately demonstrates the methods by which it proposes to promote safety and quality in the provision of dialysis services in Cabarrus County. However, the applicant did not adequately demonstrate that it has provided quality care in its existing Copperfield Dialysis Center. See Criterion (20) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal would ensure quality care.

Document Plans for Access to Healthcare by Underserved

In Section VI.1, page 39, the applicant states,

"The Harrisburg Dialysis Center, by policy, make [sic] dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic or socioeconomic situation.

The Harrisburg Dialysis Center make [sic] every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

The Harrisburg Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons."

The applicant adequately documented its plans for providing access to health care by the underserved groups.

Maximize Healthcare Value

In Section III.9, on page 31, the applicant states,

- "The parent corporation, DaVita, operates over 1,400 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price.
- The Harrisburg Dialysis Center will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.
- The Harrisburg Dialysis Center will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.
- The Harrisburg Dialysis Center will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.
- The Harrisburg Dialysis Center Bio-Medical Technician assigned to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines."

The applicant adequately documents its plans for providing access to services for patients with limited financial resources. However, the applicant did not demonstrate that its projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served, because the applicant has not demonstrated that it has provided quality care and ensured the safety of the patients it serves in its Copperfield Dialysis Facility. See Criteria (18a) and (20) for additional discussion. Consequently, the application is not consistent with Policy Gen-3, and therefore is not conforming to this criterion.

F-8581-10 Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis:

Promote Safety and Quality

In Section II, page 24, the applicant states,

"DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita's Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. ... The program exemplifies DaVita's total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals."

On page 26, the applicant states,

"Cabarrus County Dialysis will be attended by the [sic] Dr. William Halstenberg and other admitting Nephrologists who directly oversee the quality of care of the dialysis facility. ... The facility unit administrator is the day to day manager of the facility and maintains the company's Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care and patient outcomes."

In addition, in Exhibit 18 the applicant provides a copy of DaVita, Inc. Policies, Procedures, and Guidelines that address safety in the dialysis facility. Therefore, the applicant adequately demonstrates the methods by which it proposes to promote safety and quality in the provision of dialysis services in Cabarrus County. However, the applicant did not adequately demonstrate that it has provided quality care in its existing Copperfield Dialysis Center. See Criterion (20) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal would ensure quality care.

Document Plans for Access to Healthcare by Underserved

In Section VI.1, page 41, the applicant states,

"Cabarrus County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

Cabarrus County Dialysis will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

Cabarrus County Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial

and ethnic minorities, women, handicapped persons, elderly and other under-served persons."

On page 42, the applicant states:

"Cabarrus County Dialysis will make no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians will identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status. If a patient is medically indigent, meaning they have no means to pay for their treatments, Alexander County Dialysis will provide these patients will dialysis services, understanding that we will not receive payment for the treatments provided."

The applicant adequately documented its plans for providing access to health care by the underserved groups.

Maximize Healthcare Value

In Section III.9, on pages 33 - 34, the applicant states,

- "This application calls for the development of a new, state of the art facility that will require the purchase of hundreds of times that will include dialysis machines, chairs and TVs. The parent corporation, DaVita, operates over 1,500 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.
- Cabarrus County Dialysis will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.
- Cabarrus County Dialysis will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility....
- Cabarrus County Dialysis will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.
- Cabarrus County Dialysis Bio-Medical Technician assigned to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines."

The applicant adequately documents its plans for providing access to services for patients with limited financial resources. However, the applicant did not demonstrate that its projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served, because the applicant has not demonstrated that it has provided quality care and ensured the safety of the patients it serves in its Copperfield Dialysis Facility.

See Criteria (18a) and (20) for additional discussion. Consequently, the application is not consistent with Policy Gen-3, and therefore is not conforming to this criterion.

F-8584-10 Copperfield Dialysis Center

Promote Safety and Quality

In Section II, pages 21 - 22, the applicant states,

"DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita's Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. ...The program exemplifies DaVita's total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals."

"Dr. William Halstenberg is an admitting Nephrologist who directly oversees the quality of care of the dialysis facility. Dr. Halstenberg serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company's Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. This Quality Assurance Program addresses the Copperfield Dialysis Center as a whole, then compares each sister unit to the whole and to industry standards. The Committee then makes recommendations to improve quality. Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes."

In addition, in Exhibit 24 the applicant provides a copy of DaVita, Inc. Health and Safety, Policy and Procedure Manual that address safety in the dialysis facility. In Exhibit 4, the applicant provides a copy of publications and articles about DaVita and its approach to safety and quality in clinical outcomes. Therefore, the applicant adequately demonstrates the methods by which it proposes to promote safety and quality in the provision of dialysis services in Cabarrus County. However, the applicant did not adequately demonstrate that it has provided quality care in this facility. See Criterion (20) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal would ensure quality care.

Document Plans for Access to Healthcare by Underserved

In Section VI.1, page 40, the applicant states,

"The Copperfield Dialysis Center, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

The Copperfield Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

The Copperfield Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons."

The applicant adequately documented its plans for providing access to health care by the underserved groups.

Maximize Healthcare Value

In Section III.9, on page 31, the applicant states,

"The Copperfield Dialysis Center promotes cost-effective approaches in the facility in the following ways:

- The parent corporation, DaVita, operates over 1,500 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price.
- The Copperfield Dialysis Center purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.
- The Copperfield Dialysis Center will utilizes [sic] the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.
- The Copperfield Dialysis Center installs an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.
- The Copperfield Dialysis Center Bio-medical Technician assigns [sic] to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines."

The applicant adequately documents its plans for providing access to services for patients with limited financial resources. However, the applicant did not demonstrate that its projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served, because the applicant has not demonstrated that it has provided quality care and ensured the safety of the patients it serves in its Copperfield Dialysis Facility. See Criteria (18a) and (20) for additional discussion. Consequently, the application is not consistent with Policy Gen-3, and therefore is not conforming to this criterion.

F-8590-10 RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers - Concord ["RAI"]:

Promote Safety and Quality

In Section II, pages 20-21, the applicant states,

"Like no one else in our industry, RAI follows a business philosophy centered on providing support to meet the needs of each unique dialysis center. RAI establishes a framework within which all of its dialysis centers operate. As a process-oriented company, RAI focuses on the essential aspects for the way care is delivered in its centers. This framework includes quality initiatives, staffing models for staffing center personnel based on patient volumes, formularies for drugs and supplies, patient scheduling programs, extensive personnel training programs and advancement opportunities, customer service programs, compensation programs that reward outstanding clinical outcomes, physician rounding tools, and other physician programs and tools to assist our physicians in providing care in our dialysis centers."

In Section II, page 29, the applicant states,

"RAI-NC and RAI-Concord are committed to maintaining quality care. The objective of the quality management plan is to make certain a mechanism is in place, which ensures the occurrence of an ongoing evaluation of various aspects of the RAI-Concord operation, both medical and non-medical. Moreover, at such time as this evaluation process reveals questions associated with a facet of the RAI-Concord operation, the plan provides a method of further evaluation, method of correction, and follow up of corrective action taken."

Additionally, in Exhibit 6 the applicant provides a copy of its *Policy* #G-18, *Quality Assessment and Performance Improvement*," which describes measures that RAI facilities take to ensure quality in the delivery of dialysis services.

Therefore, the applicant adequately demonstrates the methods by which it proposes to promote safety and quality in the provision of dialysis services in Cabarrus County.

Document Plans for Access to Healthcare by Underserved

In Section II, page 24, the applicant states,

"To guarantee that all patients have access to RAI-Concord, the Patient Financial Indigence Policy insures that patients at 2 times the national poverty level will have any outstanding balances written-off.

In addition to the RAI Patient Financial Indigence Policy, RAI is an active participant in the American Kidney Fund that provides grants to patients in need, RAI contributes a significant amount each year to the fund. RAI also applies for and receive grants from the National Kidney Foundation for patients who are in need as well. Each RAI dialysis center has a social worker who performs invaluable service to patients in obtaining assistance (including medication assistance). The RAI Regional Financial Coordinators work with patients to assist them in obtaining or maintaining insurance coverage for dialysis care.

As a company, RAI provided over \$24.3 million in charity care in 2009 and has a commitment as a company to continue and expand our charity care. RAI does not deny treatment to patients who are unable to pay for their services. RAI works with patients to attempt to find a way for their care to be covered, either through a payor or a government program or grants.

Access will be enhanced by this project because it will be centrally located in Cabarrus County. It is also located conveniently to northern Mecklenburg County so it will provide access to residents of that area (such as Huntersville) where there is presently no dialysis facility."

In Section VI.1, page 53, the applicant states,

"Patients in RAI-NC's region who are in need or will be in need of dialysis services are admitted regardless of insurance coverage or ability to pay. RAI-Concord staff will assist patients by identifying available sources of funding and by completing the required information necessary to obtain financial assistance.

The applicant adequately documented its plans for providing access to health care by the underserved groups.

Maximize Healthcare Value

In Section II, page 25, the applicant states,

"The RAI development team has approached the planning of the RAI-Concord facility as it has in many other states. Renovation and construction costs are estimated using widely available square footage estimates, established supply partnerships minimize

the supply costs per dialysis treatments, and staffing meets nursing standards, while permitting cross-training to minimize staff expenses; these three cost containment tools are essential because dialysis treatment, being mostly Medicare-reimbursed, is reimbursed to all dialysis facilities at the same rate. RAI has also completed a cost comparison between utilizing disposable dialyzer filters and re-usable dialyzer filters and has decided that being a single use (disposable dialyzer filter) facility will contain costs to the patient and avoid any patient concerns related to reuse of dialyzer filters."

The applicant adequately documents its plans for providing access to services for patients with limited financial resources. However, the applicant does not demonstrate that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served, because the applicant's projection of need is based upon unsupported and thus unreliable assumptions of the patients proposed to be served by the dialysis facility. See Criterion (3) for additional discussion. Consequently, the application is not consistent with Policy Gen-3, is not consistent with the need determination and therefore is not 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.

C
Harrisburg Dialysis Center
Cabarrus County Dialysis
Copperfield Dialysis Center

NC RAI Care Center-Concord

There are currently two dialysis facilities in Cabarrus County, both of which are operated by Total Renal Care of North Carolina, LLC. TRC Harrisburg is on Perry Street in Concord, and TRC Copperfield is on Vinehaven Drive in Concord. The July 2010 Semiannual Dialysis Report (SDR) in Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates indicates that as of December 31, 2009, there were 109 in-center dialysis patients in the 2 existing Cabarrus County facilities, dialyzing on 31 dialysis stations. The 2010 State Medical Facilities Plan (2010 SMFP) and the July 2010 SDR have identified a need for 23 dialysis stations in Cabarrus County.

F-8577-10, Harrisburg Dialysis Center - proposes to add five stations to the existing facility in Concord, for a facility total of 20 stations after completion of this project. The applicant projects that 100% of its patients will reside in Cabarrus County, and that the

facility will dialyze 70 patients on 20 dialysis stations at the end of project year one, which is 3.5 patients per station, or a utilization rate of 87.5% [70 patients / 20 stations = 3.5 patients per station. 70 patients / $(20 \times 4) = 0.875$].

Population to be Served

In Section III.7, page 25 of the application, the applicant states 100% of its patients are projected to reside in Cabarrus County. See the following table:

COUNTY	OPERATE 2017	GYRRI Z012	OPERATI 2012	GYTARZ 2013	COUNTYP	ONTOTAL
Cabarrus Total	70 70	#:HOMEP152:11: 0 0	76 76	0 0	100% 100%	100% 100%

*Source: Application page 25

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.7, pages 25 - 29, the applicant provides the assumptions and methodology it used to calculate its projections. Specifically, on pages 25 - 26, the applicant states,

- "• TRC assumes that ESRD patients residing in Cabarrus County will want to dialyze at a facility in Cabarrus County.
- The patient population in Cabarrus County will be projected forward using the current Five Year Average Annual Change Rate as published in the July 2010 SDR.
- The percentage of patients dialyzing on home therapies will remain constant. The July 2010 SDR indicates that as of December 31, 2009, 13.9% of the dialysis patients in Cabarrus County were home dialysis patients.
- The July 2010 SDR indicates that the Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center had an in-center dialysis patient population of 49 patients as of December 31, 2009 (July 2010 SDR, Table A., Page 8).
- The July 2010 SDR indicates that the Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center had an in-center dialysis patient population of 60 patients as of December 31, 2009 (July 2010 SDR, Table A., Page 8).

Further, in Section III.7, on pages 26-29, the applicant describes the methodology it used to project the number of patients to be served in the Harrisburg Dialysis Center by first projecting the dialysis patient population for the entire county, and then determining how much of that dialysis patient population will be served by the Harrisburg Dialysis Center. On page 26, the applicant states,

"TRC begins with the ESRD patient population of 201 total dialysis patients in Cabarrus County as of December 31, 2009.

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census as of December 31, 2010.

 $201 \times 0.085 = 17.085 + 201 = 218.085$

TRC again projects that census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for December 31, 2011.

 $218.0 \times 0.085 = 18.53 + 218.0 = 236.53$

TRC then projects this census forward for one half year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, 2012. This is day before the projected certification date for the project.

 $236.5 \times 0.0425 = 10.05125 + 236.5 = 246.55125$

On June 30, 2012, TRC is projecting that there will be 246.5 total dialysis patients residing in Cabarrus County. TRC notes that this calculation methodology is consistent with that in the SDR Table B. ...

Given that the calculations will project 246.5 patients for June 30, 2012, TRC will now reduce this number by the percentage of patients using home therapies. The July 2010 SDR indicates that 13.9% of the patients residing in Cabarrus County were home dialysis patients.

 $246.5 \times 0.139 = 34.2635$.

246.5 - 34.2635 = 212.2365"

Thus, the applicant projects that as of June 30, 2012, there will be 212.2365 in-center dialysis patients residing in Cabarrus County.

On pages 27 – 28 the applicant projects the combined dialysis population of the Harrisburg and Copperfield dialysis facilities, and then subtracts that total from the total projected incenter dialysis patient population in Cabarrus County for 2012. On page 27, the applicant states,

"TRC recognizes that TRC Harrisburg and Copperfield were serving 109 in-center

patients (Harrisburg 49 and Copperfield 60) at their facilities on December 31, 2009. It is reasonable to conclude that this census will grow in proportion with the Cabarrus County Five Year Average Annual Change Rate. TRC offers the following projections for this patient population.

TRC begins with the reported patient population of the TRC Harrisburg and Copperfield facilities as of December 31, 2009. As noted above, 109 of these patients are apparently residents of Cabarrus County.

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected Harrisburg and Copperfield combined in-center patient census for December 31, 2010.

 $109 \times 0.085 = 9.265 + 109 = 118.265.$ "

The applicant projects that figure forward 1.5 additional years, to arrive at the projected Harrisburg and Copperfield in-center dialysis population as of June 30, 2012:

- $118.2 \times 0.085 = 10.047 + 118.2 = 128.247$
- \bullet 128.2 X 0.425 = 5.4485 + 128.2 = 133.6485

On page 28, the applicant states Operating Year One is projected to be July 1, 2011- June 30, 2012; likewise, Operating Year Two is projected to begin July 1, 2012 and end on June 30, 2013. The applicant states the difference between the projected aggregate population of the Harrisburg and Copperfield dialysis centers and the projected total Cabarrus County in-center dialysis population is 78.6 in-center dialysis patients [212.2 Cabarrus County in-center dialysis patients as of June 30, 2012 – 133.6 in-center combined Harrisburg and Copperfield dialysis patients as of June 30, 2012 = 78.6 as of June 30, 2012].

On page 28, the applicant states that this projected patient population "is not being served by any facility within Cabarrus County. Therefore, these in-center patients could be reasonably served by a TRC facility."

The applicant continues with projected patient population of the Harrisburg Dialysis Center, on pages 28 – 29. The applicant states,

"Based on the above assumptions, we have grown the in-center patient population for the Harrisburg Dialysis Center as of December 31, 2009 using the AACR of 8.5% beginning with July 1, 2010, the date the July 2010 SDR was published. We have projected the patient population over a three year period that includes the first two years of operation after the five stations are certified.

July 1, 2010-June 30, 2011 — 49 in-center patients X 1.085 = 53.165

July 1, 2011-June 30, 2012 — 53.165 in-center patients X 1.085= 57.684025

July 1, 2012-June 30, 2013 -57.684285 in-center patients X 1.085 = 62.58716712."

The project analyst notes that the applicant states it begins its projection of dialysis patients based on the July 2010 SDR, which reports patient census as of December 31, 2009. Rather than growing the population from January 1, 2010, however, the applicant begins growing the population beginning July 1, 2010. The starting point for growth projections used by the applicant actually results in his "loss" of six months of growth; thus, the projections of the number of patients to be served are understated, which is not adverse to the application.

In addition, the applicant states on page 28,

"Since there is a 23-station deficit of dialysis stations in Cabarrus County, it has been determined that Harrisburg Dialysis Center will begin the first year of operations (July 1, 2011) with 16f [sic] the 78.6 in-center patients.

TRC projects that the patient population forward to calculate the expected patient populations for the end of Operating Years 1 and 2.

TRC begins with the projected patient population of 36 in-center patients as noted above. This is the projected census as of July 1, 2011."

Although the applicant states it will project 36 in-center patients, the calculations in the application show the projection of 16 in-center patients, which is consistent with the conclusions reached by the applicant on page 28. Following are the calculations as reported by the applicant on pages 28-29:

"TRC projects this census forward one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, [2012] the last day of Operating Year 1.

16X.085 = 1.36 + 16 = 17.36

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, 2014, the last day of Operating Year 2.

 $17.3 \times .085 = [1.4075] + 17.3 = 18.7705.$ "

The applicant states here that the 18.77 patients are projected for the end of OY 2, however, the date supplied (June 30, 2014) is not consistent with the date the applicant states is the end of OY2 (June 30, 2013). Furthermore, on page 29, the applicant calculates utilization of the five proposed stations and the 16 patients that it concluded could reasonably be served by TRC. However, the applicant has projected 18.8 patients grown from the 16 original

patients, but calculates utilization based on 17 patients and five stations. On page 29, the applicant states,

"The result is that the in-center patient population utilizing the 5 new dialysis stations will have a patient census of 17 in-center patients at the end of operating year one for a utilization rate of 85% or 3.4 patients per station."

The result is that the in-center patient population utilizing the 15 existing dialysis stations will have a patient census of 57 in-center patients at the end of operating year one for a utilization rate of 95% or 3.8 patients per station."

The inconsistencies and math errors notwithstanding, on page 29, the applicant combines the 49 patients currently dialyzing at Harrisburg Dialysis Center as of December 31, 2009 [from the July 2010 SDR] and the 16 patients [subtracted from the 78 patients not being served by any facility in Cabarrus County as of June 30, 2012], for a beginning census of 65 in-center dialysis patients. The applicant states,

"July 1, 2011-June 30, 2012-65 in-center patients X 1.085 = 70.525

July 1, 2012-June 30, 2013 - 70.525 in-center patients X 1.085 = 76.519625

The result is that the in-center patient population utilizing 20 existing and new dialysis stations will have a patient census of 70 in-center patients at the end of operating year one for a utilization rate of 87.5% or 3.5 patients per station."

The project analyst notes that the applicant states it begins its projection of dialysis patients based on the July 2010 SDR, which reports patient census as of December 31, 2009. Rather than growing the population from January 1, 2010, however, the applicant begins growing the population beginning July 1, 2010. The starting point for growth projections used by the applicant actually results in his "loss" of six months of growth; thus, the projections of the number of patients to be served are understated, which is not adverse to the application. In addition, the applicant takes the 16 dialysis patients from the projection grown from December 31, 2009 to June 30, 2012, but adds that to the 49 patients dialyzing at the facility as of December 31 2009. Thus the two dates from which the applicant takes the numbers of patients to be served, and begins projecting the patient census for the Harrisburg Dialysis Center are different. The 16 additional patients are from June 30, 2012 and the 49 existing patients are from December 31, 2009. However, this also results in a more conservative projection and thus is not adverse to the application.

Thus, by the end of the first year of operation, the applicant projects to serve 70 in-center dialysis patients on 20 dialysis stations. This results in an 87.5% utilization rate, which is above the minimum required by the performance standards promulgated in 10A NCAC 14C .2303(b). In the second project year, the applicant projected that it would serve 76 in-center patients on 20 stations, for a rate of 3.8 patients per station, or 95%.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for the five additional dialysis stations at the Harrisburg Dialysis Center. Consequently, the application is conforming to this criterion.

F-8581-10, Cabarrus County Dialysis - proposes to develop a new dialysis facility with 12 in-center stations on a parcel of land identified as number 5539950390, fronting N.C. Highway 49 in Concord. TRC states in Section I.8, page 3 of the application that a third party lessor, RHGC Investments, LLC will purchase the property and construct a building shell. TRC will then upfit the shell building to develop the 12-station dialysis facility. The applicant projects that all of its patients will be residents of Cabarrus County. The applicant projects to begin facility operation on July 1, 2012; and projects that the facility will be certified by July 1, 2012.

Population to be Served

In Section III, page 29, the applicant projects that 100% of its patients will reside in Cabarrus County, as illustrated in following table provided by the applicant:

	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients
Cabarrus	39	2.	42	4	100.0%	100.0%
Total	39	2,	42	4	100.0%	100.0%

Also on page 29 the applicant assumes that dialysis patients currently residing in Cabarrus County would want to remain in Cabarrus County to receive their dialysis treatments; and furthermore, that Cabarrus County dialysis patients would prefer a Nephrologist who resides in Cabarrus County. Therefore, the applicant projects that all of its patients will reside in Cabarrus County. The applicant adequately identified the population to be served by the proposed dialysis facility.

Demonstration of Need

In Section III.7, pages 29 - 33, the applicant provides the assumptions and methodology it used to calculate its projections. Specifically, on pages 29 - 30, the applicant states,

- "TRC assumes that ESRD patients residing in Cabarrus County will want to dialyze at a facility in Cabarrus County.
- TRC assumes that End Stage Renal Disease dialysis patients residing in Cabarrus County will want their Nephrologist to live and practice within Cabarrus County.
- The patient population in Cabarrus County will be projected forward using the current Five Year Average Annual Change Rate as published in the July 2010 SDR.

- The percentage of patients dialyzing on home therapies will remain constant. The July 2010 SDR indicates that as of December 31, 2009, 13.9% of the dialysis patients in Cabarrus County were home dialysis patients.
- The July 2010 SDR indicates that the Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center had an in-center dialysis patient population of 49 patients as of December 31, 2009 (July 2010 SDR, Table A., Page 8).
- TRC begins with the ESRD patient population of 201 total dialysis patients in Cabarrus County as of December 31, 2009.
- TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census as of December 31, 2010.

 $201 \times 0.085 = 17.085 + 201 = 218.085$ "

The applicant performs the same calculation for 1.5 additional years, to project the total Cabarrus County dialysis patient census as of June 30, 2012:

- ♦ 218.085 x 1.085 = 236.622
- * 236.622 x 1.0425 = 246.677

On page 30, the applicant subtracts 13.9% from that total dialysis patient population, to extract the percentage of patients projected to use home hemodialysis

- $246.7 \times 0.139 = 34.288$
- 246.7 34.3 = 212.4, or 212

Thus, on page 30, the applicant projects there will be 212 in-center dialysis patients residing in Cabarrus County as of June 30, 2012.

On page 31, the applicant projects the combined in-center population of the Harrisburg and Copperfield Dialysis facilities to June 30, 2012, based on the in-center population reported in the July 2010 SDR. The applicant states,

"TRC recognizes that TRC Harrisburg and Copperfield were serving 109 in-center patients (Harrisburg 49 and Copperfield 60) at their facilities on December 31, 2009. It is reasonable to conclude that this census will grow in proportion with the Cabarrus County Five Year Average Annual Change Rate. TRC offers the following projections for this patient population.

TRC begins with the reported patient population of the TRC Harrisburg and Copperfield facilities as of December 31, 2009. As noted above, 109 of these patients are apparently residents of Cabarrus County.

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected Harrisburg and Copperfield combined in-center patient census for December 31, 2010.

 $109 \times 0.085 = 9.265 + 109 = 118.265$."

The applicant performs the same calculation for 1.5 additional years, to project the total combined dialysis patient census in the Harrisburg and Copperfield dialysis centers as of June 30, 2012:

- $118.265 \times 1.085 = 128.318$
- 128.318 x 1.0425 = 133.77

On page 31, the applicant subtracts the combined Harrisburg and Copperfield dialysis patient population projections from the total Cabarrus County dialysis patient population: [212.4 – 133.77 = 78.6]. Thus, on page 33, the applicant projects there will be 78.6 in-center dialysis patients not being served by any facility as of June 30, 2012.

On page 32, the applicant states,

"Since there is a 23-station deficit of dialysis stations in Cabarrus County, it has been determined that Cabarrus County Dialysis will begin the first year of operations (July 1, 2012) with 36 of the 78.6 in-center patients.

TRC projects that the patient population forward to calculate the expected patient populations for the end of Operating Years 1 and 2.

TRC begins with the projected patient population of 36 in-center patients as noted above. This is the projected census as of July 1, 2012.

TRC projects this census forward one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, 2013, the last day of Operating Year 1.

36 X 0.085=3.06+36=39.06

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for

June 30, 2014, the last day of Operating Year 2.

 $39.0 \times .085 = 3.315 + 39.0 = 42.315$."

Thus, the applicant projects to serve, in the proposed new 12-station dialysis facility, 39 incenter patients in Operating Year 1 and 42 in-center patients in Operating Year 2. 39 incenter patients would result in a utilization of 81.25%, or 3.3 patients per station per week, which is above the minimum utilization required by 10A NCAC 14C .2203(a) [39 patients / 12 stations = 3.25 / 4 = 0.8125]. Similarly, 42 in-center patients dialyzing on 12 dialysis stations would result in a utilization of 87.5%, or 3.5 patients per station per week [42 patients / 12 stations = 3.5 / 4 = 0.8750].

In Exhibit 16 the applicant provides five letters of support from the nephrologists associated with Central Carolina Nephrology, PA. that state in part:

"...As a practicing Nephrologist in Cabarrus County, I support the efforts of Total Renal Care to expand this much service.

Our Nephrology practice has had a longstanding, solid professional relationship with DaVita for several years. They provide outstanding patient care resulting in superior patient clinical outcomes.

I am aware that many of the End Stage Renal Disease patients residing in Cabarrus County travel to other dialysis facilities in contiguous counties three times a week for their life-sustaining dialysis treatments. I understand that DaVita is stepping up and committing the resources to meet the needs of these dialysis patients.

I am requesting that you approve their Certificate of Need application so that the residents of Cabarrus County in need of hemodialysis treatments can receive services in their home county. The addition of this new facility in Cabarrus County will enhance the quality of life for the ESRD patients who reside here."

Also in Exhibit 16, the applicant provided 117 patient letters of support that state in part:

"I am a dialysis patient living in Cabarrus County. My Nephrologist is associated with Central Carolina Nephrology, located in Concord in Cabarrus County. I receive my dialysis treatments three times a week at a dialysis facility operated by Total Renal Care of North Carolina, LLC. I receive my treatments at a facility in Cabarrus County or in a county contiguous to Cabarrus County.

I understand that DaVita, Inc. operating as Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis, is submitting a Certificate of Need Application to the State of North Carolina to develop a new twelve-station End Stage Renal disease (ESRD) dialysis facility in Concord in Cabarrus County.

I understand that this facility being proposed by Total Renal Care of North Carolina will be located at a site very close to the geographical center of Cabarrus County. This will give me and all of the other patients living in Cabarrus County who receive their dialysis treatments either in Cabarrus County or in a county contiguous to Cabarrus County the option of transferring to this new facility. Some important factors you may want to consider when you review the Certificate of Need application being submitted by various providers:

- 1. I am a dialysis patient living in Cabarrus County.
- 2. My Nephrologist is associated with Central Carolina Nephrology.
- 3. I receive my dialysis treatments at a dialysis facility operated by Total Renal Care of North Carolina.
- 4. I have no intention of changing the Nephrologist who follows my care for End Stage Renal Disease
- 5. I have intention of changing the dialysis provider that provides my treatments three times a week."

Thus, the applicant provides letters from 58.2% [117 patient letters / 201 total Cabarrus County dialysis patients = 0.582] of the entire Cabarrus County dialysis patient population indicating that those patients who signed the letters are currently being served by a TRC facility in Cabarrus County and, further, that they would like to continue to receive their dialysis treatments at a TRC facility in Cabarrus County. It is reasonable to conclude that, since TRC is currently the only provider of dialysis services in Cabarrus County, the patients currently receiving dialysis services from a TRC facility would want to continue to do so. In addition, in its assumptions in Section III.7, page 29, the applicant projects to serve two home hemodialysis patients in Operating Year 1 and four home hemodialysis patients in Operating Year 2. In Section II, page 24, the applicant states it will offer both "home modalities and a nocturnal program." Furthermore, in Section V.2(d), page 38, the applicant describes the facility's proposed follow-up program for its home trained patients.

In summary, the applicant adequately identified the population to be served by the proposed project, and adequately demonstrated the need the proposed population has for the 12 dialysis stations proposed to establish a new facility in Cabarrus County. Consequently, the application is conforming to this Criterion.

F-8584-10, Copperfield Dialysis Center - The applicant proposes to add six stations to the existing facility in Concord, for a facility total of 27 stations after completion of this project. The applicant projects that 100% of its patients will reside in Cabarrus County, and that the facility will dialyze 91 patients on 27 dialysis stations at the end of project year one, which is 3.4 patients per station, or a utilization rate of 84.25% [91 patients / 27 stations = 3.4 patients per station. 91 patients / $(27 \times 4) = 0.8425$].

Population to be Served

In Section III.7, page 25 of the application, the applicant states 100% of its patients are projected to reside in Cabarrus County. See the following table:

Contr	OPERATION NO PROPERTIES	CYEAR1	ОРБДАТЬ 2012	6 Y248 2 2013	COUNTY P PERCENT	
	IN CIR PIE	HOME PIS	IN CIR HIS	HOME PIS	THE YEAR LIBER	YEAR 2
Cabarrus	91	0	98	0	100%	100%
Total	91	0	98	0	100%	100%

*Source: Application page 25

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.7, pages 25-29, the applicant provides the assumptions and methodology it used to calculate its projections. Specifically, on pages 25-26, the applicant states,

- "• TRC assumes that ESRD patients residing in Cabarrus County will want to dialyze at a facility in Cabarrus County.
- The patient population in Cabarrus County will be projected forward using the current Five Year Average Annual Change Rate as published in the July 2010 SDR.
- The percentage of patients dialyzing on home therapies will remain constant. The July 2010 SDR indicates that as of December 31, 2009, 13.9% of the dialysis patients in Cabarrus County were home dialysis patients.
- The July 2010 SDR indicates that the Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center had an in-center dialysis patient population of 49 patients as of December 31, 2009 (July 2010 SDR, Table A, Page 8).
- The July 2010 SDR indicates that the Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center had an in-center dialysis patient population of 60 patients as of December 31, 2009 (July 2010 SDR, Table A., Page 8)."

Further, in Section III.7, on pages 26-29, the applicant describes the methodology it used to project the number of patients to be served in the Copperfield Dialysis Center by first projecting the dialysis patient population for the entire county, and then determining how much of that dialysis patient population will be served by the Copperfield Dialysis Center. On page 26, the applicant states,

"TRC begins with the ESRD patient population of 201 total dialysis patients in Cabarrus County as of December 31, 2009.

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census as of December 31, 2010.

 $201 \times 0.085 = 17.085 + 201 = 218.085$

TRC again projects that census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for December 31, 2011.

 $218.0 \times 0.085 = 18.53 + 218.0 = 236.53$

TRC then projects this census forward for one half year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, 2012. This is day before the projected certification date for the project.

 $236.5 \times 0.0425 = 10.05125 + 236.5 = 246.55125$

On June 30, 2012, TRC is projecting that there will be 246.5 total dialysis patients residing in Cabarrus County. TRC notes that this calculation methodology is consistent with that in the SDR Table B. ...

Given that the calculations will project 246.5 patients for June 30, 2012, TRC will now reduce this number by the percentage of patients using home therapies. The July 2010 SDR indicates that 13.9% of the patients residing in Cabarrus County were home dialysis patients.

 $246.5 \times 0.139 = 34.2635$.

246.5 - 34.2635 = 212.2365"

Thus, the applicant projects that as of June 30, 2012, there will be 212.2365 in-center dialysis patients residing in Cabarrus County.

On pages 27 - 28 the applicant projects the combined dialysis population of the Harrisburg and Copperfield dialysis facilities, and then subtracts that total from the total projected incenter dialysis patient population in Cabarrus County for 2012. On page 27, the applicant states,

"TRC recognizes that TRC Harrisburg and Copperfield were serving 109 in-center patients (Harrisburg 49 and Copperfield 60) at their facilities on December 31, 2009. It is reasonable to conclude that this census will grow in proportion with the Cabarrus County Five Year Average Annual Change Rate. TRC offers the following projections for this patient population.

TRC begins with the reported patient population of the TRC Harrisburg and Copperfield facilities as of December 31, 2009. As noted above, 109 of these patients are apparently residents of Cabarrus County.

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected Harrisburg and Copperfield combined in-center patient census for December 31, 2010.

 $109 \times 0.085 = 9.265 + 109 = 118.265$."

The applicant projects that figure forward 1.5 additional years, to arrive at the projected Harrisburg and Copperfield in-center dialysis population as of June 30, 2012 [118.2 x 0.085 = 10.047 + 118.2 = 128.247. 128.2 X 0.425 = 5.4485 + 128.2 = 133.6485]. On page 28, the applicant states Operating Year One is projected to be July 1, 2011- June 30, 2012; likewise, Operating Year Two is projected to begin July 1, 2012 and end on June 30, 2013. The applicant states the difference between the projected aggregate population of the Harrisburg and Copperfield dialysis centers and the projected total Cabarrus County in-center dialysis population is 78.6 in-center dialysis patients [212.2 Cabarrus County in-center dialysis patients as of June 30, 2012 – 133.6 in-center combined Harrisburg and Copperfield dialysis patients as of June 30, 2012 = 78.6 as of June 30, 2012].

On page 28, the applicant states that this projected patient population "is not being served by any facility within Cabarrus County. Therefore, these in-center patients could be reasonably served by a TRC facility."

The applicant continues with projected patient population of the Copperfield Dialysis Center, on pages 28 – 29. The applicant states,

"Based on the above assumptions, we have grown the in-center patient population for the Copperfield Dialysis Center as of December 31, 2009 using the AACR of 8.5% beginning with July 1, 2010, the date the July 2010 SDR was published. We have projected the patient population over a three year period that includes the first two years of operation after the five stations are certified.

July 1, 2010–June 30, 2011 — 60 in-center patients X 1.085= 65.10

July 1, 2011-June 30, 2012 - 65.10 in-center patients X1.085 = 70.634

July 1, 2012-June 30, 2013 -70.634 in-center patients X 1.085 = 76.637."

In addition, the applicant states on page 28,

"Since there is a 23-station deficit of dialysis stations in Cabarrus County, it has been

determined that Harrisburg Dialysis Center will begin the first year of operations (July 1, 2011) with 19 of the 78.6 in-center patients.

TRC projects that the patient population forward to calculate the expected patient populations for the end of Operating Years 1 and 2.

TRC begins with the projected patient population of 36 [sic] in-center patients as noted above. This is the projected census as of July 1, 2011."

Following are the calculations as reported by the applicant on pages 28-29:

"TRC projects this census forward one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, 2012 the last day of Operating Year 1.

 $19 \times 0.085 = 1.615 + 16 = 20.615$

TRC projects this census forward for one year, using the Five Year Average Annual Change Rate as published in the July 2010 SDR. This is the projected patient census for June 30, 2014, the last day of Operating Year 2.

 $20.615 \times .085 = 1.752275 + 20.6 = 22.352275$.

The result is that the in-center patient population utilizing the [6] new dialysis stations will have a patient census of 20 in-center patients at the end of operating year one for a utilization rate of 83.3% or 3.3 patients per station.

We have included in the chart below the operating years one and two combined patient population with [27] dialysis stations operational (21 existing stations and 6 new stations):

July 1, 2011–June 30, 2012—84 in-center patients X 1.085= 91.14

July 1, 2012-June 30, 2013 —91.14 in-center patients X 1.085 = 98.8869

The result is that the in-center patient population utilizing 27 existing and new dialysis stations will have a patient census of 91 in-center patients at the end of operating year one for a utilization rate of 84% or 3.3 patients per station."

The applicant thus projects growth of the entire Cabarrus County dialysis patient population based on the AACR for Cabarrus County and subtracts that percentage of patents historically receiving home hemo-dialysis training, to arrive at a projected number of in-center dialysis patients for the beginning of the first project year. Further, the applicant projects growth of the aggregate Harrisburg and Copperfield Dialysis Center patient populations to the same time, and subtracts that population from the projected Cabarrus County dialysis patient

population. This is the number of patients the applicant concludes will be dialysis patients who will need dialysis services. The applicant projects that 19 of the 78 Cabarrus County dialysis patients will be served at the Copperfield Dialysis Facility. The applicant combines the projected patients from the facility with the original Copperfield patient population, and projects that, in Operating Year 1, the facility will serve 91 in-center patients on 27 stations, which is 3.4 patients per station, or 84.25% utilization [91/27 = 3.37; 3.37/4 = 0.8425]. In Operating Year 2, the applicant projects to serve 98 in-center patients on 27 stations, which is 3.6 patients per station, or 91% utilization [98/27 = 3.63; 3.63/4 = 0.9075]. Since the applicant currently serves Cabarrus County residents at this facility, it is reasonable to assume that, with the addition of dialysis stations, and considering the Cabarrus County AACR of 8.5%, the facility census would increase sufficiently to utilize the additional stations.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for the additional dialysis stations at the Copperfield Dialysis Center. Consequently, the application is conforming to this criterion.

F-8590-10, RAI Care Center-Concord — The applicant proposes to develop a new 23-station dialysis facility on Trinity Church Road in Concord. The applicant proposes 23 incenter dialysis stations on the treatment floor, including one isolation station and one station for home hemo-dialysis training. The applicant projects that the dialysis patients will be residents of Cabarrus and Mecklenburg Counties. The applicant projects to begin facility operation on January 1, 2012; and projects that the facility will be certified by January 1, 2012.

Population to be Served

In Section III.7, page 42, the applicant projects that in Operating Year One, 86.7% of its patients will reside in Cabarrus County, and 13.3% of its patients will reside in Mecklenburg County, as illustrated in following table provided by the applicant:

	(6)4 N 3(14)5 (6)4 N 3(14)5		2 (113724-154 - (1138-19			
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients
Cabarrus	65	7	67	7	86.7%	100.0%
Mecklenburg	· 10	0	11	.0	13.3%	0
Total	75	7	78	7 .	100.0%	100.0%

*In the population table provided on page 42 of the application, the applicant shows Year 1 as 2011, and Year 2 as 2012. However, in the proposed schedule in Section XII of the application, the applicant states it projects station certification and offering of services to be January 1, 2012. Thus the project analyst concludes the date indicated on page 42 is an error, and the remainder of the analysis will include that conclusion.

On page 43, the applicant states the location on Trinity Church Road in Concord is centrally located in the densest area of Cabarrus County and close to Mecklenburg County, therefore

the applicant reasonably projects to serve patients from both counties. The applicant adequately identified the population to be served by the proposed dialysis facility.

Demonstration of Need

In Section III, pages 30-38, the applicant provides the information it used to project need for the 23-station dialysis facility to be located in Concord. On pages 30-31, utilizing the information from the July 2010 SDR, the applicant provides tables to illustrate the dialysis patient population in Cabarrus County and the projected growth of that population. On page 31, the applicant provides tables to show the projected population growth in Cabarrus County. The applicant states on page 31:

From 2005 to 2010, the population of Cabarrus County grew by 19.3 percent. Based on North Carolina Office of State Budget and Management (NCOSBM) projections, Cabarrus County's population is projected to grow by an additional cumulative 13.8 percent from 2010 to 2015. In particular:

- The 45-64 population grew by 28.7 percent from 2005 to 2010, representing 25.7 percent of Cabarrus County's population. NCOSBM projects that the 45-64 population will increase by 16.7 percent from 2010 to 2015, to become 26.3 percent of Cabarrus County's total population.
- * The elderly population (65+ years old) grew by 18.7 percent from 2005 to 2010, to represent 10.7 percent of Cabarrus County's total population. NCOSBM projects that the elderly population will be the fastest growing population, increasing by 20.7 percent from 2010 to 2015, to become 11.4 percent of Cabarrus County's total population. This is also the population group that is most likely to need dialysis services.

Based on a consistent level of in-center dialysis patients and an aging population, it is reasonable to project that Cabarrus County residents will increase the number dialysis patients requiring in-center dialysis treatment."

Thus the applicant states the projected population growth in Cabarrus County supports a need for additional dialysis stations in Cabarrus County.

On page 32, the applicant states,

"RAI decided to locate the proposed 23-station ESRD facility on Trinity Church Road for the following reasons:

* Trinity Church Road is on the border of both Kannapolis and Concord, the two largest towns in Cabarrus County.

Trinity Church Road is located near the population center of Cabarrus County.

Trinity Church Road is easily accessible from the north and south via US Highway 601 and I-85 and from the east and west via NC Highway 73. It is also near the Cabarrus-Mecklenburg border which makes it a convenient location for residents of North Mecklenburg (for example, Huntersville) where there is no dialysis facility.

The local nephrologists' practice in Cabarrus County is located at CMC-

Northeast in Concord."

On page 34 the applicant provides data that shows it projects to serve dialysis patients residing in ZIP Code 28036, which includes northern Mecklenburg County. The project analyst looked at Mapquest® and determined that those residents living in the Huntersville area have access to the proposed location of the RAI facility on Trinity Church Road, using Highway 73; an east-west highway that connects that portion of Mecklenburg County with Trinity Church Road in Concord. Therefore, the applicant reasonably projects to serve some Mecklenburg County residents who live in the Huntersville area of Mecklenburg County.

In addition, on pages 35 - 36, the applicant provides graphs to illustrate the prevalence of dialysis patients in Network 6, according to the Southeastern Kidney Council. The applicant states,

"The following data supports the RAI-Concord in-center volume projections as being both reasonable and conservative.

North Carolina, South Carolina, and Georgia are the member states of the Southeastern Kidney Council, ESRD Network 6. The ESRD Network 6 2009 Annual Report shows that even though the three member states account for 10% of the United States population and 10.7% (37,143 / 347,057) of ESRD patients, ESRD Network 6 has the most ESRD patients in its network."

The graph provided on page 35 shows that as of December 31, 2009, ESRD Network 6 had 37,143 dialysis patients, the highest number of the 16 Networks. In addition, on page 36, the applicant states,

"Furthermore, annual data since 1990 shows that both the incidence and prevalence of ESRD patients in ESRD Network 6 has continued to trend upward with no plateau expected into the future.

The data also shows that ESRD is not just a Medicare-age disease. While 50.9% of the ESRD patients in ESRD Network 6 are over the age of 60, the remaining 49.1% are under the age or 60 with a majority of these patients being over 40 years of age."

On page 37, the applicant states the North Carolina Office of State Budget and Management population projections for Cabarrus County from 2010 to 2014 suggest that the over 40 age group in Cabarrus County will grow by 14.64% [(total over 40 population 2014 of 95,312 / total over 40 population 2010 of 83,140) -1 = 0.1464]. In addition, the applicant states,

"North Carolina Office of State Budget and Management (May 2010) population projections for Mecklenburg County[sic] shows that the 60+ population, which makes up over 50% of the ESRD patients in ESRD Network 6 is expected to increase by approximately 5% annually."

The project analyst notes that the paragraph heading on page 37 reads "Cabarrus County Population"; and the tables illustrating population growth projections are labeled "Cabarrus County Over 40 Population" and "Cabarrus County Over 40 Population Change." Therefore, the analyst concludes that the reference to Mecklenburg County in the above paragraph is error and the information presented is regarding Cabarrus County.

On page 38, the applicant states,

"North Carolina Office of State Budget and Management (May 2010) population projections for Cabarrus County shows that the African American 60+ population, which makes up over 50% of the ESRD patients in ESRD Network 6 is expected to increase by approximately 5%, annually."

Thus, the applicant shows that over 40 population, particularly the 60+ and 60+ African American cohorts will grow at a faster rate than younger age cohorts in Cabarrus County. Furthermore, the applicant shows that the older age cohorts use dialysis services more than people in the younger age groups.

On page 41, the applicant states that over the past five years, "Cabarrus County has experienced an increase in the number of dialysis patients...." The applicant provides tables based on information obtained from the Southeastern Kidney Council to illustrate this:

Cabarrus County Total Dialysis Patients Historical and Projected

			IST DE RECEI	和同時時時		PROJECTED
	12/05	12/06	12/07	12/08	12/09	12/10
No. Patients	1 46	150	170	174	201	218.1
% Change*		2.7%	13.3%	2.4%	15.5%	8.5%

^{*}The applicant's calculations on page 41 show a decrease in 12/06 and in 12/08; however, there was no decrease in the number of dialysis patients.

The applicant provides another table, based on information from the Southeastern Kidney Council, to show the number of dialysis patients dialyzing in Cabarrus County during the same time period:

Cabarrus County Total Dialysis Patients Dialyzed in Cabarrus County Historical and

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	12/05	12/06	12/07	12/08	12/09
No. Patients	45	47	53	55	109
% Change	_	4.4%	12.8%	3.8%	98.2%

^{*}The applicant's calculations on page 41 show a decrease in 12/06 and in 12/08; however, there was no decrease in the number of dialysis patients.

On page 41, the applicant concludes that 'nearly 50% of Cabarrus County dialysis patients receive in-center dialysis treatments outside of Cabarrus County."

The data provided in the table directly above seems to indicate the number of dialysis patients dialyzed in Cabarrus County for the years indicated. However, the project analyst consulted the Semiannual Dialysis Reports for the years indicated above back to December 2006 and found different numbers. See the table below.

	Historical	NUMBER OF CABAR	RUS COUNTY DIALY	SISPATIENTS
	12/06	12/07	12/08	12/09
Harrisburg DC**		·		49
Copperfield DC	47	53	5 5	60
Branchview*	44	. 51	50	
Total	91	104	105	. 109

^{*}Closed in 2009

It appears that the applicant extracted dialysis patient census information for only one Cabarrus County facility to use in its methodology. For example, in December 2006 Copperfield Dialysis Center had 47 in-center patients, and Branchview Dialysis had 44. The applicant reported 47 in-center patients for that time. Further, in December 2007, Copperfield Dialysis Center had 53 in-center patients and Branchview had 51. The applicant reported 53 in-center patients. In December 2008, Copperfield Dialysis Center had 55 incenter patients and Branchview had 50. The applicant reported 55 in-center patients. And in December 2009, Copperfield Dialysis Center had 60 in-center patients and Branchview no longer operated. But by this time the Harrisburg Dialysis facility was operating with 49 incenter patients, for a county total of 109 in-center dialysis patients. The applicant reported 109 patients at this point, which is consistent with the total in-center dialysis patient population for Cabarrus County. Thus it appears that the applicant's utilization of the data is inaccurate or, alternatively, the data is misrepresented. Because the data provided by the applicant is not accurate, it is likewise unreliable and is therefore unreasonable.

In addition, the project analyst consulted the Southeastern Kidney Council's (SEKC) report Zip Code of Residents for Patients Currently Dialyzing in Network 6 Units, which reports the number of patients by county of residence in Network 6 (North Carolina, South Carolina and Georgia) counties. The data regarding Cabarrus County, current as of July 1, 2010 shows that, out of a total of 200 dialysis patients residing in Cabarrus County, 172 are in-center patients. In other words, the report indicates that 172 in-center dialysis patients reside in

^{**}Opened in 2009

Cabarrus County and dialyze somewhere in a Network 6 unit. The SEKC report does not provide information regarding where residents of Cabarrus County are receiving their dialysis treatments. Likewise, there is no data provided by the applicant that illustrates how many patients who reside in Cabarrus County leave Cabarrus County for dialysis services.

Thus, the July 2010 SDR's Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates shows that, as of December 31, 2009, there were a total of 109 dialysis patients dialyzing in Cabarrus County. The SEKC report cited by the applicant indicates that there were 201 dialysis patients residing in Cabarrus County in December 2009. Thus it appears the applicant has drawn a conclusion that, since the ZIP code data report from the SEKC shows there were 201 dialysis patients in December 2009 residing in Cabarrus County; and since the July 2010 SDR indicates there were 109 people dialyzing in Cabarrus County as of December 31, 2009, then the remaining dialysis patients reported by the SEKC as residing in Cabarrus County travel outside of Cabarrus County to receive their dialysis treatments. Furthermore, although the SDR reports the number of patients who are dialyzing in a particular facility, it provides no information or data to show where the reported patients actually reside. Thus, based on the information presented in the application, it is not reasonable to conclude that, since the SEKC reported that there were 201 Cabarus County dialysis patients in December 2009; and since the July 2010 SDR reported that there were 109 dialysis patients dialyzing in a facility in Cabarrus County as of December 31, 2009, then 201 - 109, or 92 (45.7%) Cabarrus County residents are leaving Cabarrus County for dialysis. The two data sets report different data; therefore, the conclusion drawn by the applicant about the number of dialysis patients leaving Cabarrus County that is based upon a combination of those two varying data sets cannot be accurate because it is not supported by the information.

Nevertheless, if the project analyst were to assume that, as of December 31, 2009, there were 92 Cabarrus County residents leaving Cabarrus County for dialysis services; those 92 dialysis patients, when grown by the Cabarrus County AACR, results in the following number of patients:

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92 x 1.085 = 99.8 (December 2010)
99.8 x 1.085 = 108.3 (December 2011)
108.3 x 1.085 = 117.5 (December 2012)
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In Section III.7, on page 42 the applicant provides two tables to show that it projects to serve 75 in-center dialysis patients in Operating Year One, and 78 in-center dialysis patients in Operating Year Two. See the following tables, from page 42 of the application:

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Population 65+	20,752	21,608	
Home Dialysis Patients	7	7	
In-Center Dialysis Patients	. 75	78	

^{*}Applicant states this includes a "Year 1 ramp-up period"

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COUNTY	皆事。理論: Y	EAR I IIII III III III		AR 2 向 4 1
	IN-CENTER	HOME	IN-CENTER	HOME.
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Cabarrus	65		11	
Mecklenburg	. 10	7	78	7
Total	/3		/ 0	

The applicant states on page 42: "The RAI-Concord Year 1 projection of 75 dialysis patients is equivalent to 3.26 patients per dialysis station (75 dialysis patients/23 dialysis stations)."

The applicant thus projects to serve 75 in-center dialysis patients in Cabarrus County (65 Cabarrus County residents and 10 Mecklenburg County residents) in Operating Year 1, or 60% of the total dialysis patient population which the applicant concluded are residents of Cabarrus County and are leaving the county for dialysis services [the applicant projects 65 Cabarrus County residents / 108 projected = 0.6018].

In Exhibit 5, the applicant provides seven letters signed by patients of Dr. Kathleen Doman, the proposed Medical Director for the facility. Each letter states,

"I am a current patient of Dr. Kathleen Doma	n. I live in the	area.	I
understand from Dr. Doman that she will be s	erving as medic	al director of a new	diałysis
center to be located in, which will	be owned by RA	I Care Centers.	

I have signed this letter to show my support for Dr. Doman and RAI Care Centers for developing a dialysis center in _____. If I require dialysis services to treat my kidney disease, I will want to use this dialysis center so that I would not have to travel for dialysis care. Because Dr. Doman would serve as the medical director for this dialysis center, I would be comfortable about the care I would receive at this center."

At the end of each letter is a space in which the author of the letter can complete his/her name and address. The project analyst prepared a table to show the patient addresses as indicated on the letters:

	CONTACT	Leinkes
Concord	Cabarrus	1
Harrisburg	Cabarrus	2
Charlotte	Mecklenburg	11
Huntersville	Mecklenburg	3
Total Cabarrus	3	
Total Mecklenb	A	

From the information presented in the patient letters and in the application, it is not reasonable to conclude that 75 in-center patients will dialyze at the proposed new facility, particularly since there is no methodology proffered; there is simply data regarding the number of patients needing dialysis and patient letters. Without a methodology based on

supported assumptions; the projections of dialysis patients to be served at the proposed facility are unsupported and unreliable.

In Exhibit 12, the applicant provides additional letters of support. Five of the letters are from physicians in the area indicating their willingness to refer patients to the proposed facility. There are fourteen additional letters in Exhibit 12, one of which indicates support for a facility in Cornelius County. Of the fourteen additional letters, six are from physicians, two are from businesses in the area, and six are from people who are not identified as either patient or physician; so the project analyst cannot identify the source of the letters.

In Section III.7, page 42, the applicant projects to serve 65 in-center patients from Cabarrus County, and 10 in-center patients from Mecklenburg County in its new facility in Operating Year 1. However, the applicant has not offered an analysis of Mecklenburg County residents who currently receive dialysis services, has not provided data regarding the AACR for Mecklenburg County, and has not given growth projections or, the letters in Exhibit 5 notwithstanding, an indication of how many Mecklenburg County residents will leave the county for dialysis services in Cabarrus County.

Thus the applicant has not provided any information to substantiate its projection to serve 10 in-center dialysis patients who are residents of Mecklenburg County in Operating Year 1. Additionally, a certificate of need was issued to RAI-Glenwater on January 10, 2011 to expand its Glenwater facility, in Mecklenburg County, by 8 stations for a facility total of 42 in-center dialysis stations. The applicant has not indicated, in this application, how it will serve Mecklenburg County patients in a Cabarrus County facility. Therefore, the projections of Mecklenburg County in-center dialysis patients to be served in the proposed Concord facility are unsupported and unreliable, and thus are unreasonable.

In addition, in Section V.2(d), page 48, the applicant states, "Historically, Cabarrus County averages only one dialysis patients [sic] on home dialysis per year." However, in Section III.7, page 42, the applicant projects to serve seven home-trained dialysis patients per year in both operating years. The applicant offers no other information in the application to support its projection to serve the 7 home trained dialysis patients.

In summary, the applicant adequately identified the population it proposes to serve, but failed to adequately demonstrate the need the population would have for the proposed dialysis services, since the applicant did not state its assumptions regarding how it proposes to capture those dialysis patients not being served or leaving the county. Therefore, the application is not conforming to 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.

NA All Applicants

(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 All Applicants

Harrisburg Dialysis Center — The applicant states in Application Section III.9 the alternatives considered before proposing the addition of 5 stations to its existing dialysis facility in Concord in Cabarus County. However the applicant, Total Renal Care of North Carolina, LLC did not demonstrate that it has provided quality dialysis services to the patients it has served in the past 18 months. See discussion in Criteria (1), (18a) and (20). Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative. Additionally, the application does not conform to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200: specifically, .2204(7) and .2204(10) as indicated below. Consequently, the application is not conforming to this criterion.

Cabarrus County Dialysis - The applicant proposes the development of a new 12-station dialysis facility in Concord in Cabarrus County that will include a separate isolation room and a home training department. The applicant states in Section III.9 that it considered several alternatives before proposing this project. However the applicant, Total Renal Care of North Carolina, LLC did not demonstrate that it has provided quality dialysis services to the patients it has served in the past 18 months. See discussion in Criteria (1), (18a) and (20). Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative. Consequently, the application is not conforming to this criterion.

Copperfield Dialysis Center - The applicant proposes to add five dialysis stations to the existing facility for a total of 20 dialysis stations after project completion. In Section III.9, the applicant describes the alternative it considered before proposing this project. However the applicant, Total Renal Care of North Carolina, LLC did not demonstrate that it has provided quality dialysis services to the patients it has served in the past 18 months. See discussion in Criteria (1), (18a) and (20). Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative. Additionally, the application does not conform to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200: specifically, .2204(7) and .2204(10) as indicated below. Consequently, the application is not conforming to this criterion.

RAI Care Center-Concord - The applicant proposes the development of a new 23-station dialysis facility in Concord in Cabarrus County that will include a separate isolation room and a home training room. The applicant states in Section III.9 that it considered several alternatives before proposing this project. However, the applicant failed to adequately

demonstrate the need the population has for the proposed services. See discussion in Criteria (1) and (3). Furthermore, the applicant did not adequately demonstrate that the projections of costs and revenues are reasonable, since the applicant's assumptions with regard to need are unsupported and therefore unreliable. See discussion in Criterion (5). Additionally, the application does not conform to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200: specifically, .2202(b)(5), .2202(b)(7), .2203(a) and .2203(c), as indicated below. Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative. Consequently, the application is not conforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C Harrisburg Dialysis Center Copperfield Dialysis Center Cabarrus Dialysis Center

NC RAI Care Center-Concord

Harrisburg Dialysis Center (F-8577-10) - states in Section VIII.1, page 49, that the total capital cost of the project will be \$113,000, including \$20,000 in construction costs, \$69,000 for dialysis machines, \$4,000 for other equipment and furniture, and \$20,000 in miscellaneous project costs, including dialysis chairs, chair side computers, and televisions. In Section IX, page 52, the applicant projects there will be no start-up costs or initial operating expenses. In Section VIII.2, page 49, the applicant states that 100% of the capital cost of the project will be financed with the cash reserves of DaVita, Inc., the parent company of Total Renal Care of North Carolina, LLC.

Exhibit 20 contains a September 9, 2010 letter signed by James K. Hilger, Chief Accounting Officer, DaVita, which states,

"I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care Inc., which owns 85% of Total Renal Care of North Carolina, LLC.

We are submitting a Certificate of Need Application to expand our Harrisburg Dialysis Center ESRD facility by five dialysis stations. The project calls for a capital expenditure of \$113,000. This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$113,000. [sic] for the project capital expenditure. DaVita, Inc. will make these funds, along with any other funds that are necessary for the development and initial operation of the project, available to Total Renal Care of North Carolina, LLC."

In Exhibit 21, the applicant provides the audited consolidated Balance Sheets for DaVita, Inc. which confirm that, as of December 31, 2009, DaVita, Inc. had total assets in the amount of \$7,558,236,000, including \$539,549,000 in cash and cash equivalents. The balance sheets also show that DaVita, Inc. had net assets (total current assets less total current liabilities) of \$1,255,580,000 as of December 31, 2009.

In Section X of the application, on pages 54 and 57, the applicant projects costs and net revenue for the first two operating years of the proposed project. See the following table:

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Projected Operating Costs	\$2,990,071	\$3,189,462
Projected Operating Costs	42,00,014	
Net Patient Revenue	\$3,393,664	\$3,625,976

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in the first two operating years of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates.

In summary, the applicant adequately demonstrated the availability of funds for the total capital costs of the project and adequately demonstrated the long-term financial feasibility of the proposal. Further, the applicant adequately demonstrated that the projections of costs and charges are based upon reasonable projections of the population to be served. See Criteria (3), (4), and (7) for discussion of reasonableness. Consequently, the application is conforming to this criterion.

F-8581-10, Cabarrus County Dialysis - states in Section VIII.1, page 50, that the total capital cost of the project will be \$1,416,767; including \$820,000 in construction costs, \$165,600 for dialysis machines, \$90,000 for (RO) water treatment equipment, \$222,067 for other equipment and furniture, \$69,000 in architect and engineering fees, and \$50,100 in miscellaneous project costs, including dialysis chairs, chair side computers, and televisions. In Section IX, page 53, the applicant projects start-up costs of \$134,797, and initial operating expenses in the amount of \$947,261, for total estimated start up expenses in the amount of \$1,082,058. Thus, the applicant projects total capital cost and start up expenses in the amount of \$2,498,825. In Section VIII.2, page 50, the applicant states that 100% of the capital cost of the project will be financed with the cash reserves of DaVita, Inc., the parent company of Total Renal Care of North Carolina, LLC.

Exhibit 21 contains a September 10, 2010 letter signed by James K. Hilger, Chief Accounting Officer, DaVita, which states,

"I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.

We are submitting a Certificate of Need Application to develop a twelve-station End Stage Renal Disease hemodialysis facility in Concord in Cabarrus County. The project calls for a capital expenditure of \$1,416,767, start-up expenses of \$136,230 and a working capital requirement of \$947,261.

DaVita and Total Renal Care of North Carolina, LLC have committed cash reserves in the amount of \$2,500,258 for this project. We will ensure that these funds are made available for the development and operation of this project. As Chief Accounting Officer of Total Renal Care of North Carolina, LLC, I can also confirm that we will provide all of the funds that we receive from DaVita for this project to Total Renal Care of North Carolina, LLC for the development of this project."

In Exhibit 22, the applicant provides the audited consolidated Balance Sheets for DaVita, Inc. which confirm that, as of December 31, 2009, DaVita, Inc. had total assets in the amount of \$7,558,236,000, including \$539,549,000 in cash and cash equivalents. The balance sheets also show that DaVita, Inc. had net assets (total current assets less total current liabilities) of \$1,255,580,000 as of December 31, 2009.

In Section X of the application, on pages 55 and 57, the applicant projects costs and net revenue for the first two operating years of the proposed project. See the following table:

PROZTED EXPENSE AND DEI REVINDE	OFYZAKT	OK YEAR 2
Projected Operating Costs	\$1,894,521	\$2,072,639
Net Patient Revenue	\$1,995,824	\$2,248,536

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in the first two operating years of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates.

Further, the applicant adequately demonstrated that the projections of costs and charges are based upon reasonable projections of the population to be served. See Criteria (3), (4), and (7) for discussion of reasonableness. Consequently, the application is conforming to this criterion.

F-8584-10, Copperfield Dialysis Center – states in Section VIII.1, page 49 that the total capital cost of the project will be \$139,200, including \$32,000 in construction costs, \$82,800 for dialysis machines, \$4,000 for other equipment and furniture, and \$20,400 in patient chairs, televisions, and chair side Snappy Computers. In Section IX, pages 53 - 54, the applicant projects there will be no start-up costs or initial operating expenses. In Section VIII.2, page 50, the applicant states that 100% of the capital cost of the project will be financed with the cash reserves of DaVita, Inc., the parent company of Total Renal Care of North Carolina, LLC.

Exhibit 19 contains a September 6, 2010 letter signed by James K. Hilger, Chief Accounting Officer, DaVita, which states,

"I am the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.

We are submitting a Certificate of Need Application to expand our Copperfield Dialysis Center ESRD facility by six dialysis stations. The project calls for a capital expenditure of \$139,200. This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$139,200. [sic] for the project capital expenditure. DaVita Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC."

In Exhibit 20, the applicant provides the audited consolidated Balance Sheets for DaVita, Inc. which confirm that, as of December 31, 2009, DaVita, Inc. had total assets in the amount of \$7,558,236,000, including \$539,549,000 in cash and cash equivalents. The balance sheets also show that DaVita, Inc. had net assets (total current assets less total current liabilities) of \$1,255,580,000 as of December 31, 2009.

In Section X of the application, on pages 55 and 58, the applicant projects costs and net revenue for the first two operating years of the proposed project. See the following table:

PROTECTED PAPERSES AND NET REVENUE	OF A SECTION	TOK YEARZ
Projected Operating Costs	\$3,873,451	\$4,141,685
Net Patient Revenue	\$4,495,936	\$4,855,496

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in the first two operating years of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates.

Further, the applicant adequately demonstrated that the projections of costs and charges are based upon reasonable projections of the population to be served. See Criteria (3), (4), and (7) for discussion of reasonableness. Consequently, the application is conforming to this criterion.

F-8590-10, RAI Care Center-Concord — states in Section VIII.1, page 61, that the total capital cost of the project will be \$1,724,683, including \$797,040 in construction costs, \$290,400 for dialysis machines, \$134,181 for (RO) water treatment equipment, \$190,122 for other equipment and furniture, \$120,000 in architect and engineering fees, and \$192,940 in miscellaneous project costs, including consultant fees, freight charges, and taxes and other fees. In Section IX, page 65, the applicant projects start-up costs of \$69,384, and initial operating expenses in the amount of \$577,500, for total estimated start up expenses in the amount of \$646,884. Thus, the applicant projects total capital cost and start up expenses in

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the amount of \$2,371,567. In Section VIII.2, page 61, the applicant states that 100% of the capital cost of the project will be financed with the cash reserves of RAI Care Centers of North Carolina, II, LLC (RAI-NC), the parent company of RAI Care Center-Concord.

Exhibit 19 contains a September 10, 2010 letter signed by Monte Frankenfield, Vice President of Finance and Controller, Renal Advantage, Inc., which states,

"Renal Advantage, Inc. (RAI) will transfer \$1,724,683 to RAI Care Centers of North Carolina II, LLC (RAI-NC) for the sole purpose of establishing a 23-stations [sic] dialysis facility in Concord, NC. RAI will provide the funds through Cash.

Furthermore, RAI will transfer up to \$684,884 to RAI-NC, for the sole purpose of capitalizing the working capital associated with initial operating expenses of RAI-Concord. RAI will provide the funds through Cash.

Please accept my assurance that the anticipated \$2,371,567 (\$1,724,683 + \$646,884) will be paid from these identified funds for this project."

In Exhibit 20, the applicant provides the audited consolidated Balance Sheets for RA Group Holdings, Inc., the ultimate parent company of RAI-NC, which confirm that, as of December 31, 2009, RA Group Holdings, Inc. and its subsidiaries had total assets in the amount of \$153,688,000, including \$43,314,000 in cash and cash equivalents. The balance sheets also show that RA Group Holdings, Inc. had net assets (total current assets less total current liabilities) of \$77,197,000 as of December 31, 2009.

In Section X of the application, on pages 68 and 72, the applicant projects costs and net revenue for the first two operating years of the proposed project. See the following table:

PROBLIKI EXPENSES AND YET REVENUE	1 (0,77,7,7,7)	TOTAL T
Projected Operating Costs	\$2,078,878	\$3,049,459
Net Patient Revenue	\$1,982,269	\$3,602,277

In the ProFormas in Section X of the application, the applicant projects that revenue will exceed expenses in the second operating year of the project. The rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates. However, the applicant did not adequately demonstrate the need it has for the dialysis services it proposed, because the assumptions and methodology provided did not substantiate the number of patients the applicant projects to serve in Operating Years One and Two. Therefore, the applicant's projection of costs and charges are not based upon reasonable and reliable projections of the population proposed to be served. See Criteria (3), (4), and (7) for discussion of reasonableness. Consequently, the application is not 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.

C
Harrisburg Dialysis Center
Cabarrus County Dialysis Center
Copperfield Dialysis Center

NC RAI Care Center-Concord

Harrisburg Dialysis Center – The 2010 SMFP indicates a need for 23 dialysis stations in Cabarrus County. Harrisburg Dialysis facility proposes to add five stations to its existing facility, for a facility total of 20 stations after project completion. See discussion in Criterion (1) for conformity to the 2010 SMFP need methodology and the July 2010 Semiannual Dialysis Report. In Section III the applicant demonstrated the need for additional dialysis stations. See Criterion (3) for discussion regarding demonstration of need. The applicant demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

Cabarrus County Dialysis - The 2010 SMFP indicates a need for 23 dialysis stations in Cabarrus County. The applicant proposes to develop a new twelve-station dialysis facility in Concord. See discussion in Criterion (1) for conformity to the 2010 SMFP need methodology and the July 2010 Semiannual Dialysis Report. In Section III the applicant demonstrated the need for additional dialysis stations. See Criterion (3) for discussion regarding demonstration of need. The applicant demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

Copperfield Dialysis Center — The 2010 SMFP indicates a need for 23 dialysis stations in Cabarrus County. Copperfield Dialysis facility proposes to add six stations to its existing facility, for a facility total of 27 stations after project completion. See discussion in Criterion (1) for conformity to the 2010 SMFP need methodology and the July 2010 Semiannual Dialysis Report. In Section III the applicant demonstrated the need for additional dialysis stations. See Criterion (3) for discussion regarding demonstration of need. The applicant demonstrated that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is conforming to this criterion.

RAI Care Center-Concord - The 2010 SMFP indicates a need for 23 dialysis stations in Cabarrus County. RAI Care Center-Concord proposes to develop a new 23-station dialysis facility in Concord. However, the applicant did not adequately demonstrate the need it has for the services it proposes, for the following reason: the assumptions and methodology provided by the applicant to support its projection of need are unsupported and therefore unreliable. See discussion in Criteria (1) for conformity to the 2010 SMFP and the July 2010 Semiannual Dialysis Report; and Criterion (3) for discussion regarding the applicant's failure

to demonstrate need for the 23-station dialysis facility it proposes. The applicant did not demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities, and therefore the application is not conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C All Applicants

F-8577-10, Harrisburg Dialysis Center - In Section V.4(c), page 36, the applicant states that Dr. Charles Stoddard currently serves as Medical Director for Harrisburg Dialysis Center and has agreed to continue to serve as Medical Director for the facility. Exhibit 14 contains a September 1, 2010 letter from Dr. Stoddard confirming his intent to serve in that role. In Section VII, page 43, the applicant projects the following staffing during the first two operating years.

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THE PROTITION HE HELD	WITCH SELECTION OF THE SECOND
RN (dc)	3.0
Pt. Care Technician (dc)	8.0
Bio-Med Tech	0.5
Medical Director	Contract Position
Admin (dc)	1.0
Dieticien	0.5
Social Worker	2.0
Unit Secretary	. 1.0
Other - Reuse	1.0
TOTAL	15.5

*dc: direct care staff

As shown in the above table, TRC proposes a total of 15.5 FTE positions, 12.0 of which will be direct care positions. In Section VII.4, page 44, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section VII.6, page 45, the applicant states all of the nephrologists associated with Central Carolina Nephrology have admitting privileges at Harrisburg Dialysis Center.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 46:

	EEKLY HOURS	P OPERATION	
III III DAYS PIE	MORNING	AFTERNOON	Torach
Monday	5	5	10
Tuesday	5	5	. 10
Wednesday	5	5	10
Thursday	5	5	10,
Friday	5	5	10
Saturday	5	5	10
Sunday	0	0	0
Total	30	. 30	60
Total Hours Operation per Year			3,120
(weekly hours x 52)			

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 43:

	#WTES	HSCYRFTE	TOTALITE !	TOTAL BAS ON BEFORE THE PROPERTY OF THE PROPER	HRS HES ON OPERATION
RNs	3	2,080	6,240	3,120	2.0
Techs	8.5	2,080	17,680	3,120	5.7
Total	11.5	2,080	23,920	3,120	7.7

Based on the operating hours and direct care staffing, the applicant has 3,120 hours to cover. The applicant proposed more hours than are necessary; thus, the applicant proposes sufficient staffing. In Section VII, page 43, the applicant projects 12.0 total direct care FTEs. Assuming one FTE works 2,080 hours annually, the project analyst calculated actual total direct care FTE hours projected in staffing for the proposed facility. For example, 3 RNs x 2,080 annual hours = 6,240, and the proposed hours of operation call for 3,120 FTE hours for RN FTEs. Therefore, the applicant proposes more than sufficient staffing to cover direct care staff FTE positions.

In addition, the Harrisburg dialysis facility projects to serve 20 in-center patients on 20 chairs per shift daily, for a total of 40 patients served per day. The dialysis shifts run Monday, Wednesday and Friday, and two other shifts run on Tuesday, Thursday, and Saturday. See the following chart, prepared by the project analyst:

UTWKSIIT I		PETERS AND
Morning (10 stations)	20	20
Afternoon (10 Stations)	20	20

The table illustrates that the Harrisburg Dialysis Center facility will be able to dialyze up to a maximum of 80 in-center patients in Operating Year One on 20 dialysis stations, assuming one patient per station per patient shift, which is sufficient to accommodate the 70 in-center patients it projects to serve. In the Second Project Year, the applicant projects to serve 76 in-

center patients on 20 stations. Likewise, the applicant has sufficient capacity to accommodate the 76 in-center patients it projects to serve in the second Operating Year.

In summary, the applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed. Consequently, the application is conforming to this criterion.

F-8581-10, Cabarrus County Dialysis - In Section V.4(c), page 39, the applicant states that Dr. William Halstenberg has agreed to serve as Medical Director for the Cabarrus County Dialysis facility. Exhibit 15 contains a September 6, 2010 letter from Dr. Halstenberg confirming his intent to serve in that role. The Exhibit also contains a copy of DaVita's Medical Director Agreement - Summary Sheet. In Section VII, page 45, the applicant projects the following staffing during the first two operating years.

HIMITAL POSTTION BUTTLE LEFT	TOTAL ETER YEAR ?!!
RN (dc)	1.5
RN HT (de)	0.3
Pt. Care Technician (dc)	5.0
Nocturnal RN (dc)	0.75
Nocturnal PCT (dc)	0.75
Blo-Med Tech	0.3
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0.3
Social Worker	0.3
Unit Secretary	1.0
Other - Reuse	0.5
TOTAL	11.7

*dc: direct care staff

As shown in the above table, TRC proposes a total of 11.7 FTE positions, 9.3 of which will be direct care positions. In Section VII.4, page 47, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section VII.8, page 47, the applicant states all of the nephrologists associated with Central Carolina Nephrology have admitting privileges at Cabarrus County Dialysis Center.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 48:

	Writing	Hours of Open		HELIMONIALISM SECTION
ii borie ii	MORNING	ARIERNOON	EVENING	TOTAL
Monday	3	3	2	8
Tuesday	3	3	0	6
Wednesday	3	3	2	. 8
Thursday	3	3	0	6
Friday	3	3	· · 2	8
Saturday	3	3	0	6
Sunday	0	0	0	0
Total	18	18	6	42
Total Hours	Total Hours Operation per Year (weekly hours x 52) 2,148			2,148

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 45:

	#FIES	HRSAYR/FTE	TOTAL FLE	TOTAL HRS. OR OPERATION	FIRS/HRS OF
RNs	2.5 5	2,08 0	5,304	2,148	2.5
Techs	5.75	2,080	11,960	2,148	5.6
Total	8.3	2,080	17,264	2,148	8.0

Based on the operating hours and direct care staffing, the applicant has 2,148 hours to cover. The applicant proposed more hours than are necessary; thus, the applicant proposes sufficient staffing. In Section VII, page 45, the applicant projects 9.3 total direct care FTEs. Assuming one FTE works 2,080 hours annually, the project analyst calculated actual total direct care FTE hours projected in staffing for the proposed facility. For example, 2.55 RNs x 2,080 annual hours = 5,304, and 2,148 FTE hours are needed. Therefore, the applicant proposes more than sufficient staffing to cover direct care staff FTE positions.

In addition, the Cabarrus County Dialysis Center facility projects to serve 39 in-center patients on 12 stations in three shifts on Monday, Wednesday and Friday, and two shifts on Tuesday and Thursday, and Saturday. See the following chart, prepared by the project analyst:

1 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		PYTT/SA
Morning (12 stations)	12	12
Afternoon (12 Stations)	. 12	12
Evening (12 Stations)	12	0

The table illustrates that the Cabarrus County Dialysis Center facility will be able to dialyze up to a maximum of 60 in-center patients in Operating Year One on 12 dialysis stations, assuming one patient per station per patient shift, which is sufficient to accommodate the 39 in-center patients it projects to serve. In the Second Project Year, the applicant projects to serve 42 in-center patients on 12 stations. Likewise, the applicant has sufficient capacity to accommodate the 42 in-center patients it projects to serve in the second Operating Year.

In summary, the applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed. Consequently, the application is conforming to this criterion.

F-8584-10, Copperfield Dialysis Center - In Section V.4(c), page 37, the applicant states that Dr. William K. Halstenberg currently serves as Medical Director for Copperfield Dialysis Center and has agreed to continue to serve as Medical Director for the facility following the addition of the proposed stations. Exhibit 14 contains a September 13, 2010

letter from Dr. Halstenberg confirming his support for the project. The project analyst notes that Dr. Halstenberg does not explicitly state he will continue to serve as Medical Director for the facility following the addition of stations, but it is reasonable to conclude that he will do so, based on his current status as Medical Director and his letter of support. In Section VII, page 44, the applicant projects the following staffing during the first two operating years.

Company of the Compan	
THE PROTEST OF THE PROPERTY OF	TOTAL FIE'S YEAR 2
RN (dc)	4.0
Pt. Care Technician (dc)	11.0
Bio-Med Tech	0.7
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0.7
Social Worker	0.7
Unit Secretary	1.0
Other - Reuse	1.5
TOTAL	20.6

^{*}dc: direct care staff

As shown in the above table, TRC proposes a total of 20.6 FTE positions, 16.0 of which will be direct care positions. In Section VII.4, page 45, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section VII.9, page 46, the applicant states all of the nephrologists associated with Central Carolina Nephrology have admitting privileges at Copperfield Dialysis Center.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 47, for the facility following the expansion:

	VERKTY HOURS I	E OPERATION	
	MORNING	AFTERNOON	III TOTAL III
Monday	7	7	14
Tuesday	7	7	14
Wednesday	7	7	14
Thursday	7	. 7	14
Friday	7	7	14
Saturday	7	7	14
Sunday	. 0	0	0
Total	42.	42	72
Total Hours Operation per Year (weekly hours x 52)			4,368

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 44:

	#CES	HRS/YNS CC	TOTALETE HOURS	TOTAL HER OF BOTTON	FIG. HRS./HRS.OF OPERATION
RNs	4	2,080	8,320	4,368	1.9
Techs	11.7	2,080	24,336	4,368	5.6
Total	15.7	2,080	32,656	4,368	7.5

Based on the operating hours and direct care staffing, the applicant has 4,368 hours to cover. The applicant proposed more hours than are necessary; thus, the applicant proposes sufficient staffing. In Section VII, page 44, the applicant projects 16.0 total direct care FTEs. Assuming one FTE works 2,080 hours annually, the project analyst calculated actual total direct care FTE hours projected in staffing for the proposed facility. For example, 4 RNs x 2,080 annual hours = 8,320, and the proposed hours of operation call for 4,368 FTE hours for RN FTEs. Therefore, the applicant proposes more than sufficient staffing to cover direct care staff FTE positions.

In addition, the Copperfield dialysis facility projects to serve 91 in-center patients on 27 chairs per shift per day in Operating Year One, for a total of 54 patients served per day. One dialysis shift runs Monday, Wednesday and Friday, and another shift runs on Tuesday, Thursday, and Saturday. See the following chart, prepared by the project analyst:

No. of Concession, Name of Street, or other Persons and Street, or other P	Tivesiner		TYTHSA
	Morning (10 stations)	27	27
	Afternoon (10 Stations)	27	27

The table illustrates that the Harrisburg Dialysis Center facility will be able to dialyze up to a maximum of 108 in-center patients in Operating Year One on 27 dialysis stations, assuming one patient per station per patient shift, which is sufficient to accommodate the 91 in-center patients it projects to serve. In the Second Project Year, the applicant projects to serve 98 incenter patients on 27 stations. Likewise, the applicant has sufficient capacity to accommodate the 98 in-center patients it projects to serve in the second Operating Year.

In summary, the applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed. Consequently, the application is conforming to this criterion.

F-8590-10, RAI Care Center-Concord - In Section V.4(c), page 49, the applicant states that Dr. Kathleen Doman has agreed to serve as Medical Director for the Cabarrus County Dialysis facility. Exhibit 13 contains a September 10, 2010 letter from Dr. Doman confirming her intent to serve in that role. The Exhibit also contains a copy of Dr. Doman's Curriculum Vitae. In Section VII.1, page 56, the applicant projects the following staffing during the first two operating years.

FRISTEN I	TOTAL ETE'S YEARSE
RN (dc)	4.5
Pt. Care Technician (dc)	7.0
Medical Director	1.0
Dietician	1.0
Social Worker	1.0
Unit Secretary	1,0
TOTAL	15,5

*dc: direct care staff

As shown in the above table, TRC proposes a total of 15.5 FTE positions, 11.5 of which will be direct care positions. In Section VII.4, page 57, the applicant states that it does not anticipate having any difficulty staffing the proposed facility. In Section VII.8, page 58, the applicant states Dr. Doman has admitting privileges at CMC-University and is seeking privileges at CMC-Northeast.

The following table shows hours of operation as proposed by the applicant in Section VII, on page 59:

	We've'v	Hours of Ore	CATTON DE LE	
	MORNING	EATTERNOOM	BYENING	TOTATION
Monday	. 4	4	4	12
Tuesday	4	0	0	. 4
Wednesday	4	4	4	12
Thursday	4	0	Ó	4
Friday	4	4	4	12
Saturday	. 4	0	0	4
Sunday	0	0	0	0
Total	24	12	12	48
Total Hours Operation per Year (weekly hours x 52)				
			_	2,496

The following table shows the number of FTE direct care staff positions the applicant proposes based on the number of hours the facility will operate, as reported by the applicant in Section VII, page 59:

	Litera St	H0507//CF3		Orthodox	TORS/TORSOF TORS/TORSOF
RNs	4.5	2,080	9,360	2,496	3.7
Techs	7.0	2,080	14,560	2,496	5.8
Total	11.5	2,0 80	23,920	2,496	9:5

Based on the operating hours and direct care staffing, the applicant has 2,496 hours to cover. The applicant proposed more hours than are necessary; thus, the applicant proposes sufficient staffing. In Section VII, page 56, the applicant projects 11.5 total direct care FTEs. Assuming one FTE works 2,080 hours annually, the project analyst calculated actual total direct care FTE hours projected in staffing for the proposed facility. For example, 4.5 RNs x 2,080 annual hours = 9,360, and 2,496 FTE hours are needed. Therefore, the applicant proposes more than sufficient staffing to cover direct care staff FTE positions.

In addition, the Cabarrus Dialysis Center facility projects to serve 75 in-center patients on 23 stations in three shifts on Monday, Wednesday and Friday, and one shift on Tuesday and Thursday, and Saturday. See the following chart, prepared by the project analyst:

TIME/SHIPT	M/W/F	T/TH/SA
Morning (12 stations)	23	23
Afternoon (12 Stations)	23	0
Evening (12 Stations)	23	0

The table illustrates that the RAI Care Center-Concord facility will be able to dialyze up to a maximum of 92 in-center patients in Operating Year One on 23 dialysis stations, assuming one patient per station per patient shift, which is sufficient to accommodate the 75 in-center patients it projects to serve. In the Second Project Year, the applicant projects to serve 78 incenter patients on 23 stations. Likewise, the applicant has sufficient capacity to accommodate the 78 in-center patients it projects to serve in the second Operating Year.

In summary, the applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed. Consequently, 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 All Applicants

F-8577-10 Harrisburg Dialysis Center – states in Section V.1 and referenced Exhibits that Northeast Medical Center and Carolinas Medical Center will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, blood bank services and acute dialysis in an acute care setting. In Exhibit 12 the applicant provides a copy of a laboratory services agreement that exists between the Harrisburg Dialysis Center and DVA Laboratory Services for the provision of laboratory services to the facility. The applicant states transportation services will be provided by Cabarrus County Transportation Services. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

F-8581-10, Cabarrus County Dialysis - states in Section V.1 and referenced Exhibits that Northeast Medical Center and Carolinas Medical Center will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, blood bank services and acute dialysis in an acute care setting. In Exhibit 10 the applicant provides a copy of a laboratory services agreement that exists between the Cabarrus County Dialysis Center and DVA Laboratory Services for the provision of laboratory services to the facility. The applicant states transportation services will be provided by Cabarrus County Transportation Services. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

F-8584-10 Copperfield Dialysis Center – states in Section V.1 and referenced Exhibits that Northeast Medical Center and Carolinas Medical Center will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, blood bank services and acute dialysis in an acute care setting. In Exhibit 12 the applicant provides a copy of a laboratory services agreement that exists between the Copperfield Dialysis Center and DVA Laboratory Services for the provision of laboratory services to the facility. The applicant states transportation services will be provided by Cabarrus County Transportation Services. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

F-8590-10, RAI Care Center-Concord – states in Section V.1 and referenced Exhibits that Carolinas Medical Center NorthEast (CMC-NE) will provide ancillary and support services to the proposed facility, including diagnostic and emergency services, blood bank services and acute dialysis in an acute care setting. Laboratory services will be provided by CMC-NE as well. The applicant states on page 46 that transportation services will be provided by "public transportation or community agency." The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed 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

When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv)would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA Harrisburg Dialysis Center Copperfield Dialysis Center

C
Cabarrus County Dialysis
RAI Care Center-Concord

F-8581-10, Cabarrus County Dialysis – The applicant proposes to construct a new facility on parcel of land identified as Parcel #5539950390 that fronts NC Highway 49, between Ericson Court and Accent Avenue in Concord. In Section XI.6(h), page 67 of the application, the applicant provides a table to illustrate the projected 6,428 square feet of new space for the proposed dialysis facility in Concord. In Section XI.6(d), page 65 of the application, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans, and in Section XI.6(g), pages 65 – 66, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment, and other health and safety requirements. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

F-8590-10, RAI Care Centers-Concord – the applicant proposes to construct a new facility located at 1937 Trinity Church Road in Concord, which is just north of U.S. Highway 85. In Section XI.6(h), page 87, the applicant provides a table to illustrate the projected 8,586 square feet of new space for the proposed dialysis facility in Concord. In Section XI.6(d), page 82, the applicant states that applicable energy saving features and water treatment equipment will be incorporated into the construction plans, and in Section XI.6(g), pages 65 – 66, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment, and other health and safety requirements. In Exhibit 22 the applicant provides a September 10, 2010 letter from the project architect that confirms the construction plans conform to all applicable laws and regulations. The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

- (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
Harrisburg Dialysis Center
Cabarrus County Dialysis
Copperfield Dialysis Center

NA RAI Care Center-Concord

F-8577-10, Harrisburg Dialysis Center — In Section VI.1, page 39, the applicant states "The Harrisburg Dialysis Center, by policy, make [sic] dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap." In addition, the applicant states the Harrisburg Dialysis Center does not require payment upon admission for dialysis services, thus making dialysis available to all persons. The applicant provides a table on page 39 that shows 81.6% of dialysis services were provided to Medicare and/or Medicaid patients.

The applicant demonstrated its facilities, including the Harrisburg Dialysis Center, provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

F-8584-10, Copperfield Dialysis Center – In Section VI.1, page 40, the applicant states "The Copperfield Dialysis Center, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic or socioeconomic situation." In addition, the applicant states the Copperfield Dialysis Center does not require payment upon admission for dialysis services, thus making dialysis available to all persons. The applicant provides a table on page 40 that shows 34.90% of dialysis services were provided to Medicare and/or Medicaid patients. The applicant states,

"These are actual percentages of patients who are currently dialyzing at the Copperfield Dialysis Center. These percentages are not a reflection of any

policy that identifies a specific percentage of patients that we will treat who have Medicare or Medicaid funding. DaVita, Total Renal Care, Inc. and Total Renal Care of North Carolina serve all End Stage Renal Disease patients regardless of socioeconomic situation. We have Total Renal Care of North Carolina facilities that have between 95% and 100% of the patients funded by Medicare and Medicaid."

The applicant demonstrated its facilities, including the Copperfield Dialysis Center, provide adequate access to medically underserved populations. 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 Harrisburg Dialysis Center Copperfield Dialysis Center

NA Cabarrus County Dialysis RAI Care Center Cabarrus County

F-8577-10, Harrisburg Dialysis Center - states in Application Section VI.6, page 42 that "There have been no civil rights equal access complaints filed within the last five years."

F-8581-10, Cabarrus County Dialysis – states in Application Section VI.6, page 44 that "There have been no civil rights equal access complaints filed within the last five years against any facility operated by Total Renal Care of North Carolina, LLC or by any facility in North Carolina owned by DaVita, Inc."

F-8584-10, Copperfield Dialysis Center – states in Application Section VI.6, page 43 that "There have been no civil rights equal access complaints filed within the last five years."

F-8590-10, RAI Care Center-Concord – states in Application Section VI.6, page 55 that "No civil rights equal access complaints have been filed against RAI-NC or any facility owned by RAI-NC."

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 All Applicants

F-8577-10, Harrisburg Dialysis Center - In Section VI.1(c), page 40, the applicant projects that 81.6% of its patients who will be served at the facility following the addition of stations will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected payor mix. See the following table:

TESTICAL DISPLEMENTAL	Par Par Carrie
Medicare	24.5%
Medicaid	2.0%
Medicare/Medicaid	28.6%
Medicare/Commercial	26.5%
VA	8.2%
Commercial Insurance	10.2%
Total	100.0%

The applicant demonstrated the facility will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

F-8581-10, Cabarras County Dialysis - In Section VI.1(c), page 41, the applicant projects that 83.3% of its patients who will be served at the proposed facility will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected percentage mix. See the following table:

Medicare	19.8%
Medicaid	4.8%
Medicare/Medicaid	31.3%
Medicare/Commercial	27.4%
VA	5.0%
Commercial Insurance	11.5%
Total	100.0%

The applicant demonstrated the facility will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion

F-8584-10, Copperfield Dialysis Center - In Section VI.1(c), page 41, the applicant projects that 84.9% of its patients who will be served at the facility following the addition of stations will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected payor mix. See the following table:

Mason Conferment	
Medicare	15.1%
Medicaid	7.5%
Medicare/Medicaid	34.0%
Medicare/Commercial	28.3%
VA	1.9%
Commercial Insurance	.13.2%
Total	100.0%

The applicant demonstrated the facility will provide adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

F-8590-10, RAI Care Center-Concord – In Section VL1(c), page 53, the applicant projects that 80.5% of its patients who will be served at the proposed facility will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected payor mix. See the following table:

	. Zerocene z
Medicare	77.5%
Medicaid	3.0%
Self Pay	3.3%
Commercial Insurance	16.1%
Total	100.0%

The applicant demonstrated the facility will provide adequate access to medically underserved populations. 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 All Applicants

F-8577-10, Harrisburg Dialysis Center – In Section VI.5(a), page 41 of the application, the applicant states that patients with End Stage Renal Disease will have access to the facility through referrals by a Nephrologist who will have privileges at Harrisburg Dialysis Center. The applicant states most of these referrals come from primary care physicians, other specialty physicians, or other Nephrologists within the service area or from just outside the service area. The applicant states copies of the facility transfer and transient policies are provided in Exhibit 16; however, the documents are provided in Exhibit 15. The application is conforming to this criterion.

F-8581-10, Cabarrus County Dialysis - In Section VI.5(a), pages 42 - 43 of the application, the applicant states that patients with End Stage Renal Disease will have access to the facility through referrals by a Nephrologist who will have privileges at

Harrisburg Dialysis Center. The applicant states most of these referrals come from primary care physicians, other specialty physicians, or other Nephrologists within the service area or from just outside the service area. The applicant provides copies of the facility transfer and transient policies in Exhibit 17. The application is conforming to this criterion.

F-8584-10, Copperfield Dialysis Center — In Section VI.5(a), page 42 of the application, the applicant states that patients with End Stage Renal Disease will have access to the facility through referrals by a Nephrologist who will have privileges at Copperfield Dialysis Center. The applicant states most of these referrals come from primary care physicians, other specialty physicians, or other Nephrologists within the service area or from just outside the service area. The applicant provides copies of the facility transfer and transient policies in Exhibit 15. The application is conforming to this criterion.

F-8590-10, RAI Care Center-Concord — In Section VI.5(a), page 54 of the application, the applicant states that patients will have access to RAI-Concord through physician referral. The applicant also states the facility will accept patients referred through nursing facilities and even self-referral upon acceptance by the Medical Director.

(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 All Applicants

F-8577-10, Harrisburg Dialysis Center - In Section V.3 of the application, page 36, the applicant states "Total Renal Care of North Carolina, LLC has sent correspondence on behalf of the Harrisburg Dialysis Center to Rowan Cabarrus Community College to offer the facility as a clinical rotation site for mursing students." In Exhibit 13, the applicant provides a copy of a September 10, 2010 letter from DaVita to Rowan Cabarrus Community College, offering the Harrisburg Dialysis Center facility as a clinical rotation site when the new stations are transferred.

F-8581-10, Cabarrus County Dialysis – In Section V.3 of the application, pages 38 - 39, the applicant states

"Cabarrus County Dialysis will employ registered nurses, patient care technicians, a social worker and dietician. The local community colleges are engaged in the training of nursing students and Certified Nursing Assistant students. Cabarrus County Dialysis will be offered as a clinical learning site for nursing and CNA students at Rowan-Cabarrus Community College."

In Exhibit 14, the applicant provides a copy of a September 10, 2010 letter from DaVita to Rowan Cabarrus Community College, offering Cabarrus County Dialysis as a clinical rotation site when the new stations are certified.

F-8584-10, Copperfield Dialysis Center - In Section V.3 of the application, page 37, the applicant states "Total Renal Care of North Carolina, LLC has sent correspondence on behalf of the Copperfield Dialysis Center to Rowan Cabarrus Community College to offer the facility as a clinical rotation site for mursing students." In Exhibit 13, the applicant provides a copy of a March 6, 2009 letter from DaVita to Rowan Cabarrus Community College, offering the Harrisburg Dialysis Center facility as a clinical rotation site when the new stations are transferred.

F-8590-10, RAI Care Center-Concord — In Section V.3, page 48 of the application, the applicant states "RAI-Concord will be available to students in nursing training programs that would benefit from the experience of working with ESRD patients at the request of their health professional training program." In Exhibit 11 the applicant provides copies of letters to various community colleges in the area offering RAI Care Center-Concord as a clinical training site for nursing students when the project is certified.

- (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 All Applicants

F-8577-10, Harrisburg Dialysis Center, F-8581-10, Cabarrus County Dialysis, F-8584-10, Copperfield Dialysis Center - In Section V.7 of each application, the applicant, DaVita, projects how each proposed project will have a positive impact on the cost effectiveness, quality of care and access of underserved groups to the services proposed. The applicant adequately demonstrated that each proposed project would have a positive impact on cost effectiveness. See discussion in Criteria (1), (3), (5), and (6). The applicant adequately demonstrated that its proposals would have a positive impact on access to the proposed services. See discussion in Criterion (13). The applicant did not adequately demonstrate that any of its proposals would have a positive impact upon the quality of the proposed dialysis services in any of its Cabarrus County facilities, for the following reasons: 1) The files in the

Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, indicate that a survey of Copperfield Dialysis Center in January 2010 identified failure to conform to four Medicare Conditions of Participation, resulting in a finding that the facility was unable to ensure the provision of quality care in a safe environment for its patients, and 2) the same Nephrology practice provides medical services to all of the TRC Cabarrus County dialysis facilities. See Criteria (1) and (20). Therefore, the application is not conforming to this criterion.

F-8590-10, RAI Care Center-Concord – The applicant did not adequately demonstrate that the proposal will have a positive impact on the cost effectiveness, quality, and access to the proposed dialysis services, for the following reasons: 1) the applicant did not adequately demonstrate the need the population proposed to be served has for the proposed services; 2) the applicant did not adequately project costs and revenues, since the projections of costs and revenues were based upon unreliable and unsupported assumptions. See Criteria (1), (3), (4), (5), and (13). 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.

NC F-8577-10, Harrisburg Dialysis Center F-8581-10, Cabarrus County Dialysis F-8584-10, Copperfield Dialysis Center

NA F-8590-10, RAI Care Center-Concord

F-8577-10, Harrisburg Dialysis Center, F-8581-10, Cabarrus County Dialysis, F-8584-10, Copperfield Dialysis Center - The applicant, Total Renal Care of North Carolina, LLC, currently provides dialysis services at the Harrisburg Dialysis Center and the Copperfield Dialysis Facility in Cabarrus County. The files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, indicate that a survey of Copperfield Dialysis Center completed in January 2010 identified failure to conform to four Medicare Conditions of Participation, resulting in a finding that the facility was unable to ensure the provision of quality care in a safe environment for its patients. Therefore, the application is nonconforming 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.

C
Cabarrus County Dialysis Center
NC
Copperfield Dialysis Center
Harrisburg Dialysis Center
RAI Care Center-Concord

Harrisburg Dialysis Center's application is not conforming to all the applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200, as indicated below.

Cabarrus County Dialysis Center's application is conforming to all the applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200, as indicated below.

Copperfield Dialysis Center's application is not conforming to all the applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200, as indicated below.

RAI Care Center-Concord's—application is not conforming to all the applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C Section .2200, as indicated below.

SECTION .2200 - CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

2202 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:
 - (1) Utilization rates;
 - (2) Mortality rates;

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- (3) The number of patients that are home trained and the number of patients on home dialysis;
- (4) The number of transplants performed or referred;
- (5) The number of patients currently on the transplant waiting list;
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.

- -C- Harrisburg Dialysis Center The applicant provides the requested information in Section IV, questions 1-7, on pages 32-33 of the application.
- -C- Cabarrus County Dialysis The applicant provides the requested information in Section IV, questions 1 7, on page 9 of the application.
- -C- Copperfield Dialysis Center The applicant provides the requested information in Section IV, questions 1 7, on page 8 of the application.
- -C- RAI Care Center-Concord The applicant provides the requested information in Section IV, questions 1 7, on page 15 of the application.
- (b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:
 - (1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA-Harrisburg Dialysis Center -

-C- Cabarrus County Dialysis — In Exhibit 6 of the application, the applicant provides a September 9, 2010 letter signed by the vice president of clinical services at Carolina Medical Center Northeast which states the hospital will enter into a transfer agreement with Cabarrus County Dialysis in the event a certificate of need is issued. The application is conforming to this rule.

-NA- Copperfield Dialysis Center -

- C- RAI Care Center-Concord In Exhibit 9 the applicant provides a September 10, 2010 letter signed by the Vice President of Clinical Services at Carolinas Medical Center-NorthEast that outlines the services to be provided to RAI patients. In addition, the applicant provides similar letters from other Carolinas Medical Center facilities as well as from Presbyterian Healthcare. The applicant also provides copies of laboratory services agreements between RAI and Renalab, Inc. The application is conforming to this rule.
- (2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:
 - (A) timeframe for initial assessment and evaluation of patients for transplantation,
 - (B) composition of the assessment/evaluation team at the transplant center,
 - (C) method for periodic re-evaluation,
 - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and

- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.
- -NA- Harrisburg Dialysis Center Harrisburg Dialysis Facility is not a new facility, but the applicant provides a copy of a transfer agreement Harrisburg Dialysis facility has with the Charlotte-Mecklenburg Hospital Authority in Exhibit 8.
- -C- Cabarrus County Dialysis In Exhibit 7, the applicant provides an September 8, 2010 letter signed by the Assistant Vice President of Transplant Services at Carolinas Medical Center which states the hospital will enter into a transplant agreement with Cabarrus County Dialysis in the event a certificate of need is issued. Further, the agreement commits that the hospital will provide the information required by this rule. Therefore, the application is conforming to this rule.
- -NA- Copperfield Dialysis Center Copperfield Dialysis Center is not a new facility but the applicant provides a copy of a transfer agreement Copperfield Dialysis facility has with Carolinas Medical Center in Exhibit 8...
- -C- RAI Care Center-Concord in Exhibit 10 the applicant provides a September 13, 2010 letter from Carolinas Medical Center which outlines the terms of the transplant agreement to be entered into between RAI Concord and CMC. Therefore, the application is conforming to this rule.
- (3) For new or replacement facilities, documentation that power and water will be available at the proposed site.
- -NA- Harrisburg Dialysis Center Harrisburg Dialysis Center is not a new facility.
- -C- Cabarrus County Dialysis Center In Section XI.5(e), page 65 of the application, the applicant states the facility will have power and water available at the proposed location, and that the facility will comply with 42 CFR §405.2100. In Exhibit 9, the applicant provides a copy of the DaVita policy regarding water supply in dialysis facilities.
- -NA- Copperfield Dialysis Center Copperfield Dialysis Center is not a new facility.
- -C- RAI Care Center-Concord In Section XI.6(f), page 86, the applicant states a house currently exists on the site chosen for the dialysis facility, and therefore power and water are both available at the site.
- (4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.
- -C- Harrisburg Dialysis Center In Exhibit 9, the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- -C- Cabarrus County Dialysis Center In Exhibit 8, the applicant provides a copy of a September 8, 2010 letter requesting that the Cabarrus County Dialysis Center be included in the back up service that currently provides service to the Harrisburg and Copperfield facilities. The applicant also provides a copy of a DaVita policy regarding actions to be taken in the even of a power outage.

- -C- Copperfield Dialysis Center In Exhibit 9, the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- -C- RAI Care Center-Concord In Exhibit 24 the applicant provides copies of written policies and procedures for back-up for electrical service in the event of a power outage.
- (5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.
- -NA- Harrisburg Dialysis Center Harrisburg Dialysis Center is not a new facility.
- -C- Cabarrus County Dialysis Center In Section XI.1, pages 61 62, the applicant describes the location of both the primary and secondary sites for the facility. Furthermore, the applicant states a third-party lessor, RHGC Investments, LLC, will purchase the property and lease it to TRC for development of the proposed dialysis facility.
- -NA- Copperfield Dialysis Center Copperfield Dialysis Center is not a new facility.
- -NC- RAI Care Center-Concord In Section XI.2(c), page 75 and in Exhibit 22, the applicant describes and provides documentation for the proposed primary site for the facility. However, the applicant states in Section XI.3, page 80, that "RAI and RAI-NC do not propose a secondary site."
- (6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.
- -C- Harrisburg Dialysis Center In Exhibit 10, the applicant provides documentation of water service. Further, Sections VII.3, page 43 and XI.6(g), pages 63 64 of the application provide documentation that services will be provided in conformity with applicable laws and regulations concerning staffing, fire safety, physical environment, and health and safety.
- -C- Cabarrus County Dialysis Center In Section XI.6(g), page 65 of the application, the applicant states the proposed dialysis center will provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements. In addition, in Section VII.3, page 46, the applicant provides further information documenting the training and certification staff will undergo.
- -C- Copperfield Dialysis Center In Section XI.6(g), pages 64 65, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to fire safety equipment, physical environment, water

supply, and other relevant health and safety requirements. In Section VII.3, page 45, the applicant states applicable staffing requirements will be followed for the facility.

- RAI Care Center-Concord In Section XI.6(g), page 87, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements. In Exhibit 22, the applicant provides a September 10, 2010 letter from the facility architect that confirms the plans conform to all regulatory requirements.
- (7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.
- -C- Harrisburg Dialysis Center —The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 10—19, and in Section III, pages 25-30 of the application. All patients are projected to reside in Cabarrus County.
- -C- Cabarrus County Dialysis Center The information regarding patient origin and all of the assumptions provided by the applicant are found in Section III, pages 29 33 of the application. All patients are projected to reside in Cabarrus County.
- -C- Copperfield Dialysis Center The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 11 19, and Section III.7, pages 25 30 of the application. All patients are projected to reside in Cabarrus County.
- -NC- RAI Care Center-Concord The information regarding patient origin provided by the applicant are found in Section III.1, pages 30 38, and in Section III.7, pages 41 42 of the application. However, the applicant did not state assumptions or methodology to support its projections of patients proposed to be served; thus, the projections are unsupported and unreliable. See Criterion (3) for discussion.
- (8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.
- -NA- Harrisburg Dialysis Center Harrisburg Dialysis Center is not a new facility.
- -C- Cabarrus County Dialysis Center The applicant states, in Section II.7, page 14, that all of the patients projected to dialyze at Cabarrus County dialysis facility will reside within 30 miles of the proposed facility, particularly since it will be centrally located in Concord.
- -NA- Copperfield Dialysis Center Copperfield Dialysis Center is not a new facility.
- -C- RAI Care Center-Concord The applicant states, in Section III.8, page 42, that 100% of the patients projected to dialyze at RAI Care Center-Concord will reside within 30 miles of the proposed facility.

- (9) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.
- -C- Harrisburg Dialysis Center The applicant states in Section II, page 10 of the application that "Total Renal Care of North Carolina, LLC will admit and provide dialysis services to patient who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement amount for such services."
- -C- Cabarrus County Dialysis Center The applicant states in Section II, page 15 of the application that the facility "...will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."
- -C- Copperfield Dialysis Center The applicant states in Section II, page 10 that "Total Renal Care of North Carolina, LLC will admit and provide dialysis services to patient who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement amount for such services."
- -C- RAI Care Center-Concord The applicant states in Section VI.1, page 52 that the proposed facility "will offer its services to all area residents in need of dialysis services. The availability of dialysis services will be offered at RAI-Concord without regard to a patient's income, race, ethnicity, gender, disability, or age."

2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
 - -NA- Harrisburg Dialysis Center Harrisburg Dialysis Facility is not a new facility.
 - -C- Cabarrus County Dialysis Center The applicant proposes to develop a twelve-station dialysis facility and to serve 3.2 patients per station at the end of the first year of operation, based on projections of serving 39 patients in the first operating year. Thus, the requirement of 3.2 patients per station is satisfied. Consequently, the applicant is conforming to this rule. See Criterion (3) for discussion.
 - -NA- Copperfield Dialysis Center Copperfield Dialysis Center is not a new facility.
 - -NC- RAI Care Center-Concord The applicant proposes to develop a new twelvestation dialysis facility and to serve 75 patients on 23 stations at the end of the first year of operation, which calculates to 3.2 patients per station. However, the applicant failed to adequately demonstrate the number of patients projected to be served is based on reasonable and supported assumptions and methodology.

Therefore, the application is not conforming to this rule. See Criterion (3) for discussion.

- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
 - -C- Harrisburg Dialysis Center In Section II, pages 10 19, and in Section III, pages 25 30, the applicant documents the need for five additional stations at the facility based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations. See Criterion (3) for discussion.

-NA- Cabarrus County Dialysis Center - This is a new facility.

- Copperfield Dialysis Center In Section II, pages 10 19, and in Section III, pages 25 30, the applicant documents the need for six additional stations at the Copperfield Dialysis facility based on utilization of 3.2 patients per station per week at the end of the first operating year of the additional stations. See Criterion (3) for discussion.
- -NA- RAI Care Center-Concord This is a new facility.

(c) An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.

-C- Harrisburg Dialysis Center - The applicant provides documentation of its assumptions in Section II, pages 10 – 19 and in Section III, pages 25 - 30 of the application. See Criterion (3) for discussion.

-C- Cabarrus County Dialysis Center - The applicant provides documentation of its assumptions in Section III.7, pages 18 - 22 of the application. See Criterion (3) for discussion.

-C- Copperfield Dialysis Center – The applicant provides documentation of its assumptions in Sections II.1, pages 10 – 19, and in Section III.7, pages 25 - 30 of the application. See Criterion (3) for discussion.

-NC- RAI Care Center-Concord — The applicant failed to provide assumptions and methodology to support its projections of the number of patients projected to be served. See Criterion (3) for discussion of reasonableness.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- (1) diagnostic and evaluation services;
- -C- Harrisburg Dialysis Center See Application Section V.1.
- -C- Cabarrus County Dialysis Center See Application Section V.1.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.

- (2) maintenance dialysis;
- -C- Harrisburg Dialysis Center See Application Section V.1.
- -C- Cabarrus County Dialysis Center See Application Section V.1.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.
- (3) accessible self-care training;
- -C- Harrisburg Dialysis Center In Application Section II, page 20, the applicant refers to Application Section V.1, page 34 for the information regarding accessible self-care training. However, the information is contained in Section V.2, pages 35 36.
- -C- Cabarrus County Dialysis Center The applicant states that self-care training will be provided by the applicant. See Application Sections II.2 and V.1.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.
- (4) accessible follow-up program for support of patients dialyzing at home;
- -C- Harrisburg Dialysis Center See Section V.1, page 34 of the application and Exhibit 11.
- -C- Cabarrus County Dialysis Center See Section V.1 of the application.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.
- (5) x-ray services;
- -C- Harrisburg Dialysis Center See Section V.1, page 34 of the application. The applicant refers to Exhibit 7 for information regarding the provision of x-ray services; however, Exhibit 7 does not contain the stated information.
- -C- Cabarrus County Dialysis Center See Section V.1 of the application
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.
- (6) laboratory services,
- -C- Harrisburg Dialysis Center See Section V.1, page 34 and Exhibit 12 of the application.
- -C- Cabarrus County Dialysis Center See Section V.1 of the application.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.
- (7) blood bank services;
 - -NC-Harrisburg Dialysis Center See Section V.1, page 34 of the application. The applicant refers to Exhibit 7 for information regarding blood bank services; however, Exhibit 7 contains procedures for back-up dialysis services, and information regarding blood bank services is not contained within the remaining exhibits. Therefore, the application is not conforming to this rule.

- -C- Cabarrus County Dialysis Center See Section V.1, page 37 of the application, and Exhibit 6.
- -NC-Copperfield Dialysis Center See Application Section V.1, page 35 of the application. The applicant refers to Exhibit 7 for information regarding blood bank services; however, Exhibit 7 contains a copy of a transfer agreement, and information regarding blood bank services is not contained within the remaining exhibits. Therefore, the application is not conforming to this rule.
- -C- RAI Care Center-Concord See Application Section V.1, page 46, and Exhibit 9.

(8) emergency care;

- -C- Harrisburg Dialysis Center See Section V.1, page 34, and Exhibit 7 of the application.
- -C- Cabarrus County Dialysis Center See Section V.1 of the application.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.

(9) acute dialysis in an acute care setting;

- -C- Harrisburg Dialysis Center See Section V.1, page 34, and Exhibit 7 of the application.
- -C- Cabarrus County Dialysis Center See Section V.1 of the application.
- -C- Copperfield Dialysis Center See Application Section V.1.
- -C- RAI Care Center-Concord See Application Section V.1, page 46.

(10) yascular surgery for dialysis treatment patients;

- -NC-Harrisburg Dialysis Center See Section V.1, page 34 of the application. The applicant refers to Exhibit 7 for information regarding vascular surgery services; however, Exhibit 7 contains a copy of a backup dialysis services agreement, and the documentation of vascular surgery services is not provided in the remaining exhibits. Therefore, the application is not conforming to this criterion.
- -C- Cabarrus County Dialysis Center See Section V.1, page 37 and Exhibit 6 of the application.
- -NC-Copperfield Dialysis Center See Application Section V.1 page 35 of the application. The applicant refers to Exhibit 7 for information regarding vascular surgery services; however, Exhibit 7 contains a copy of a transfer agreement, and the documentation of vascular surgery services is not provided in the remaining exhibits. Therefore, the application is not conforming to this criterion.
- -C- RAI Care Center-Concord See Application Section V.1, page 46 and Exhibit 9.
- (11) transplantation services;
 - -C- Harrisburg Dialysis Center See Section V.1, page 34 and Exhibit 8.
 - -C- Cabarrus County Dialysis Center See Section V.1 of the application.

- -C- Copperfield Dialysis Center See Application Section V.1, page 36, and Exhibit 17.
- -C- RAI Care Center-Concord The information regarding transplant services is in Exhibit 10.
- (12) vocational rehabilitation counseling and services; and
 - -C- Harrisburg Dialysis Center See Section V.1 of the application.
 - -C- Cabarrus County Dialysis Center See Section V.1 of the application.
 - -C- Copperfield Dialysis Center See Application Section V.1.
 - -C- RAI Care Center-Concord See Application Section V.1, page 46.
- (13) transportation.
 - -C- Harrisburg Dialysis Center See Section V.1, page 34 of the application.
 - -C- Cabarrus County Dialysis Center See Section V.1 of the application.
 - -C- Copperfield Dialysis Center See Application Section V.1.
 - -C- RAI Care Center-Concord See Application Section V.1, page 46.

.2205 STAFFING AND STAFF TRAINING

- (a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.
 - -C- Harrisburg Dialysis Center The applicant states in Section II that staffing at the proposed facility will be sufficient to meet the requirements in 42 CFR 405.2100. See also Section VII.1, page 43, and Section VII.10, page 46.
 - -C- Cabarrus County Dialysis Center The applicant states in Section II that staffing at the facility will be sufficient to meet the requirements in 42 CFR 405.2100. See also Section VII.1, page 45 of the application and Criterion (7) for discussion.
 - -C- Copperfield Dialysis Center The applicant states in Sections VII.1, VII.2, and VII.3 of the application that staffing at the facility will be sufficient to meet the requirements in 42 CFR 405.2100.
 - -C- RAI Care Center-Concord The applicant states in Section VII.2, page 57 that the facility staffing will be sufficient to meet the requirements in 42 CFR 405.2100. See also Section VII.10, page 59.
- (b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.
 - -C- Harrisburg Dialysis Center See Section VII.5, page 45 of the application. In addition, the applicant refers to Exhibit 19; however, the information required by this rule is provided in Exhibit 18.
 - -C- Cabarrus County Dialysis Center See Section VII.5, page 47 and Exhibit 20 of the application.
 - -C- Copperfield Dialysis Center See VII.5, page 46 of the application.
 - -C- RAI Care Center-Concord See Section VII.5, page 58 of the application.

COMPARATIVE ANALYSIS OF THE COMPETING APPLICATIONS

Pursuant to N.C.G.S. 131E-183(a)(1) and the need determination in the July 2010 SDR, no more than 23 new dialysis stations may be approved in this review for Cabarrus County. Because all four applications in this review collectively propose the development of more than 23 dialysis stations, all four applications cannot be approved, since it would result in the approval of dialysis stations in excess of the need determination in the 2010 SMFP. Furthermore, all four applications in this review are disapproved for the following reasons:

- The application submitted by Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center was found non-conforming under Criteria (1), (4), (18a), and (20), and 10A NCAC 14C .2204(7), and .2204(10).
- The application submitted by Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis was found non-conforming under Criteria (1), (4), (18a), and (20).
- The application submitted by Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center was found non-conforming under Criteria (1), (4), (18a), and (20).
- The application submitted by RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers Concord was found non-conforming under Criteria (1), (3), (4), (5), (6), (13c), (18a), and 10A NCAC 14C .2203(a).

However, after considering the information in each application and reviewing each application individually against all applicable review criteria, the project analyst also conducted a comparative analysis of the four proposals.

SMFP Principles

Basic Principle 12 regarding the Availability of Dialysis Care as contained in Chapter 14, page 331 of the 2010 State Medical Facilities Plan states:

"The NC State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:

- a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient's residence;
- b. ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedule;
- c. Services in rural, remote areas."

a) Home Training

Harrisburg Dialysis – In Section V.2(d), page 35 the applicant states home training services will be provided by Dialysis Care of Kannapolis, which is approximately 8 miles Northwest of the Harrisburg Dialysis facility.

Cabarrus County Dialysis – In Section V.2(d), page 38 the applicant states the Cabarrus County Dialysis facility will provide home training to its patients in need of home training.

Copperfield Dialysis Center – In section V 2(d), page 37 the applicant states home training services will be provided by Dialysis Care of Kannapolis, which is approximately 8 miles Northwest of the Copperfield Dialysis Center.

RAI Care Center-Concord — In Section V.2(d), page 48 the applicant states it will offer home hemodialysis training to its patients in need of home training.

With respect to home training, Harrisburg Dialysis and Copperfield Dialysis Center are the less effective alternatives, since the home patients would have to travel to another facility for home training.

b) Hours of Availability

Harrisburg Dialysis – In Section VII.10, page 46, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Harrisburg Dialysis Center does not propose a third shift.

Cabarrus County Dialysis – In Section VII.10, page 48, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. The applicant will also operate a third shift that runs from 3:00 PM to 7:00 PM on Monday, Wednesday and Friday.

Copperfield Dialysis Center – In Section VII.10, page 47, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday. Copperfield Dialysis Center does not propose a third shift.

RAI Care Center-Concord — In Section VII.10, page 59, the applicant states dialysis services will be available from 6:00 AM to 6:00 PM, on Monday, Wednesday, and Friday. However, the applicant proposes operating only one shift on Tuesday, Thursday, and Saturday, from 6:00 AM to 10:00 AM.

With respect to hours of availability, Harrisburg Dialysis Center and Copperfield Dialysis Center are the less effective alternatives, since those facilities do not propose a third dialysis shift. Cabarrus County Dialysis Center is the most effective alternative, since it offers two shifts six days per week, in addition to a third shift that would run three days per week.

c) Services in rural, remote areas

Cabarrus County is not a rural, remote area.

Facility Location

Two of the facilities, Harrisburg Dialysis Center and Copperfield Dialysis Center, are currently located in Concord, south of Interstate 85, which is a major highway that bisects Cabarrus County from the northeast to the southwest. The proposed Cabarrus County Dialysis facility is to be located on NC Highway 49, close to the intersection of NC Highway 49 and NC Highway 601, which is on the southern side of Concord approximately 8 miles south of Interstate 85. RAI Care Center-Concord facility is to be located on Trinity church Road, which is just north of Interstate 85 and approximately 6.5 miles from the center of Concord. Since each facility either exists or is proposed to be located along a major road that bisects the county either east to west or north to south, facility location is not a comparative issue in this review.

Access by Underserved Groups

Harrisburg Dialysis Center – In Section VI.1, page 40, the applicant states that 81.6% of its patients will have some or all of their services covered by Medicare or Medicaid.

Cabarrus County Dialysis – In Section VI.1, page 41, the applicant states that 83.3% of its patients will have some or all of their services covered by Medicare or Medicaid.

Copperfield Dialysis Center – In Section VI.1, page 41, the applicant states that 85.3% of its patients will have some or all of their services covered by Medicare or Medicaid.

RAI Care Center-Concord – In Section VI.1, page 53, the applicant states that 80.5% of its patients will have some or all of their services covered by Medicare or Medicaid. The application submitted by Copperfield Dialysis Center proposes the highest percentage of patients to have some or all of their services paid for by Medicare or Medicaid. Therefore, the proposal submitted by Copperfield Dialysis Center is the more effective alternative with regard to access by underserved groups.

Service to Cabarrus County Residents

Total Renal Care of North Carolina, LLC (TRC) currently serves 109 in-center hemodialysis patients in two existing facilities located in Cabarrus County. The nephrologists currently serving these patients will continue to do so at each facility proposing to add stations, and at the proposed new Cabarrus County Dialysis facility. On the other hand, RAI Care Center does not currently operate an in-center hemodialysis facility in Cabarrus County, but does serve hemodialysis patients from Mecklenburg County, which is contiguous to Cabarrus County. Nephrologists in Mecklenburg County have stated their intent to follow patients who will utilize the proposed RAI Cabarrus County facility. With regard to service to Cabarrus County patients, the proposals submitted by TRC are the more effective alternatives.

Access to Alternative Providers

Currently, TRC operates two dialysis facilities in Cabarrus County, and is the only provider of dialysis services in the county. RAI operates two dialysis facilities in Mecklenburg

County, which is contiguous to Cabarrus County. TRC owns six additional dialysis facilities in other counties which are contiguous to Cabarrus County. Therefore, with regard to providing dialysis patients access to an alternative provider, the proposal submitted by RAI is the more effective alternative.

Operating Costs and Revenues

In Section X of the application, each applicant projects the costs and revenue for the first two operating years of the proposed project, which results in the following operating costs and revenue per treatment, as demonstrated in the tables below.

Operating Costs

PHILIPPER HARRISBURG DIALYSIS CENTER HERE		THE PROPERTY OF THE PROPERTY O
Projected Expenses	\$2,990,071	\$3,189,462
# Dialysis Treatments	10,530	11,388
Average Cost per Treatment	\$283.96	\$280.10

PHILICAEXERUS COUNTY DIALYSIS CENTER THE BERN THE BEYOUT ALERS HE PYZHOLES SHOW				
Projected Expenses \$1,894,521 \$2,072,639				
# Dialysis Treatments	5,850	6,318		
Average Cost per Treatment	\$323.85	\$328.05		

THE PROPERTY DIXTISS CONTROL THE		
Projected Expenses	\$3,873,451	\$4,141,685
# Dialysis Treatments	13,650	14,742
Average Cost per Treatment	\$284.14	\$280.95

MATCARE CENTER CONCORD 学典期间和	讲即唐伊· 主Yi th	THE PROPERTY OF THE PROPERTY O
Projected Expenses	\$2,078,878	\$3,049,459
# Dialysis Treatments	6,165	11,466
Average Cost per Treatment	\$337.21	\$265.96

The operating costs in Operating Year Two projected by RAI Care Center-Concord and Harrisburg Dialysis Center are the lowest, and the operating costs projected by Cabarrus County Dialysis Center are the highest of all the applicants. However, RAI Care Center-Concord failed to provide reasonable and supported assumptions and methodology to support its projections of need for the patients it projects to serve. Thus, the projections of costs and revenue that are based on those assumptions are likewise unsupported and thus unreasonable. Therefore, with regard to operating costs in Operating Year Two, the application submitted by Harrisburg Dialysis Center is the more effective alternative.

Net Revenue

THE HARRISBURG DIALVSIS CHAPTER THE PROPERTY OF THE PROPERTY O			
Projected Net Revenue	\$3,393,664	\$3,625,976	
# Dialysis Treatments	10,530	11,388	
Revenue per Treatment	\$322.85	\$318.40	

THE CABANNOS COUNTY DIALYSIS CENTER THE		
Projected Net Revenue	\$1,995,824	\$2,248,536
# Dialysis Treatments	. 5,850	6,318
Revenue per Treatment	\$341.17	\$355.89

COPPERVICAD DIALYSIS COPPERING SPECIAL PROPERTY SPECIAL PROPER			
Projected Net Revenue	\$4,495,936	\$4,855,496	
# Dialysis Treatments	13,650	14,742	
Revenue per Treatment	\$329.37	\$329.36	

提拍翻譯BIRAT TAXAS CENTER-CONCORD 新出出清晰的理识图以图以图以图以图如识图识图的图像是图像是			
Projected Net Revenue	\$1,982,269	\$3,602,277	
# Dialysis Treatments	6,165	11,466	
Revenue per Treatment	\$321.54	\$314.17	

In Operating Year Two Cabarrus County Dialysis Center projects the highest revenue per treatment, and RAI Care Center-Concord projects the lowest revenue per treatment. However, RAI Care Center-Concord failed to provide reasonable and supported assumptions and methodology to support its projections of need for the patients it projects to serve. Thus, the projections of costs and revenue that are based on those assumptions are likewise unsupported and thus unreasonable. Therefore, with regard to revenue per treatment, the application submitted by Harrisburg Dialysis Center is the more effective alternative.

Staffing

Direct Care Staff Salaries

The following table summarizes the staff salary information for the registered nurse and dialysis technician positions for the first year of operation for each of the applications, as reported in the table in Section VII.1 of the applications.

	Harrisburg	CARARRUS	COPPERFIELD	RAI CARE
POSITION	DIALYSIS	COUNTY DIALYSIS	Dialysis	CENTER-
	CENTER	CENTER	CENTER	CONCORD
RN	\$51,500	\$52,000	\$51,500	\$62,976
Technician .	\$25,750	\$26,000	\$25,750	\$35,152

RAI Care Center-Concord projects higher registered nurse salaries, and higher Technician salaries than either of the other facilities. Harrisburg Dialysis Center and Copperfield

Dialysis Center project the lowest salary in each category. Therefore, with regard to direct care staff salaries, RAI Care Center-Concord proposes the more effective alternative because that applicant offers the highest salaries.

Availability of Staff

All competing applications projected sufficient shifts and sufficient number of FTE staff positions to accommodate the in-center patients it projects to serve in the second year of operation, and all have budgeted sufficient staff salaries. See Criteria (4) and (7) in each application.

Provision of Quality of Care

Total Renal Care of North Carolina, LLC, owned by DaVita, Inc. currently provides dialysis services at the Harrisburg Dialysis Center and the Copperfield Dialysis Center in Cabarrus County. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, a survey of the Copperfield Dialysis Center conducted on January 28, 2010 indicate that the facility failed to conform to four Medicare Conditions of Participation, resulting in a finding that the facility was unable to ensure the provision of quality care in a safe environment for its patients. Since Total Renal Care of North Carolina, LLC is also the proposed owner of the Cabarrus County Dialysis Center, since the facilities are all in or proposed to be in the same county, and since the same nephrology practice is or will be providing nephrology services to facility patients. the quality of care issue is directly relevant to each DaVita, Inc. / Total Renal Care of North Carolina, LLC facility. RAI does not own or operate a dialysis facility within Cabarrus County; however, it does operate dialysis facilities in Mecklenburg County, which is contiguous to Cabarrus County. The files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation do not report any issues regarding quality of care with regard to RAI facilities in contiguous counties. Therefore, with regard to quality of care provided to patients, RAI Care Center is the more effective alternative.

CONCLUSION

N.C. General Statute Section 131E-183(a)(1) states that the need determination in the SMFP is a determinative limit on the number of dialysis stations that can be approved by the CON Section. The CON Section determined that the all four applications submitted in this review are disapproved for reasons set forth in this comparative analysis and in the rest of the findings.

Consequently, the applications submitted by Total Renal Care of North Carolina, LLC d/b/a Harrisburg County Dialysis Center, Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis Center, Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center, and RAI Care Centers of North Carolina II, LLC, d/b/a RAI Care Center-Concord are disapproved, and no application is approved.

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DATE:

February 10, 2009

PROJECT ANALYST: TEAM LEADER:

Angie Matthes Martha Frisone

PROJECT I.D. NUMBER:

G-8222-08/ Total Renal Care of North Carolina, LLC d/b/a Davie County Dialysis Center/ Develop a new 10-station dialysis facility/ Davie County

G-8227-08/ Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee)/ Develop a new 11-station dialysis facility, including 10 in-center hemodialysis stations and one additional station to be used for home

hemodialysis training/ Davie County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC – TRC CA – WFU

The 2008 State Medical Facilities Plan (SMFP) and the July 2008 Semiannual Dialysis Report provide a county need methodology for determining the need for additional dialysis stations. According to the county need methodology, found on page 297 of the 2008 SMFP, "If a county's December 31, 2008 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80% or greater, the December 31, 2008 county station need determination is the same as the December 31, 2008 projected station deficit." The county need methodology results in a need determination of 10 dialysis stations in

Davie County. Two competing applications were received by the Certificate of Need Section, proposing a total of 21 dialysis stations. However, pursuant to the need determination, 10 stations is the limit on the number of dialysis stations that may be approved in this review for Davie County. See the comparative analysis for the decision. A brief description of the two proposals follows.

Total Renal Care of North Carolina, LLC d/b/a Davie County Dialysis Center (TRC) proposes to develop a new 10-station dialysis facility in Mocksville, near the intersection of Highways 64 and 601.

Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) (WFU) propose to develop a new dialysis facility in Mocksville with a total of 11 stations, including 10 for in-center hemodialysis and 1 additional station for home hemodialysis training.

Additionally, Policy GEN-3 on page 32 of the 2008 SMFP is applicable to this review. Policy GEN-3 states:

"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."

The applicants respond to Policy GEN-3 as follows:

TRC - In Section III.9, page 24, the applicant discusses how the proposal would promote cost effectiveness. The applicant states

"Our developer will purchase a parcel of property and build a shell building. Total Renal Care of North Carolina will then upfit the shell building and turn it into a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in Davie County. The Davie County Dialysis

Center will promote cost-effective approaches in the facility in the following ways:

- This application calls for the development of a new, stated [sic] of the art facility that will require the purchase of hundreds of items that will include dialysis machines, chairs and TVs. (see section Exhibit 20 [emphasis in original] for a copy of the many of the larger items). The parent corporation, DaVita, operates over 1,400 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.
- The Davie County Dialysis Center will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.
- The Davie County Dialysis Center will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers will be purchased under a national contract in order to get the best quality dialyzer for the best price.
- The Davie County Dialysis Center will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on computer which reduces the need for paper.
- The Davie County Dialysis Center Bio-medical Technician assigned to the facility will conduct preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This will extend the life of the dialysis machines.
- The Davie County Dialysis Center will have an inventory control plan that ensures enough supplies are available without having in inordinate amount of supplies on hand. Supply orders will be done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly."

TRC adequately demonstrates that the proposal would be a cost-effective approach.

In Section VI.1, pages 33-34, TRC discusses how the proposal will promote access by the medically underserved. TRC states the following:

"The Davie County Dialysis Center, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

The Davie County Dialysis Center will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

The Davie County Dialysis Center will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons."

TRC adequately demonstrates that the proposal would enhance access by medically underserved groups.

In Section II, pages 17-18, TRC discusses how it will ensure quality care. The applicant states:

"DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita's Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita's total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals. ...

DaVita's Quality Management team works closely with each facility's Quality Improvement team to:

- Improve patient outcomes
- Provide patient and teammate training

2008 Davie County Competitive Dialysis Review

- Develop Quality Improvement Programs
- Facilitate the Quality Improvement Process
- · Continuously improve care delivered
- Assure facilities meet high quality standards"

However, TRC did not adequately demonstrate that it provided quality care in its existing Dialysis Care of Rowan County facility, which will share the same Medical Director with the proposed facility. See Criterion (20) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal would ensure quality care. Consequently, the application is not consistent with Policy GEN-3 in the 2008 SMFP and the application is nonconforming with this criterion.

WFU - In Section V.7, page 28, WFU discusses how the proposal would promote cost effectiveness. The applicants state:

"The development of DKC will have a favorable impact on costeffectiveness as nearly all of the existing DCRP [Davie County resident
patients] already receive their dialysis services from a WFUHS dialysis
facility outside of Davie County and ICH [in-center hemodialysis]
patients face the burden of traveling out of county for that service three
times weekly. Since all WFUHS certified dialysis facilities share
patient information throughout their network, transition to in-county
services at DKC would be effortless, travel expense would be
substantially reduced. Missed treatments due to travel difficulties will
be greatly reduced, in turn, improving patient outcomes. Home dialysis
patients who travel to WFUHS certified dialysis facilities for their
backup care will also benefit from the approval and development of
DKC."

In Section VI.1, pages 29-31, WFU discusses how the proposal would promote access by the medically underserved. The applicants state:

"DKC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with End Stage Renal Disease.

DKC will accept patients regardless of Medicare, Medicaid, other insurance coverage, or ability to pay. DKC's Social Worker will assist patients in obtaining some type of coverage for the medical expenses related to their condition.

As indicated previously, DKC will accept patients regardless of their ability to pay, thus meeting the needs of the community with regards to indigent care. Due to the nature of the ESRD program, the majority of our patients are covered by Medicare or Medicaid; therefore, the indigent care figures should remain fairly stable. It is anticipated that the amount of indigent care will vary according to the total patient population. The social workers at DKC will work diligently to aide patients and their families in obtaining any medical or other assistance, which might be available through state or federal agencies. The staff at the facility will also assist patients in any way possible to enable them to return to gainful employment.

In projecting indigent care at 0.5% of gross revenue, the definition of indigent care is described as the dollar amount of medical care provided to an individual who has no form of medical insurance or means to ever meet the financial requirements of their medical condition.

The facility will be accessible to minorities and handicapped persons as further described in Section VI., #2 and Section VI., #1 (a), and strives to provide services to all patients with End Stage Renal Disease.

DKC will not require payment upon initial treatment for those patients transferring their care to the facility."

WFU addresses how the proposal will ensure quality care in Attachment N where they provided a copy of their "Quality Management Program." The Overview states:

"The facility is committed to continually improving the quality of the health care services they provide. To this end, the dynamic process of continuous improvement of systems and processes is integrated within clinical, managerial, an [sic] support services. Improvements in care and services are dependent on the ongoing assessment and analysis of the functions, processes, and interrelationships of these systems, and the impact of individual performance on them. Quality Control (QC) measurements are integrated into the CQI structure as a means of assuring the safe and effective provision of care for certain high risk aspects of care. Fundamental to quality improvement is the respect for

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the values, concerns, and needs of patients and their families, members of the organization, and the community."

WFU adequately demonstrates that the proposal would ensure quality care. Further, the applicants adequately demonstrate that projected volumes for the proposed dialysis facility incorporate the basic principles in meeting the needs of patients to be served. Therefore, the application is consistent with Policy GEN-3 in the 2008 SMFP.

However, in Section I.9(a), page 2, WFU proposes a total of 11 dialysis stations. On page 3, WFU states:

"Due to recent changes in the protocol for Survey and Certification, DKC respectfully requests an additional 'station' designation for the provision of home hemodialysis training services. ... We request this so that if DKC is approved for the CON, it will not be limited to 9 ICH stations and 1 home hemodialysis training station resulting in an inability to adequately meet the prescribed need as defined in the July 2008 SDR."

However, the need determination is for only 10 dialysis stations in Davie County. Therefore, the application is conforming to this criterion subject to the following condition.

Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall develop no more than 10 certified dialysis stations, which shall include any home hemodialysis and isolation stations.

Although both applications are conforming, as conditioned in the case of WFU, to the need determination in the 2008 SMFP, the limit on the number of dialysis stations that may be approved is 10 stations. Since the two applications combined propose a total of more than 10 dialysis stations, both applications cannot be approved. See the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C-TRC CA-WFU

TRC proposes to develop a new 10-station dialysis facility near the intersection of Highways 64 and 601 in Mocksville. TRC proposes to provide in-center hemodialysis and home training services.

Population to be Served

In Sections II.1, page 12, and III.7, pages 21-22, TRC discusses the patient population proposed to be served. The applicant states:

"We propose to serve all patients living in Davie County zip codes 27014 (Cooleemee) and 27028 (Mocksville). We assume that some of the patients living in the 27006 zip code (Advance) will continue to dialyze at a location in Winston-Salem. The Advance zip code includes the Town of Bermuda Run and the Hillsdale Community at the intersection of Highways 158 and 801 in northeastern Davie County, close to the Forsyth County line. For some of these patients it will [sic] about the same distance to a Winston-Salem dialysis facility. It is 24 miles from Mocksville to Winston-Salem and about 12 miles from the Hillsdale/Bermuda Run area to both Mocksville and Winston-Salem. Overall we project that we will serve 90% of the Davie County incenter patient population. ... We also project that one patient living in the zip code 27054 in Rowan County will choose to dialyze at the Davie County Dialysis Center."

The following table illustrates projected patient origin during the second operating year for the proposed dialysis center, as reported by the applicant in Section III.7, page 21.

County	2011/2012 Operating Year 2		County Patients as % of Total
	In-center patients	Home patients	Operating Year 2
Davie	39	2	97.6%
Rowan	1	0	2.4%

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

In Section III, pages 19-24, TRC describes the need methodology and assumptions it used to project utilization. The applicant states that Mocksville was chosen as

the proposed location because it is the county seat of Davie County, is centrally located in the county, is near the intersection of major highways, and is close to the center of zip code 28028 where the majority of existing Davie County dialysis patients reside. The methodology and assumptions provided in the application are as follows.

"It is our assumption that the ESRD patients living in Davie County receive their dialysis treatments at dialysis facilities located in Winston-Salem in Forsyth County, Statesville in Iredell County, Lexington in Davidson County and Yadkinville in Yadkin County. All of these counties are contiguous to Davie County. All of these facilities are operated by another provider. We have designated the service area for the Davie County Dialysis Center to be Davie County and the 27054 zip code in northern Rowan County which includes the town of Woodleaf. However, Total Renal Care of North Carolina will not turn patients away if they live outside the service area."

TRC discusses zip code reports published in 2007 and 2008 by the Southeastern Kidney Council found in Exhibit 10, where the applicant states

"The reports indicate that the Davie County in-center patient population increased from 25 patients to 29 patients during the first seven months of 2008. The home-trained population increased from 7 patients to 11 patients in the same time frame. ... The in-center patient population for the 28054 zip code [Woodleaf] has been constant at 4 in-center patients. There is one disconnect between the 'Zip Code of Residence for Patients Currently dialyzing in Network 6 Units as of 13/31/2007' and the 'July 2008 Semiannual Dialysis Report.' Page 41 of the Network 6 report indicates that there were 25 in-center patients in Davie County. Page 14 of the dialysis report indicates that there were 27 in-center patients (36 total patients – 9 home patients = 27 incenter patients) in Davie County. For the purpose of outlining our methodology, we have used 27 in-center patients.

The 28054 zip code that includes Woodleaf was included as a part of the proposed service area because the commute to Mocksville is shorter and the traffic pattern in less congested than the commute to Salisbury. Three of the four patients living in the 28054 zip code receive their dialysis treatments at the Dialysis Care of Rowan County. One of the home-trained patients living in Mocksville receives their services from the Dialysis Care of Rowan County facility.

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The July 2008 SDR indicates on page 14 that Davie County has an Average Annual Change Rate (AACR) for the Past Five Years of 13%."

The table below illustrates TRC's methodology and assumptions used to project incenter utilization. TRC uses the number of Davie County in-center patients recorded in the July 2008 SDR for the base year.

Existing Davie County In-Center Patients as of 12/31/07	27
Projected # of Davie County In-Center Patients as of 6/30/08 (a 6-month time period)	27 + (50% of 1.13) = 28.755 (applicant rounds down to 28)
Projected # of Davie County In-Center Patients as of 6/30/09 (a 12-month time period)	28 x 1.13 = 31.64 (applicant rounds down to 31)
Projected # of Davie County In-Center Patients as of 6/30/10 (a 12-month time period)	31 x 1.13 = 35.03
By the end of Operating Yr 1 (7/1/10 – 6/30/11) TRC projects to serve 35 in-center patients from Davie County and 1 in-center patient from Rowan County	35 x 1.13 = 39.55 [applicant rounds down to 39 and then projects to serve 90% (39 x .9 = 35.1)] 35 + 1 = 36
By the end of Operating Yr 2 (7/1/11 – 6/30/12) TRC projects to serve 39 in-center patients from Davie County and 1 in-center patient from Rowan County	39 x 1.13 = 44.07 [applicant rounds down to 44 and then projects to serve 90% (44 x .9 = 39.6)] 39 + 1 = 40

As shown in the above table, the applicant projects to serve 36 in-center patients, 35 from Davie County and 1 from Rowan County in the first operating year, which is 3.6 patients per station [36 / 10 = 3.6] or 90% utilization [3.6 / 4.0 = 0.9]. The applicant projects to serve 40 in-center patients, 39 from Davie County and 1 from Rowan County in the second operating year, which is four patients per station [40 / 10 = 4.0] or 100% utilization [4.0 / 4.0 = 1.0].

The applicant provides five letters of support from patients residing in zip code 27054 in Rowan County. Each letter includes the following statement: "I will consider transferring to the Davie County Dialysis Center when it opens since it will be closer to my home and will be a more convenient location for me to receive my dialysis treatments." The applicant's projected in-center hemodialysis utilization in the first two operating years is reasonable, given the historical rate of growth for Davie County in-center dialysis patients and the likelihood that a majority of Davie County dialysis patients would prefer a facility closer to their homes.

The applicant also projects to serve one home dialysis patient in the first operating year and two patients in the second operating year. In Section III.7, page 23, TRC states:

"We intend to provide home training services at the Davie County Dialysis Center to include home hemodialysis training and follow-up. The Southeastern Kidney Council Zip Code report with data as of July 31, 2008 indicated that there were 84 home hemodialysis patients in North Carolina. Total Renal Care of North Carolina was serving 45 home hemodialysis patients as of July 31, 2008 or 53.5% of the identified patient population. This data is an indication of our commitment to the home modalities."

The applicant's projected utilization is reasonable, given the total number of Davie County residents currently on home dialysis (9). See Exhibit 1 of the application for a copy of the July 2008 SDR.

In summary, the applicant adequately demonstrates the need the population proposed to be served has for the proposed dialysis facility in Mocksville. Therefore, the application is conforming to this criterion.

WFU proposes to develop a new 11-station dialysis facility, including 10 in-center dialysis stations and one home hemodialysis station, near the intersection of I-40 and Highway 601 in Mocksville.

Population to be Served

In Section III.7, page 16, the applicants project that 100% of the patients to be served at the proposed facility will be Davie County residents. The applicants state that 31 Davie County residents currently utilize existing WFUHS facilities located in contiguous counties. The applicants adequately identified that population they propose to serve.

Demonstration of Need

In Section III.7, pages 16-18, WFU describes the methodology and assumptions they used to project utilization. On page 17, the applicants state:

"The July 2008 SDR indicates a 10-station county need for Davie County based on a 12/31/07 patient population as reported by the SEKC of 36 patients, when increased per annum by the 5-year AACR for Davie County of 13%, demonstrates a total patient population projection of 40.7 patients by 12/31/2008. Based on existing patient statistics indicating a 25% home patient rate, the SDR distinguished a projection of 30.5 ICH patients and 10.2 home patients by 12/31/2008.

- As of July 2008, WFUHS dialysis facilities provide ICH [In-Center Hemodialysis] services to 31 DCRP [Davie County Resident Patients] and home dialysis training, backup, and support services to 7 DCRP.
- WFUHS, beginning with its established Davie County patient base, projected potential patient census and utilization given the 13% 5-year AACR as determined and included in the July 2008 SDR.
- Based on reasonable timeframes, DKC anticipates the proposed project to be complete as of 06/30/2009. The end of OY1 of the new facility would be 06/30/2010. The end of OY2 of the new facility would be 06/30/2011.
- Beginning with 31 ICH DCRP, one can reasonably project 35.03 or 35 DCRP by 6/30/2009, 39.58 or 40 DCRP by 6/30/2010, and 44.73 or 45 DCRP by 6/30/2011.
- Using 10 ICH stations as a basis for projecting ICH utilization, one can reasonably project utilization of 98.96% by 6/30/2010 and 111.82% by 6/30/2011."

The following table illustrates WFU's methodology and assumptions used to project in-center utilization. WFU uses the number of Davie County in-center patients currently utilizing existing WFUHS dialysis facilities as of July 1, 2008, for the base year.

Existing Davie County Patients as of 7/31/08	31
Projected In-Center Patient Census upon opening (7/1/09)	31 x 1.13= 35.03
By the end of Operating Yr 1 $(7/1/09 - 6/30/10)$, WFU projects to	
serve 40 patients	35.03 x 1.13=39.58
By the end of Operating Yr 2 (7/1/10 - 6/30/11), WFU projects to	
serve 45 patients	39.58 x 1.13= 44.73

As shown in the above table, WFU projects to serve 40 in-center patients in the first operating year, which is 3.6 patients per station [40 / 11 = 3.64] or 91% utilization [3.64 / 4.0 = 0.91]. WFU projects to serve 45 in-center patients in the second operating year, which is 4.1 patients per station [45 / 11 = 4.1] or 102.5% utilization [4.2 /4.0 = 1.025]. The applicants state that these Davie County dialysis patients are currently served by other WFUHS facilities, and thus, these patients already have existing relationships with the staff and physicians. WFU assumes existing Davie County patients will transfer to the new WFUHS facility in Davie County, where they would be able to maintain their relationship with their current physician, and potentially, some of the same staff. In Attachment W, the applicants provide 27 signed letters of support from current Davie County dialysis patients, all of whom travel outside of Davie County to WFUHS facilities for dialysis treatments. All of the letters include the following statement: "I do not wish to change dialysis providers because WFUHS has been good to me, my family and my community." The applicants' projected utilization in the first two operating years is reasonable, given the historical rate of growth for Davie County in-center dialysis patients and the likelihood that a majority of Davie County dialysis patients would prefer a facility closer to their homes.

The applicants also propose to develop an eleventh station for home hemodialysis training. Regarding the number of home dialysis patients projected to be served, the applicants used the same methodology, starting with number of the Davie County home dialysis patients currently being served by WFUHS, as of July 31, 2008. The applicants project to serve 9 home dialysis patients in the first operating year and 10 in the second operating year. The applicants' projected utilization of the proposed home hemodialysis training station is reasonable, given the number of Davie County residents currently on home dialysis utilizing existing WFUHS facilities (7). See Section III.7, page 17. However, the 2008 SMP states that there is a need for only 10 stations in Davie County. See Criterion (1) for discussion.

In Section XI.6(h), page 59, the applicants propose 121 square feet for an isolation room. However, the design schematic provide in Attachment T appears to show two isolation rooms. In their response to public comments, the applicants confirm that they are proposing two isolation rooms. However, the applicants did not document the need for two isolation rooms, given that the proposed facility would have a total of only 11 stations. Furthermore, the applicants are conditioned to develop no more than 10 certified dialysis stations. See Criterion (1) for discussion.

The application is conforming to this criterion subject to the condition in Criterion (1) and the following condition.

Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall develop no more than one isolation room at Davie Kidney 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.

NA - Both Applications

(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 – TRC CA – WFU

TRC - In Section III.9, pages 23-24, the applicant discusses the alternatives it considered. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (18a) and (20). Therefore, the applicant did not adequately demonstrate that its proposal is its most effective alternative. Consequently, the application is nonconforming with this criterion.

WFU - In Section III.9, page 18, the applicants state "There is no alternative to providing in-county ICH services to the people of Davie County than to develop a new 10-station dialysis unit as prescribed in the July 2008 SDR." Further, the application is conforming, as conditioned, to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and the Criteria and Standards for End-Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. Therefore, the applicants adequately demonstrate that their proposal is their most effective alternative. Consequently, the application is conforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – Both Applications

TRC - In Section VIII., pages 40-41, the applicant projects a total capital cost of \$1,048,812, as shown in the following table.

Cost of Materials	\$310,980
Cost of Labor	\$207,320
Equipment/Furniture	\$442,198
Architect/Engineering Fees	\$54,168
Miscellaneous Equipment	\$34,146
TOTAL	\$1,048,812

In Section IX, pages 44-45, the applicant projects that estimated start-up costs will be \$136,230, which includes supplies and staff training. Initial operating expenses are projected to be \$694,548. Thus, the total working capital is \$830,778 [\$136,230 + \$694,548= \$830,778]. The applicant states that both the capital cost and the working capital required for the project will come from the cash reserves of DaVita, Inc, the ultimate parent of TRC. Exhibit 21 contains a letter from the Vice President and Controller of DaVita, Inc. which states in part,

"I am the Vice President and Controller of DaVita, Inc., which is the parent and 100% owner of Total Renal Care, Inc. I also serve as the Vice President and Controller of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC ("TRC"). ... This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$1,879,590. for the capital expenditure, start-up expenses, and initial operating costs of this project, and that DaVita, Inc. will make these funds, along with any other funds that are necessary for the development and initial operation of the project, available to Total Renal Care of North Carolina, LLC."

Exhibit 22 contains the audited financial statements for DaVita, Inc. for fiscal years ending December 31, 2006 and December 31, 2007. As of December 31, 2007, DaVita, Inc. had \$447,046,000 in cash and cash equivalents and total assets of \$6,943,960,000. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

In Section X, pages 47 and 48, the applicant projects revenues and operating costs, as illustrated in the following table.

	Year 1	Year 2
Projected Operating Expenses	\$1,289,095	\$1,484,411
Projected # of Dialysis Treatments	4,718	6,002
Average Cost per Treatment	\$273,23	\$247.32
Net Patient Revenue	\$1,189,958	\$1,513,972
Projected # of Dialysis Treatments	4,718	6,002
Net Revenue per Treatment	\$252.22	\$252,24
Net Profit/Loss	(\$99,137)	\$29,561

As shown in the above table, revenues are projected to exceed operating expenses in Year Two. The rates in Section X.1 are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Criterion (3) for discussion of reasonableness of projections.

The applicant adequately demonstrated that the financial feasibility of the project is based on reasonable projections of revenues and costs. Therefore, the application is conforming to this criterion.

WFU - In Section VIII, pages 39-41, the applicants project a total capital cost of \$3,115,637, as shown in the following table.

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	Lessor	Lessee
Site Costs	\$641,551	-
Construction Contract	\$1,710,000	
Equipment/Furniture	-	\$265,010
Water Treatment Equipment	\$83,000	=
Generator & Other Fixed Equipment	\$147,500	•
Dialysis Machines	40	\$170,000
Initial Operating Expense	\$98,576	
TOTAL	\$2,680,627	\$435,010

In Section IX, pages 44-45, the applicants project that there will be no start-up expenses and initial operating expenses are projected to be \$98,576. The applicants state that the start-up activities will begin approximately one month prior to the opening of the proposed facility. Training costs for staff will be absorbed by the WFUHS facility in which the training is conducted. Funding for the capital costs will come from the accumulated reserves of WFUHS. In Section IX, page 45, the applicants state that the working capital required for the project, \$98,576, will come from "Unrestricted Cash of Proponent". As shown in the table above, WFU included the initial operating costs in the capital cost. Attachment D contains a letter from the Vice President and Chief Operating Officer of WFUHS which states in part,

"Davie Kidney Center (Lessee), a not-for-profit subsidiary of Wake Forest University Health Sciences, will incur expenses of \$3,115,637. Wake Forest University Health Sciences commits to provide monies to its subsidiaries in order to fund these costs."

Also included in Attachment D are the audited financial statements for WFUHS for years ending June 30, 2006 and June 30, 2007. The financial statements show that as of June 30, 2007, WFUHS had \$13,603,000 in cash and cash equivalents and \$1,145,735,000 in total assets. The applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project.

In Section X, pages 47 and 51, the applicants project revenues and operating costs, as illustrated in the following table.

•	Year 1	Year 2
Projected Expenses	\$1,298,673	\$1,532,113
# of Dialysis Treatments	4,401	6,174
Average Cost per Treatment	\$295.09	\$248,16
Net Patient Revenue	\$1,644,328	\$2,242,347
# of Dialysis Treatments	4,401	6,174
Net Revenue per Treatment	\$373.63	\$363.19
Total Net Profit	\$78,395	\$342,615

As shown in the above table, revenues are projected to exceed operating expenses in the first two operating years. The Medicare/Medicaid rates given in Section X, page 46 are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Criterion (3) for discussion of projections.

The applicants adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of revenues and costs. Therefore, 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.

C-TRC CA-WFU

TRC proposes to develop a new 10-station dialysis facility in Davie County pursuant to a county need determination in the 2008 SMFP. See Criterion (1) for discussion. The applicant adequately demonstrated the need for the proposal. See Criteria (3) for discussion. Therefore, the applicant adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved health service capabilities or facilities, and the application is conforming to this criterion.

WFU proposes to develop an 11-station dialysis facility, including 10 in-center stations and one home hemodialysis training station. However, the 2008 SMFP shows a county need determination for only 10 stations. See Criterion (1) for discussion. Additionally, the applicants did not demonstrate the need for a second isolation room. See Criterion (3) for discussion. The applicants adequately demonstrate that the proposal, as conditioned, would not result in an unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion subject to the conditions in Criteria (1) and (3).

(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 – Both Applications

TRC – In Section V.4(c), page 29, the applicant states that William K. Halstenberg, M.D. has agreed to serve as Medical Director for the facility. Exhibit 14 contains a letter from Dr. Halstenberg stating his intent to serve in that role. Additionally, the applicant states that any board-certified nephrologist may seek privileges at the proposed dialysis facility. In Section VII, page 37, the applicant projects the following staffing during the first two operating years.

Position	Total # of Full-Time Equivalents (FTEs)
RN (direct care)	1.0
RN Home Training (direct care)	0.3
Patient Care Technician (direct care)	4.5
Bio-Med Tech	0.3
Medical Director	Contracted Position
Administrator [direct care (1/2 time)] *	1.0
Dietitian	0.3
Social Worker	0.3
Unit Secretary	1.0
Other-Reuse	0.5
Total	. 9.2

The applicant states that the Administrator will work on the treatment floor as a registered nurse 20 hours per week.

As shown in the above table, TRC proposes a total of 9.2 FTE positions, 6.3 of which will be direct care positions. The applicant states that it does not anticipate having any difficulty staffing the proposed facility. The applicant adequately documented the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed to be provided. Therefore, the application is conforming to this criterion.

WFU - In Section V.4(c), page 24, the applicant states that John Burkart, M.D. has agreed to serve as the Medical Director for the proposed facility. Attachment R contains a letter from Dr. Burkart stating his intent to serve in that role. In Section VII, pages 34-38, the applicants project the following staffing for operating year one.

Position	Total FTEs
RN (direct care)	1.00
LPN (direct care)	1.00
Technician (direct care)	4.00
DON	.50
Medical Director	Contract Service
Administrator	.10
Dietitian	.50
Social Worker	.50
Home Training Nurse (direct care)	.50
Dialysis Tech	2.00
Biomed	.50
Clerical/Purchasing	1.00
Medical Records	Contract Service
Total	11.6

As shown in the above table, WFU proposes a total of 11.6 FTE positions, of which 6.5 will be direct care positions. The applicants state that they do not anticipate having any difficulty staffing the proposed facility. The applicants adequately documented the availability of resources, including health manpower and management personnel, for the level of dialysis services proposed to be provided. 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 – Both Applications

TRC - In Section V, page 27 and referenced exhibits, the applicant provides a list of the ancillary and support services provided by the facility and other area providers, including Davis Regional Medical Center and Rowan Regional Medical Center for acute dialysis services, emergency services, diagnostic evaluation, X-ray, blood bank, and vascular surgery. Carolinas Medical Center will provide renal transplantation and pediatric nephrology services and Dialysis Laboratories will provide laboratory services. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

WFU - In Section V, page 21 and referenced exhibits, the applicants provide a list of the ancillary and support services provided by the facility and other providers, including North Carolina Baptist Hospital for acute dialysis, emergency care,

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diagnostic evaluation, renal transplantation, X-ray, blood bank, and vascular surgery services. Meridian Laboratory Corporation will provide laboratory services for the proposed dialysis facility. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health 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 – Both Applications

TRC - In Section XI, page 50, the applicant states that it will upfit 5,129 square feet of leased building space located at the corner of Highways 64 and 601. On page 54, the applicant discusses the energy saving features which will be incorporated into the project. The applicant adequately demonstrates 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 for health services. See Criterion (5) for discussion of costs and charges. The application is conforming to this criterion.

WFU - The applicants propose to locate the facility on Interstate Drive, near the intersection of I-40 and Highway 601. In Section I, page 3, the applicants state that WFUHS will own the building and Davie Kidney Center, a nonprofit corporation owned by WFUHS, will own the facility. On page 59, the applicants state the facility will be 9,315 square feet, with energy saving features as described on pages 57-58. Therefore, the applicants adequately demonstrate that the cost, design and means of construction 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 for health services. See Criterion (5) for discussion of costs and charges. The application is conforming to this criterion. Consequently, 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;

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NA – Both Applications

(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;

NA – Both Applications

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C – Both Applications

TRC - In Section VI.1, page 33, the applicant states the following:

"The Davie County Dialysis Center, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

The Davie County Dialysis Center will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

The Davie County Dialysis Center will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons."

The following table illustrates the projected payor mix for the dialysis facility, as provided by the applicant in Section VI.1, page 33.

Payor Source	Percent of Total
Medicare	27.0%
Medicaid	2.7%
Medicare/Medicaid	67.6%
Commercial Insurance	2.7%
Total	100%

The applicant demonstrated that medically underserved populations would have adequate access to the proposed dialysis facility. Therefore, the application is conforming to this criterion.

WFU - In Section VI.1, page 29, the applicants state

"DKC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with End Stage Renal Disease. DKC will accept patients regardless of Medicare, Medicaid, other insurance coverage, or ability to pay. DKC's Social Worker will assist patients in obtaining some type of coverage for the medical expenses related to their condition."

The following table illustrates the projected payor mix, as provided by the applicants in Section VI.1, page 29.

Payor Source	Percent of Total
Medicare	17%
Medicaid	5%
Medicare/Medicaid	32%
Commercial Insurance	6%
Medicare/Commercial	33%
VA .	2%
Medicare HMO	5%
Total ·	100%

The applicants demonstrated that medically underserved populations would have adequate access to the proposed dialysis facility. 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 – Both Applications

TRC - In Section VI.5, pages 34-35, the applicant states that patients referred by nephrologists with admitting privileges at Davie County Dialysis Center will have access to the proposed facility. Additionally, primary care or specialty physicians in the area may refer patients to one of the nephrologists on staff. Patients and/or family members who contact the dialysis facility will be referred to a nephrologist on staff for an evaluation. Patients from other facilities requesting a transfer to the Davie County Dialysis Center will be processed in accordance with the facility's policies, which are provided in Exhibit 16. The information provided by the applicant is reasonable and credible and supports a finding of conformity with this criterion.

WFU - In Section VI.1, page 29, the applicants state that patients will be accepted based on medically defined admission criteria and that services are available to all area residents with end stage renal disease. In Section VI.5, pages 31-32, the applicants state that patients desiring treatment at Davie Kidney Center will be considered for admission by the Medical Director, Nurse Administrator, or Social Worker. Area physicians may refer patients to the dialysis facility, but a nephrologist with admitting privileges will be responsible for the admission of the patient. The information provided by the applicants is reasonable and credible and supports a finding of conformity with this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C – Both Applications

TRC - In Section V.3, page 29, the applicant describes how the proposed dialysis facility will help meet the clinical training needs of area health professional training programs. Exhibit 12 contains letters sent to area colleges inviting them to use the proposed dialysis facility as a clinical training site. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

WFU - In Section V.3, pages 23-24, the applicants describe how the proposed dialysis facility will accommodate the clinical needs of area health professional training programs. The applicants also state that onsite experience is provided by all WFUHS dialysis facilities to medical students, fellows, and nurse practitioner students from Wake Forest Health Sciences. 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.

- TRC The applicant does not adequately demonstrate that the proposal would have a positive impact upon the quality of the proposed dialysis services. See Criteria (1) and (20). Therefore, the application is not conforming to this criterion.
- WFU The applicants adequately demonstrate that their proposal, as conditioned, would have a positive impact upon the cost effectiveness, quality and access to the proposed dialysis services. See Criteria (1), (3), (5), (7), (8), (13) and (20). Therefore, the application is 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.

TRC - The applicant currently provides dialysis services at other facilities in North Carolina, including Dialysis Care of Rowan County. The current Medical Director at Dialysis Care of Rowan County, William K. Halstenberg, M.D., has agreed to serve as the Medical Director of the proposed Davie County facility. The files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, indicate that a survey of Dialysis Care of Rowan County in January 2008 identified immediate jeopardy and failure to conform to three Medicare Conditions of Participation. Therefore, the application is nonconforming to this criterion.

WFU — Wake Forest University Health Sciences (WFUHS) currently provides dialysis services at nine other facilities in North Carolina. The current Medical Director for those facilities, John Burkhart, M.D., has agreed to serve as Medical Director of the proposed Davie County facility. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, 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 any of WFUHS' existing dialysis facilities. 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.

C – TRC CA – WFU

The proposal submitted by TRC is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services, which are promulgated in 10A NCAC 14C .2200. The specific findings are discussed below.

The proposal submitted by WFU is conforming, as conditioned, to all applicable Criteria and Standards for End Stage Renal Disease Services, which are promulgated in 10A NCAC 14C .2200. The specific findings are discussed below.

SECTION .2200 - CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:
- (1) Utilization rates:
- (2) Mortality rates;
- (3) The number of patients that are home trained and the number of patients on home dialysis;
- (4) The number of transplants performed or referred;

- (5) The number of patients currently on the transplant waiting list;
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.
- -NA- Neither proposal involves increasing the number of dialysis stations in an existing facility or the relocation of existing stations.
- (b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:
- (1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.
- -C- TRC. Exhibit 6 contains a letter from Davis Regional Medical Center which states the intent to enter into a transfer agreement upon approval of the project.
- -C- WFU. Attachment E contains a signed written agreement between North Carolina Baptist Hospital and Davie Kidney Center.
- (2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:
- (A) timeframe for initial assessment and evaluation of patients for transplantation,
- (B) composition of the assessment/evaluation team at the transplant center,
- (C) method for periodic re-evaluation,
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.
- -C- TRC. Exhibit 7 contains a signed written agreement with Carolinas Medical Center for services related to renal transplantation.
- -C- WFU. Attachment F contains a signed written agreement with North Carolina Baptist Hospital for services related to renal transplantation.
- (3) Documentation of standing service from a power company and back-up capabilities.

- -C- TRC. Exhibit 8 contains a letter from Duke Energy, which states "This letter confirms that Duke Energy Carolinas will provide electric service to the above referenced property" [corner of Hwy 64 and 601, parcel 400000096]. The applicant provides policies regarding procedures for power failures and emergencies in Exhibit 8.
- -CA-WFU. Attachment P contains facility policies regarding disasters and power failures. Letters from the local fire department, police department, and emergency medical services provider are also included in the attachment. In Section XI.6, page 58, the applicants state that the facility will have an emergency generator. However, the applicants did not provide documentation of standing service from a power company. Therefore, the application is conforming to this rule subject to the following condition.

Prior to issuance of the certificate of need, Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall provide the Certificate of Need Section with documentation of standing service from a power company.

- (4) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.
- -C- TRC. In Section XI, pages 50-52, the applicant identifies the proposed primary and secondary sites. Exhibit 24 contains documentation of the availability of both sites and a written commitment from TRC to pursue the acquisition of the sites.
- -C- WFU. In Section XI, pages 54-57, the applicants identify the proposed primary and secondary sites. On pages 55 and 56, the applicants affirm that they will diligently pursue acquisition of the sites. Attachment T contains documentation of the availability of both sites.
- (5) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.
- -C- TRC. In Section XI.6, pages 54-55, the applicant documents that services will be provided in conformity with applicable laws and regulations concerning, staffing, fire, health, and safety.
- -C-WFU. In Section XI.6, page 58, the applicants document that services will be provided in conformity with applicable laws and regulations concerning, staffing, fire, health, and safety.

- (6) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.
- -C- TRC. In Section III.7, pages 21-24, the applicant provides the assumptions used to project patient origin. TRC proposes to serve patients from Davie County and ZIP code 27054, which is in northern Rowan County.
- -C- WFU. In Section III.7, pages 16-18, the applicants provide projections and the assumptions used for patient origin. WFU proposes that all patients will come from Davie County.
- (7) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.
- -C- TRC. In Section III, page 23, the applicant states that no patients will travel more than 30 miles one way from their homes to the proposed facility and that most will travel less than 20 miles one way.
- -C- WFU. In Section III.7, page 18, the applicants state that 100% of the patients will travel less than 30 miles from their residence to the proposed facility.
- (8) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.
- -C- TRC. In Section II.1, page 11, the applicant states it "will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."
- -C- WFU. In Section II.8, page 12, the applicants state "DKC is committed to admitting and providing dialysis services to patients who have no insurance or other source of payment, but for who payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
- -C- TRC. In Section III.7, page 21, TRC projects to have an in-center total of 36 patients (3.6 patients per station) $[36 \div 10 = 3.6]$ by the end of Year 1 and 40 in-center patients (4

patients per station) $[40 \div 10 = 4]$ by the end of Year 2 for the proposed 10-station facility. See Criterion (3) for additional discussion.

- -C- WFU. In Section III.7, page 16, WFU projects to have an in-center total of 40 patients (3.6 patients per station) $[40 \div 11 = 3.6]$ by the end of Year 1 and 45 in-center patients (4.1 patients per station) $[45 \div 11 = 4.1]$ by the end of Year 2 for the proposed 11-station facility. [Note: with only 10 certified dialysis stations, the number of patients per station and occupancy percentages would be higher (Year One 40 / 10 = 4; 4 / 4 = 100%) (Year Two 45 / 10 = 4.5; 4.5 / 4 = 112.5%).] See Criterion (3) for additional discussion.
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- -NA- Neither proposal involves an increase in the number of stations in an existing facility.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- -C- TRC. In Section II.1, pages 13-15, the applicant provides the assumptions and methodology used in projecting utilization at the proposed facility.
- -C- WFU. In Section III.7, pages 16-18, the applicants provide the assumptions and methodology used to project utilization at the proposed facility.

10A NCAC 14C .2204 SCOPE OF SERVICES

- To be approved, the applicant must demonstrate that the following services will be available:
- (1) diagnostic and evaluation services;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (2) maintenance dialysis;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (3) accessible self-care training;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (4) accessible follow-up program for support of patients dialyzing at home;
- -C- TRC. See Section V.1, page 27 in the application.

- -C- WFU. See Section V.1, page 21 in the application.
- (5) x-ray services;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (6) laboratory services;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (7) blood bank services;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (8) emergency care;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (9) acute dialysis in an acute care setting;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (10) vascular surgery for dialysis treatment patients;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (11) transplantation services;
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (12) vocational rehabilitation counseling and services; and
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.
- (13) transportation.
- -C- TRC. See Section V.1, page 27 in the application.
- -C- WFU. See Section V.1, page 21 in the application.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

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- -C- TRC. In Section VII.1, page 37, the applicant provides the proposed staffing. The applicant states on page 38 that the proposed facility will comply with all staffing requirements set forth in 42 CFR 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services proposed to be provided. See Criterion (7) for discussion.
- -C- WFU. In Section VII.1, page 34, the applicants provide the proposed staffing. On page 35, the applicants state that the proposed facility will comply with all staffing requirements set forth in 42 CFR 405.2100. The applicants adequately demonstrate that sufficient staff is proposed for the level of dialysis services proposed to be provided. See Criterion (7) for discussion.
- (b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.
- -C- TRC. In Exhibit 19, the applicant documents that the proposed facility will provide an ongoing program of staff education and training.
- -C- WFU. In Attachment M, the applicants documents that the proposed facility will provide an ongoing program of staff education and training.

COMPARATIVE ANALYSIS OF THE COMPETING APPLICATIONS

Pursuant to N.C.G.S. 131E-183(a)(1) and the need determination in the July 2008 SDR, no more than 10 new dialysis stations may be approved in this review for Davie County. Because both applications in this review collectively propose the development of more than 10 dialysis stations, both applications cannot be approved, since it would result in the approval of dialysis stations in excess of the need determination in the 2008 SMFP. After considering the information in each application and reviewing each application individually against all applicable review criteria, the project analyst also conducted a comparative analysis of the two proposals. For the reasons set forth below and in the remainder of the findings, the application submitted by WFU is approved and the application submitted by TRC is denied.

SMFP Principles

Basic Principle 12 regarding the Availability of Dialysis Care in Chapter 14, page 295, of the 2008 State Medical Facilities Plan states:

"The North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:

- a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient's residence;
- b. ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedules;
- c. Services in rural, remote areas."

a) Home Training

In Section V.2(d), pages 28-29, TRC states it will provide home training services and follow-up at the proposed facility. In Section V.2(d), pages 22-23, WFU states it will provide home training services and follow-up at the proposed facility. Both applications are equally effective alternatives with regard to the provision of home training services.

b) Hours of Availability

In Section VII.10, page 39, TRC states that dialysis services will be available 6:00 a.m. - 4:00 p.m. Monday through Saturday, which is 60 hours per week. In Section VII.10, page 37, WFU states that dialysis services will be available 6:30 a.m. - 5 p.m. Monday through Saturday, which is 63 hours per week. Both applications are equally effective alternatives with regard to hours of availability.

c) Services in rural, remote areas

Davie County is not a remote rural area. Therefore, provision of services in a remote rural area is not a comparative issue in this review.

Facility Location

Currently, there is no dialysis facility located in Davie County. Both applicants propose a location in Mocksville, which is centrally located within Davie County and both locations are in close proximity to major highways. Therefore, both proposals are equally effective with regard to location for Davie County residents.

Service to Davie County Patients

Wake Forest University Health Sciences (WFUHS) currently serves 31 in-center hemodialysis patients and 7 home dialysis patients from Davie County in one of their nine existing facilities located in counties contiguous to Davie County. The nephrologists currently serving these patients will continue to do so at the proposed facility. On the other hand, TRC does not currently serve any in-center hemodialysis patients from Davie County and serves only one home dialysis patient from Davie County. Nephrologists in Rowan County have stated their intent to follow patients utilizing the proposed facility. With regard to service to Davie County patients, the proposal submitted by WFU is the more effective alternative.

Access to Alternative Providers

Currently, there is no dialysis facility located in Davie County. WFUHS owns nine dialysis facilities in counties contiguous to Davie County while TRC owns two dialysis facilities in Rowan County, which is contiguous to Davie County. With regard to providing dialysis patients access to an alternative provider, the proposal submitted by TRC is the more effective alternative.

Access by Underserved Groups

The following table compares access to Medicare and/or Medicaid recipients, as reported by TRC and WFU in Section VI.5 of their respective applications.

Payor Category	% of Total Patients		
	TRC	WFU	
Medicare	27.0%	17.0%	
Medicaid	2.7%	5.0%	
Medicare/Medicaid	67.6%	32.0%	
Medicare/Commercial		33.0%	
Medicare HMO		5.0%	
Total	97.3%	92:0%	

As shown in the above table, TRC proposes the highest percentage of patients to have some or all of their services paid for by Medicare or Medicaid. Therefore, the proposal submitted by TRC is the more effective alternative with regard to access by underserved groups.

Access to Support Services

In Section V of the application, the applicants are asked to identify the proposed providers of several support services including diagnostic evaluation, laboratory, blood bank, acute care, emergency care, and X-ray. With regard to accessibility to support services, the proposals submitted by TRC and WFU are equally effective alternatives.

Operating Costs and Revenues

In Section X of the application, each applicant projects revenues and operating costs for the first two operating years of the proposed project. The following tables compare operating costs and revenues.

Operating Costs

TRC	Year 1	Year 2
Projected Expenses	\$1,289,095	\$1,484,411
# of Dialysis Treatments	4,718	6,002
Average Cost per Treatment	\$273.23	\$247.32

WFU	Year I	Year 2
Projected Expenses	\$1,298,673	\$1,532,113
# of Dialysis Treatments	4,401	6,174
Average Cost per Treatment	\$295.09	\$248.16

As shown in the above table, TRC projects lower costs per treatment in each of the first two operating years.

Revenues

TRC	Year 1	Year 2
Patient Revenue	\$1,189,958	\$1,513,972
# of Dialysis Treatments	4,718	6,002
Net Revenue per Treatment	\$252.22	\$252,24

WFU	Year 1	Year 2
Net Patient Revenue	\$1,644,328	\$2,242,347
# of Dialysis Treatments	4,401	6,174
Net Revenue per Treatment	\$373.63	\$363.19

As shown in the above table, TRC projects lower revenue per treatment in each of the first two operating years. Therefore, the proposal submitted by TRC is the most effective alternative with regard to operating costs and revenues.

Charges to Insurers

TRC projected a charge of \$520.00 per treatment for commercial insurance companies. WFU projected a charge of \$706.80 per treatment for commercial insurance companies. Thus, the proposal submitted by TRC is the more effective proposal with regard to charges for commercial insurance companies.

Direct Care Staff Salaries

The following table compares annual salaries for the registered nurse and dialysis technician positions during the first year of operation, as reported by the applicants in Section VII.1 of their respective applications. Higher salaries enhance recruitment and retention of employees.

	TRC	WFU
RN & Home Training Nurse	\$52,000	\$52,474
Patient Care Technician (TRC) / Tech (WFU)	\$26,000	\$23,444

As shown in the above table, WFU projects the highest salary for registered nurses, but projects the lowest salary for technicians. TRC projects the highest salary for technicians, but projects the lowest salary for registered nurses. The two proposals are equally effective with regard to direct care salaries.

Quality of Care

WFU demonstrates that quality care has been provided in all of WFUHS' existing dialysis facilities. In contrast, TRC did not adequately demonstrate that quality care has been provided at Dialysis Care of Rowan County. See Criterion (20) for discussion. The Medical Director for Dialysis Care of Rowan County has agreed to serve as the Medical Director for the proposed facility. Therefore, with regard to provision of quality care in the past, the proposal submitted by WFU is the more effective alternative.

SUMMARY

The following is a summary of the reasons the proposal submitted by WFU is determined to be a more effective alternative than the proposal submitted by TRC.

• WFU demonstrates that quality care has been provided in all of WFUHS' existing dialysis facilities. See Criterion (20) for discussion.

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The following is a summary of the reasons the proposal submitted by TRC is determined to be a less effective alternative than the proposal submitted by WFU.

• TRC did not adequately demonstrate that quality care has been provided at Dialysis Care of Rowan County. See Criterion (20) for discussion.

Therefore, the proposal submitted by Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) materially comply with all representations made in their certificate of need application, except as specifically amended by the conditions of approval.
- 2. Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall construct plumbing and electrical wiring through the walls for no more than ten stations, which shall include any home hemodialysis and isolation stations.
- 3. Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing prior to issuance of the certificate of need.

Consequently, the proposal submitted by Total Renal Care of North Carolina, LLC d/b/a Davie County Dialysis Center to establish a new dialysis facility in Davie County is disapproved.

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming CA = Conditional NC = Nonconforming

NA = Not Applicable

DECISION DATE:

PROJECT ANALYST:

April 8, 2009 Paula Quirin

TEAM LEADER:

Martha J. Frisone

PROJECT I.D. NUMBER:

O-8252-08 / Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center/ Relocate 28 existing dialysis stations from Southeastern Dialysis Center-Wilmington to Cape Fear Dialysis Center, a new facility to be located in

Wilmington / New Hanover 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.

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Total Renal Care of North Carolina, LLC, proposes to relocate 28 existing dialysis stations from Southeastern Dialysis Center-Wilmington to establish Cape Fear Dialysis Center, which will also be located in Wilmington in New Hanover County. The applicant does not propose to develop new dialysis stations. Therefore, neither of the two need methodologies in the 2008 State Medical Facilities Plan (SMFP) is applicable to this review. However, Policies ESRD - 2 and GEN-3 are applicable to this review.

Policy ESRD-2 states:



2008 Davie County Competitive Dialysis Review

The following is a summary of the reasons the proposal submitted by TRC is determined to be a less effective alternative than the proposal submitted by WFU.

• TRC did not adequately demonstrate that quality care has been provided at Dialysis Care of Rowan County. See Criterion (20) for discussion.

Therefore, the proposal submitted by Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) materially comply with all representations made in their certificate of need application, except as specifically amended by the conditions of approval.
- 2. Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall construct plumbing and electrical wiring through the walls for no more than ten stations, which shall include any home hemodialysis and isolation stations.
- 3. Wake Forest University Health Sciences (lessor) and Davie Kidney Center of Wake Forest University d/b/a Davie Kidney Center (lessee) shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing prior to issuance of the certificate of need.

Consequently, the proposal submitted by Total Renal Care of North Carolina, LLC d/b/a Davie County Dialysis Center to establish a new dialysis facility in Davie County is disapproved.



"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:

- (A) demonstrate that the proposed shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and,
- (B) demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report."

The applicant proposes to relocate 28 existing certified dialysis stations within the host county, New Hanover County. Consequently, there is no change in the inventory of dialysis stations in New Hanover County and the application is conforming to Policy ESRD-2.

Policy Gen-3 states:

"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 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."

Promote Cost-Effective Approaches

In Section III.9, pages 21-22, the applicant describes how the proposal will promote cost-effectiveness as follows:

- "This application calls for the purchase of dialysis machines, chairs, and TVs (see section VIII of the application). The parent corporation, DaVita, operates over 1,400 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. We will be purchasing the equipment for this project under this procedure.
- The Cape Fear Dialysis Center will purchase all products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best possible price.
- The Cape Fear Dialysis Center will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national plan to get the best quality dialyzer for the best price.
- The Cape Fear Dialysis Center will install an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility will also be done on the computer which reduces the need for paper.
- The Cape fear Dialysis Center Bio-medical Technician assigned to the facility will conduct preventive maintenance on the dialysis machines on a monthly, quarterly and semiannual schedule that reduces the need for repair

maintenance and parts. This extends the life of the dialysis machines.

• The Cape fear Dialysis Center will have an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly."

The applicant adequately demonstrates the need for the proposed project. Therefore, the applicant demonstrates the project is a cost-effective approach. See Criterion (3) for discussion.

Expand Healthcare Services to the Medically Underserved

In Section VI.(a), page 29, the applicant describes how the proposal will expand healthcare services to the medically underserved, as follows:

"Cape Fear Dialysis Center, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

Cape Fear Dialysis Center will make every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Cape Fear Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need.

Cape Fear Dialysis Center will not require payment upon admissions to it services; therefore services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons." The applicant adequately demonstrates how the proposal will expand access to medically underserved groups. See also Criteria (3) and (13c) for additional discussion.

Encourage Quality Healthcare Services

In Section I.13, page 6, the applicant describes how the proposal will encourage quality as follows:

"The DaVita multidisciplinary care team works closely with our physicians to provide optimal care for our patients. In fact, DaVita has delivered patient outcomes well above national standards in terms of key dialysis metrics, URRs, Kt/V, hematocrits, and other clinical dialysis indicators. See Exhibit 4 for Clinical Outcomes Comparison Graphs.

DaVita utilizes the 'DaVita Quality Index', a unified measure of clinical performance for dialysis facilities. Seven individual clinical parameters have been weighted and combined in to a unified clinical metric. This simplified clinical scoring system allows for clinical differentiation among dialysis facilities... The intent is to evaluate overall clinical care and drive improvement to benefit the dialysis patient."

Additional information regarding quality care is provided in Exhibit 4. However, the applicant did not adequately demonstrate that it provided quality care in its existing Southeastern Dialysis Center-Wilmington facility, which will share the same Medical Director, Unit Administrator and Chief Executive Officer with the proposed facility. See Criterion (20) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal would ensure quality care. Consequently, the application is nonconforming to Policy Gen-3, and 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.

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The applicant, Total Renal Care of North Carolina, LLC, proposes to relocate 28 existing dialysis stations from Southeastern Dialysis Center-Wilmington to establish Cape Fear Dialysis Center, which will also be in New Hanover County. The applicant does not propose to develop new dialysis stations.

Population to be Served

In Section III.7, page 19, the applicant projects that 100% of the patients utilizing the proposed facility during the first two operating years will be residents of New Hanover County. In Section III.7, page 20, the applicant states that the anticipated travel distance for all patients from their homes to the proposed facility will be less than 30 miles. The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.3 page 17, the applicant states: "Total Renal Care of North Carolina proposes to relocate 28 dialysis stations and 90 patients from the Southeastern Dialysis Center in Wilmington to establish the 28-station Cape Fear Dialysis Center in New Hanover County. We feel this will improve the accessibility of services for the patients living in the identified zip codes." In Section III.3, page 18, the applicant states the stations to be relocated are needed at the proposed site as opposed to another area of county because: "Total Renal Care of North Carolina, LLC has analyzed the patient data and determined that there are at least 90 in-center patients living in New Hanover County in the zip codes that are closer to the Cape Fear Dialysis Center location. The Cape Fear facility will serve patients living in Wilmington and to the north of Wilmington in New Hanover County." In Section III.9, page 20, the applicant states: "Total Renal Care of North Carolina, LLC studied many possible alternatives to this application and has concluded that developing the Cape Fear Dialysis Center in the northern area of Wilmington is the best alternative. The Southeastern Dialysis Center - Wilmington is the largest facility operated by Total Renal Care in North Carolina. We feel it is too large to continue to meet the needs of the New

Hanover County patients as well as the needs of many patients living in northern Brunswick County and the far eastern end of Columbus County.

In Section III.7, page 20, the applicant states "Ninety six patients residing in zip codes 28401, 28405, 28429, and 28411 have signed letters of support for the Cape Fear Dialysis Center All of the patients have indicated in their letters that they live closer to the proposed Cape Fear facility or that the facility will be more convenient for them. We are anticipating that ninety of the patients receiving their treatments at the Southeastern Dialysis Center—Wilmington facility will transfer to the Cape Fear Dialysis Center."

In Section III.6, page 19 the applicant states that of the 96 patients writing letters in support of the proposed facility, "We would assume that 90 of those patients will transfer to the new facility."

In Section III.7, page 19, the applicant provides the following table summarizing the in-center and home patients projected to utilize the facility during the first two operating years.

COUNTY	Operating Year 1		Ope	rating Year 2	Percent	Patients as a of percent of OTAL
٠	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
New Hanover	95	0	97	0	100%	100%
TOTAL	95	0	97	0	100%	100%

The applicant assumes the number of in-center hemodialysis patients will increase 1.6% per year, which is the five year average annual change rate reported in the July 2008 Semiannual Dialysis Report. The following are the applicant's calculations, as reported in Section III.7, page 20:

"January 1, 2008 - December 31, 2008 - 90 patients X 1.016 = 91.4 patients

January 1, 2009 - December 31, 2009 - 91.4 patients X 1.016 = 92.8 patients

January 1, 2010 - December 31, 2010 - 92.8 patients X 1.016 = 94.2 patients

January 1, 2011 - December 31, 2011 - 94.2 patients X 1.016 = 95.7 [sic] Operating Year One

January 1, 2012 - December 31, 2012 - 95.7 patients X 1.016 = 97.2 [sic] Operating Year Two.

Thus, the applicant projects to serve 95 in-center hemodialysis patients in Year One, which is 3.4 patients per station. [95/28 = 3.39]. Further, the applicant projects to serve 97 in-center hemodialysis patients in Year Two, which is 3.46 patients per station. [97/28 = 3.46]. Projected utilization is reasonable based on historical growth rates. In summary, the applicant adequately identified the population to be served and demonstrated the need this population has for the proposed project. Therefore, the application is conforming to 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.

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The applicant proposes to relocate 28 existing stations from Southeastern Dialysis Center-Wilmington, which will leave 21 stations at Southeastern Dialysis Center-Wilmington. In section III.6, page 19, the applicant states:

"With 90 patients and 28 dialysis stations transferring from the Southeastern Dialysis Center - Wilmington to the Cape Fear Dialysis Center, this will leave 89 patients and 21 dialysis stations at the Southeastern Dialysis Center – Wilmington facility.

Once the transfer takes place the Southeastern Dialysis Center - Wilmington utilization rate will be at 106% if no stations are added to the existing facility. However, we have already determined that the Southeastern Dialysis Center - Wilmington the Facility Need qualifies under facility methodology for a 7 – station expansion. We plan to submit a Certificate of Need application to expand the Southeastern Dialysis Center - Wilmington facility by 7 stations on March 16, 2009. Therefore, the Southeastern Dialysis Center - Wilmington facility will have 28 dialysis stations upon certification of the Cape Fear Dialysis Center. The utilization rate of the facility will be 79%. Thus, the needs of the patients remaining at the Southeastern Dialysis Center - Wilmington facility will be adequately met and we will have planned for future growth of the facility."

The Southeastern Dialysis Center-Wilmington is currently certified for 49 stations and serves 179 in-center patients. Upon completion of this project, the facility will be certified for 28 stations and serve 89 in-center patients, which is a utilization rate of 3.18 in-center patients per station [89/28 = 3.18]. The applicant demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations, and 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.

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In Section II.9, page 20-21, the applicant describes the alternatives considered. However, the application is not conforming to all applicable statutory and regulatory review criteria. See Criteria (1), (18a) and (20). Therefore, the applicant did not adequately demonstrate that the proposal is its most effective alternative and the application is nonconforming to this criterion and is disapproved.

(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.

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In Section VIII.1, page 39, the applicant projects that the total capital cost of the project will be \$1,840,191, including:

- \$899,500 in construction costs;
- \$404,550 for dialysis machines;
- \$90,000 for water treatment equipment;
- \$272,611 for other equipment;
- \$107,500 engineering and architect fees; and
- \$66,030 for dialysis chairs, scales and televisions.

In Section IX.1, page 42, the applicant states that expected start-up expenses will be \$136,230 and initial operating expenses will be \$2,208,358 for a total working capital of \$2,344,588. In Exhibit 24, the applicant provides a letter signed by the Vice President and Controller of DaVita Inc., the ultimate parent of the applicant, which states "the project calls for a capital expenditure of \$1,840,190, start-up expenses of \$136,230, and a working capital requirement of \$2,208,358. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$4,184,779, for the capital expenditure, start-up expenses, and initial operating costs of this project, and that DaVita, Inc. will make these funds, along with any other funds that are necessary for the development and initial operation of the project, available to Total Renal Care of North Carolina, Inc." In Exhibit 25, the applicant provides audited consolidated financial statements for DaVita Inc. which show that, as of December 31, 2007, DaVita, Inc. had \$447,046,000 in cash and cash equivalents, \$6,943,960,000 in total assets, and \$1,732,250,000 in total shareholders equity (total assts less total liabilities). The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the project.

The rates in Section X.1, page 44, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. In the revenue and expense statement in Sections X.2, X.3, and X.4, pages 44 - 47, the applicant projects that revenues will exceed operating costs in each of the first two years of

operation. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Criterion (3) for discussion of reasonableness of projections. In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, 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.

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The applicant proposes to establish a new 28-station End Stage Renal Disease facility by relocating 28 existing dialysis stations from Southeastern Dialysis Center-Wilmington. The applicant adequately demonstrated the need for the proposal. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposed facility would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section VII.1, page 34, the applicant projects the following staffing for the proposed facility.

Position	Proposed Full Time Equivalent Positions
RN	4
PCT	10
Bio-Med	0.75
Tech	_
Med. Dir.	(Contract position)
Admin.	1
Dietitian	1
Social Worker	1
Unit Secretary	1
Reuse Tech	1.5



Nine direct care staff members are scheduled to be on duty during both shifts each day of operation. Exhibit 17 contains a letter from Derrick Robinson, M.D., stating he has agreed to serve as Medical Director for the new facility. The information provided in Section VII is reasonable and credible and supports a finding of conformity with this criterion.

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.

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In Section V.1, pages 25-28, the applicant identifies the providers of the necessary ancillary and support services. The information provided in Section V and referenced exhibits is reasonable and credible and supports a finding of conformity 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.

NA

- (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;



In Section VI.1(b), pages 29 - 30, the applicant reports that 85% of the patients served at Southeastern Dialysis Center-Wilmington had some or all of their services paid for by Medicare or Medicaid. Therefore, the applicant demonstrates that adequate access is provided to medically underserved groups, and 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;

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In Section VI.6(a), page 33, the applicant states: "There have been no civil rights equal access complaints filed within the last five years." The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

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In Section VI.(a), page 29, the applicant states: "The Cape Fear Dialysis Center will not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethic minorities, women, handicapped persons, elderly and other underserved persons."

In Section VI.1(c), page 20, the applicant projects that 84% of the patients to be served at Cape Fear Dialysis Center projected will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrated that medically underserved populations will 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.

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In Section VI.5, pages 32-33, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 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.

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In Section VI.5(d), page 33, the applicant states: "The Cape Fear Dialysis Center will work to develop a working relationship with the Cape Fear Community College. We have contacted them to let them know our intent to establish a second facility in Wilmington and have offered the facility as a clinical rotation site for their nursing students." Exhibit 16 contains a copy of a letter from the Director of Healthcare Planning for DaVita, Inc. to the President of Cape Fear Community College offering the proposed facility as a clinical training site for nursing students. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicant did not adequately demonstrate that the proposal would have a positive impact on the quality of the proposed dialysis services. See Criteria (1) and (20). Therefore, the application is nonconforming 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.

NC

The applicant currently provides dialysis services at Southeastern Dialysis Center-Wilmington. The current Medical Director at Southeastern Dialysis Center-Wilmington, Derrick Robinson, MD, has agreed to serve as the Medical Director for the proposed facility. Further, the applicant states that the Unit Administrator and Chief Executive Officer for Southeastern Dialysis Center-Wilmington will serve in those roles at the proposed facility. The files in the Acute and Home Care Licensure and Certification Section, DHSR, indicate that a survey conducted at Southeastern Dialysis Center-Wilmington on June 5, 2008 identified immediate jeopardy and failure to conform to Medicare conditions of participation. Therefore, the application is nonconforming 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.

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End

Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

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.2202 INFORMATION REQUIRED OF APPLICANTS

- (a) An applicant that proposes to increase stations in an existing certified facility or relocated stations must provide the following information:
 - .2202(a)(1) Utilization Rates;
 - -C- See Section III.7, page 19-20.
 - .2202(a)(2) Mortality rates;
 - -C- See Section IV.2, page 23.
 - .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;
 - -C- See Section IV.3, page 23.
 - .2202(a)(4) The number of transplants performed or referred;
 - -C- See Section IV.4, page 23.
 - .2202(a)(5) The number of patients currently on the transplant waiting list;
 - -C- See Section IV.5, page 24.
 - .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
 - -C- See Section IV.6, page 24.
 - .2202(a)(7) The number of patients with infectious disease, i.e. hepatitis and AIDS, and the number converted to infectious status during the last calendar year.
 - -C- See Section IV.7, page 24.
- (b) An applicant that proposed to increase the number of stations in an existing facility, establish a new dialysis station, or the relocation of existing dialysis stations must provide the information requested on the End Stage Renal Disease (ESRD) Treatment application form:
 - .2202(b)(1) For new facilities, a letter of intent to sign a written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.
 - -C- Exhibit 8 contains a letter of intent to sign a written agreement from New Hanover Regional Hospital.

- .2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must comply with 42 C.F.R., Section 405.2100.
 - (A) timeframe for initial assessment and evaluation of patients for transplantation,
 - (B) composition of the assessment/evaluation team at the transplant center,
 - (C) method for periodic re-evaluation,
 - (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
 - (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.
 - -C- Exhibit 9 contains a letter of intent to contract for renal transplantation services with Carolinas Medical Center.
- .2202(b)(3) Documentation of standing service from a power company and backup capabilities.
 - -C- See Section XI.6(f), page 52, and Exhibit 11.
- .2202(b)(4) For new facilities, the location of the site on which the services are to be operated. if such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.
 - -C- The applicant identifies a primary site and a secondary site in Section XI. On page 48, the applicant states it will lease the space for the proposed facility. Exhibit 27 contains a document signed by the applicant and the lessor indicating that 2 sites are available and an intent for the lessor to lease 11,000 square feet of space to the applicant for the proposed facility.
- .2202(b)(5) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.
 - -C- See Section II, pages 9-15, Section VII.1, pages 34-37, and Section XI.5, page 51.

- .2202(b)(6) The projected patient origin for the services. All assumptions, including the specific methodology by which patient origin is projected, must be clearly stated.
 - -C- See Section III.7, pages 19-21.
- .2202(b)(7) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.
 - -C- See Section III.7, page 20. The applicant states that "100% of patients will travel less than 30 miles for dialysis treatments."
- .2202(b)(8) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.
 - -C- In Section II.1 page 11, the applicant states: "Total Renal Care of North Carolina, LLC will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

.2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per week as of the end of the first operating year of the facility with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
 - -C- In Section III, page 8, the applicant projects that the proposed 28-station facility will serve 95 in-center patients by the end of the first operating year, for a utilization rate of 3.4 patients per station. [95/28 = 3.4]
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
 - -NA- The applicant does not propose to increase the number of dialysis stations in an existing facility.
- .2203(c) An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.
 - -C- See Section III.7, pages 17 20. The applicant provides all assumptions and the methodology used to project utilization

of the proposed facility.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- .2204(1) Diagnostic and evaluation services;
 -C- See Section V.1, page 25.
- .2204(2) Maintenance dialysis;
 - -C- See Section V.1, page 25.
- .2204(3) Accessible self-care training;
 - -C- See Section V.1, page 25.
- .2204(4) Accessible follow-up program for support of patients dialyzing at home;
 - -C- See Section V.1, page 25.
- .2204(5) X-ray services;
 - -C- See Section V.1, page 25.
- .2204(6) Laboratory services;
 - -C- See Section V.1, page 25.
- .2204(7) Blood bank services;
 - -C- See Section V.1, page 25.
- .2204(8) Emergency care;
 - -C- See Section V.1, page 25.
- .2204(9) Acute dialysis in an acute care setting;
 - -C- See Section V.1, page 25.
- .2204(10) Vascular surgery for dialysis treatment patients;
 - -C- See Section V.1, page 25.
- .2204(11) Transplantation services;
 - -C- See Section V.1, page 25.
- .2204(12) Vocational rehabilitation counseling and services;
 - -C- See Section V.1, page 25.
- .2204(13) Transportation
 - -C- See Section V.1, page 26.

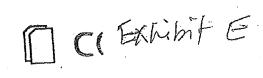
.2205 STAFFING AND STAFF TRAINING

- .2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.
 - -C- See Sections VII., pages 34-37.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- See Section VII.5, page 36, and Exhibit 22.





North Carolina Department of Health and Human Services Division of Health Service Regulation

Acute and Home Care Licensure and Certification Section

2712 Mail Service Center • Raleigh, North Carolina 27699-2701 http://www.ncdbhs.gov/dhsr/

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary Drexdal Pratt, Director

Azzie Y. Conley, Chief Phone: 919-855-4620 Fax: 919-715-8476

January 10, 2011

Charles Sheppard, Facility Administrator Charlotte East Dialysis 3204 Sharon Amity Road Charlotte, NC 28205

Re: Follow-up Survey

ESRD CMS Certification Number (CCN):34-2627

Dear Mr. Sheppard

Thank you for the cooperation and courtesy extended during my recent visit on December 21, 2010, for the purpose of conducting a follow up to the condition level deficiencies 494.180 Governance, 494.30 Infection Control and 494.60 Physical Environment that was cited during your Medicare recertification survey on October 1, 2010. It was determined that the condition level deficiency has been corrected, as well as the standard level deficiencies, and you are back in compliance with Medicare's Conditions of Coverage for End Stage Renal Disease facilities.

Should you have any questions or if this office can be of other assistance, please do not hesitate to call me at (919) 218-2638.

Sincerely,

Ralph Mills

Ralph Mills,RN,BSN
Facility Survey Consultant
Acute & Home Care Licensure & Certification

RECEIVED NOV 2 9 2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicate & Medicate Services
1301 Young Street, Room 833
Dallas, Texas 75202



Division of Survey and Certification, Region VI

November 15, 2010

CMS Certification Number (CCN): 342627

Charlotte East Dialysis 3204 Sharon Amily Charlotte, NC 28205

Dear Administrator:

The Centers for Medicare & Medicaid Services (CMS) has been notified your facility had a survey on October 26, 2010, and that while the immediate and serious threat to patient health and safety has been removed Charlotte East Dialysis remains out of compliance with the following Medicare Conditions for Coverage:

42 CFR 494.30 Infection Control
42 CFR 494.60 Physical Environment; and
42 CFR 494.180 Governance.

The date on which your hospital's Medicare agreement terminates is December 30, 2010. A listing of deficiencies for the October 26, 2010, survey is enclosed for your response. Note that the on-site visit of October 26, 2010 was conducted to determine whether or not the immediate jeopardy situation had been abated. Correction of the deficiencies not related to the immediate jeopardy was not assessed; these deficiencies are included in the attached report as cited on the resurvey and complaint investigation of October 1, 2010. You must submit a plan of correction to include corrective action dates no later than December 23, 2010, to ensure time for another revisit by the North Carolina Department of Health and Human Services prior to the termination date. Please submit these your plans of correction within 10 days of receipt of this letter to:

Azzic Conley
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center
Raleigh, North Carolina 27699-2712

An acceptable plan of correction must contain the following elements:

 The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited.

- 2. The procedure for implementing the acceptable plan of correction for the specific deficiency cited.
- The maintering procedure to ensure that the plan of correction is effective and that specific
 deficiency cited remains corrected and/or in compliance with the regulatory requirements.
- 4. The title of the person responsible for correcting the deficiency and/or for implementing the acceptable plan of correction.

Compliance with all Conditions for Coverage must be achieved at the time of this second revisit if termination is to be avoided. If the deficiencies have not been satisfactorily corrected at the time of this revisit, you can expect to receive a letter advising you of your termination and appeal rights. No further revisits will be authorized at that time. In addition, a legal notice will be placed in The Charlotta Observer in Charlotte, North Carolina advising the public of your termination from the Medicare program. Please be advised that, under Medicare, a provider is not entitled to a formal hearing before termination, but only after adverse action actually takes place.

If you have any questions concerning this action, please contact Glenda Payne at (214) 767-3350 or Rachel McCarty at (214) 767-2082.

Sincerely,

Ginger Odle, Manager

Non-Long Term Care Certification & Enforcement Branch

ce:

North Carolina Department of Health and Human Scrvices





North Carolina Department of Health and Human Services Division of Health Service Regulation Acute and Home Care Licensure and Certification Section

2712 Mail Service Center # Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr Drexdall Pratt, Division Director Azzie Y. Conley, Chief . Phone: 919-855-4620 Fax: 919-715-8476

** VIA FASCIMILE **

October 4, 2010

Charles Sheppard, Facility Administrator Charlotte East Dialysis 3204 Sharon Amity Charlotte, NC 28205

RE: Recertifiction Survey Immediate Jeopardy]

Dear Mr. Sheppard,

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the survey conducted September 22, 2010 through October 1, 2010. The purpose of conducting the complaint survey was to evaluate the Facility's compliance with the Federal Medicare Conditions for Coverage. The complaint investigation resulted in an Immediate Jeopardy (IJ) identification as of October 1, 2010 at 1130am as a result of survey findings from a Life Safety Code survey occuring on 09/30/2010.

Specifically, pursuant to 494.60 Physical Environment-Life Safety Code, the facility failed to have a fire alarm system or battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire.

As discussed during the survey, the information gathered was forwarded to the CMS Regional Office in Atlanta (Region IV). Our state agency is recommending 23 day termination due to noncompliance with the Conditions for Coverage: 494.60 Physical Environment, 494.30 Infection Control and 494.180 Governance. The Immediate Jeopardy is ongoing. CMS Regional Office in Dallas will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina: Ms. Glenda Payne

Division of Survey and Certification CMS Dallas Regional Office 1301 Young Street, Room 827 Dallas, Texas 75202 214-767-6301





Page two of two Charles Sheppard, Facility Administrator, CEO October 4, 2010

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Ralph Mills, R.BSN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief



North Carolina Department of Health and Human Services Division of Health Service Regulation Acute and Home Care Licensure and Certification Section

2712 Mail Service Center • Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr Drexdall Pratt, Division Director Azzie Y. Conley, Chief Phone: 919-855-4620 Fax: 919-715-8476

October 4, 2010

Charles Sheppard, Facility Administrator Charlotte East Dialysis 3204 Sharon Amity Charlotte, NC 28205

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Page two of two Charles Sheppard, Facility Administrator, CEO October 4, 2010

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Sincerely,

Ralph Mills, RaBSN
Facility Survey Consultant
Facility Survey Consultant Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief

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EPARTMENT OF HEALTH AND HUMAN SEPTICES

CENTERS FOR

DICARE & MEDICAID SERVICES

MEDICARE/M. CAID CERTIFICATION AND TRANSMITTA. PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

Facility ID: 001554

CAT REMARKS - CMS 1539 FORM

'ification survey was conducted onsite September 22-October 1, 2010. As a result of the survey in conjunction with a Life Safety Code survey, an immediate jeopardy (II) incarion survey was connucted onsite deptember 22-October 1, 2010. As a result of the survey in conjunction with a Late Safety cone survey, an immediate jeopardy (II) entified on October 1, 2010 at 1130. The II was no removed during the recertification survey. Condition level deficiencies were identified in 494.180 Governance, 494.30 was no removed change in 494.50 Reuse, 494.80 Patient Rights Infection Control and 494.60 Physician Environment, Standard level deficiencies were also identified in 494.40 Water and Dialysate Quality, 494.50 Reuse, 494.80 Patient Rights and 494.140 Personnel Qualifications. A plan of correction was requested.

An onsite follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the II at 1250 based on compliance with a fire alarm system in An onsite tohow up was committed at the facility October 20, 2010, the State Agency recommended removal of the 10 at 1200 based on compliance with a life alarm system in place. The CMS Dallas regional office was notified of the recommendation. The conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended to be in compliance based on the plan of correction not completed during follow up survey. (RM)

Another follow up survey was conducted December 21, 2010. The State Agency recommends that the condition level deficiencies in 494.30 Infection Control, 4894.60 Physical Environment and 494.180 Governance are back in compliance. No other deficiencies were found during the follow up survey.

epartment of Health and Human Services enters for Medicare & Medicaid Services

Form Approved OMB NO. 0938-0390

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Post-Certification	REVISIL	L/C NOT N
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(Y2) Multiple Construction 12/21/2010 Provider / Supplier / CLIA / A. Building Identification Number B. Wing Street Address, City, State, Zip Code 342627 3204 SHARON AMITY lame of Facility CHARLOTTE, NC 28205 CHARLOTTE EAST DIALYSIS

nis report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously ported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should provide the content of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should provide the content of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should provide the content of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should provide the corrective action was accomplished. Each deficiency should provide action was accomplished. Each deficiency should be content of the corrective action was accomplished. Each deficiency should be content of the corrective action was accomplished. Each deficiency should be content of the corrective action was accomplished. Each deficiency should be content of the correction of the corrective action was accomplished. equirement on the survey report form).

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D Prefix V0120	Correction Completed 12/21/2010	ID Prefi	x <u>\\0122</u> # 494.30(a)(4)(ii)	Com	ection pleted 1/2010	ID Prefix _ Reg. # 4 LSC _		Correction Completed 12/21/2010
LSC	Correction Completed 12/21/2010	ID Pre	fix V0340 .# 494.50(b)(1)	Co	rection npleted 21/2010	ID Prefix Reg. # LSC	494.60	Correction Completed 12/21/2010
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lepartment of Health and Human Services enters for Medicare & Medicaid Services

Form Approved OMB NO. 0938-0390

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his report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously sported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number end the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each equirement on the survey report form),

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SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

uba. Porting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, acarching existing data sources, gathering and natural particular and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information. Including a legislation for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction reject(0838-0583), Washington, D.C. 20503.

Provider/Supplier Number	Provider/Supplier Name CHARLOTTE EAST DIALYSIS	
342627 Type of Survey (select all that apply) I D	A Complaint Investigation E Initial Certification I Recertification B Dumping Investigation F Inspection of Care J Sanctions/Hearing C Federal Monitoring G Validation K State License D Follow-up Visit H Life Safety Code L CHOW M Other	
Extent of Survey (select all that apply)	A Routine/Standard Survey (all providers/suppliers) B Extended Survey (HHA or Long Term Care Facility) C Partial Extended Survey (HHA) D Other Survey	

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

	Please	e enter the worklo	ad information for	r each surveyor.		iemnezaoù nambe	77	Off-Site Report
nveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Preparation Hours (I)
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Total SA Supervisory Review Hours.....

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Total SA Clerical/Data Entry Hours....

0.50

EventID: WB3113

Total RO Clerical/Data Entry Hours.....

0.00

was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

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Provider/Supplier Number 342627	Provider/Supplier Name CHARLOTTE EAST DIALYSIS
Type of Survey (select all that apply)	A Complaint Investigation E Initial Certification I Recertification B Dumping Investigation F Inspection of Care J Sanctions/Hearing C Federal Monitoring G Validation K State License D Follow-up Visit H Life Safety Code L CHOW M Other
Extent of Survey (select all that apply)	A Routine/Standard Survey (all providers/suppliers) B Extended Survey (HHA or Long Terin Care Facility) C Partial Extended Survey (HHA) D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	12/21/2010	12/21/2010	1.00	0.00	3.00	0.00	5,00	2.00
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14.					Total RO	Supervisory Revi	ew Hours	0.00

Total SA Supervisory Review Hours....

1.00

Total SA Clerical/Data Entry Hours....

0.50

Total RO Clerical/Data Entry Hours.....

0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

Page

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PRINTED: 11/16/2010 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED CENTERS FOR MEDICARE & MEDICAID SERVICES DMB NO. 0838-0381 RECOGNIZACIONE DE DESCRIPTOR (XT) PROVIDENSUPPLIERCHA (KZ) IĄ ILTIPLE CIENSTPILIOTION (X3) DATE SURVEY AND PLATE OF CORRECTION IDENTIFICATION NUMBER: COMPLETED a. Guilding B. WW 347827 10/20/2010 NAME OF PROVIDER OR BUPPLIER STREET ADDRESS, CITY, STATE, 21P CODE year sharon analy CHARLOTTE EAST DIALYSIS CHARLOTTE, NC 20200 SLAGARY STATEMENT OF DEFICIENCIES
(BACH DEFICIENCY AUST BE PRECEDED BY FLAL PROMOCRE PLAN OF CORRECTION TEACH CORRECTIVE ACTION BHOULD BE (X4) ID PREPX TAG COUNTRINON PREFIX recleatory or lec rentifying information CROSS-HERENCED TO THE APPROPRIATE TAG DEPICIENCY V000-(V 000) INITIAL COMMENTS V 000 Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of An oneite follow up was conducted at the facility Correction (POC). The standards under the Oplober 26, 2010. The State Agency Conditions of Infection Control (V110); recommended removal of the U at 1250 based on Physical Environment (V400); and compliance with a fire clarm eyelum in place. The Governance (V750 that are not met as well as CMB Dallas regional office was notified of the other standards, contain specifics of recommendation. The conditions in 494.30 corrective plans. The facility will ensure that Infection Control, 494.50 Physical Environment the GB provides oversight and has systems in and 494,180 Governmoz were not recommended place to see that the facility is equipped and to be in compilance based on the plan of maintained to provide a safe, functional and comfortable environment and an effective correction not completed during follow up survey. infection control program is in place. The (V 110) 494.30 CFC-INFECTION CONTROL (V 11p) facility has been diligently working on correcting all the issues cited since the survey. The fire alarm was installed as required. The physical plant issues will This CONDITION is not mat as syldenced by: require more time as they are also dependent Not reviewed onelte on 10/26/2010. upon pennits and vendor availability as well the fact that much of the work will have to be Based on facility policy ravisw, observations, completed during non-operational hours. These issues have been evaluated by an refrigerator temperature top review and staff architect and a plan to move forward is in interviews, it was determined that the facility falled place. Estimated time frame to complete is to implament and maintain an effective infection 9-12 weeks. We request your consideration control program. The facility falled to ensure that in these particular issues. a clean area was designated to prevent potential cross-contamination of medicational supplies and The Governing Body will meet monthly x 3 for staff to prepare, handle and store medications or more often as required to ensure to be administered to patients; falled to change compliance with POC. Further compliance and inspect contaminated external transducer to the POC will be reviewed during monthly protectors in 2 of 2 observed patients with wet or QA meetings and reported to the Governing blood tinged external transducer protectors, failed Body no less than semi-annually. The to ensure that siaff implemented standard Facility administrator (FA) representing the infection control precautions by cleaning GB will be responsible for ensuring implementation and ongoing compliance equipment surfaces with removal of trash from floors in the patient treatment area, appropriate with this POC. cleaning and disinfacting of vascular clamps used

Any descency statement entiry with an assented (7 descence a descency which we inclinion may be accounted from correcting providing it is determined that other sateglastes provide sufficient projection to the pations. (See instructions.) Except for costing frugue, the findings stated above the disciplinion of the pations. (See instructions.) Except for costing frugue, the findings stated above the disciplinion of the disciplinion and the disciplinion of the disc

in patient treatments and cleaning blood stains from work surfaces during patient hemodisiye's treatments; falled to ensure that patient used dialyzers were adequately refrigerated to inhibit theory. The provincing provi

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DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICARD SERVICES PRINTED: 11/15/2010 FORM AFFROYED OMB NO. 0938-0381

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(V 170)	bacterial growth baft to ensure that patient to atment and towels evaluable at a patient towels evaluable at a patient to extremit and these systemic problems in these systemic problems. The findings include A. The facility follows designated to proper contemination for staff to prepare, to be administrated — Cross refer to 49. The facility staff conteminated extended by the external transduces—Cross refer to 49. The facility staff conteminated extended by the external transduces—Cross refer to 48. The facility falls implemented start procautions by clean procautions by clean procautions by clean procautions by clean procautions and clean procautions and clean transcript and clean cannot be called a surfaces during p	one reprocessing, and falled the hald a supply of paper randwasthing sinks in the sea. The cumulative effect of deme resulted in the facility's in provision of quality infection districts patients. If the ensure that a clean area crownt potential in the districtions supplies and handle and store medicalions to patients. If SU(a)(1)(1) Infection Control to patients. If alled to change and inspect may transducer protectors in 2 onts with well or blood linged.	₹	110)	Members of the Governing Body (met to review the Statement of Def (SOD) and formulate the following Correction (POC). The standards Conditions of Infection Control (V Physical Environment (V400); and (V750 that are not met as well as a standards, contain specifics of correction (Valon); and (V750 that are not met as well as a standards, contain specifics of corrections of the facility will ensure that the Governight and has systems in place the facility is equipped and maintain provide a safe, functional and concentronment. Eliminated the use medication cart and the medication been relocated. A designated observated for medication prep on orisland nurse stations in the treatm 09/29/10. A plan is place to instabarriers 12" in height around the prep area to further designate this clean area. Plexiglas barriers we to prevent potential cross contain The Clinical Services Specialist serviced the teammates on polic "Changing Transducers Protect 10/07/2010 with emphasis on the change and inspect wet and/or the contaminated external transduce. Administrator or designee will everyday for 3 days, weekly on weeks, and then this will be incontily infection control and it The CSS in-serviced the teamn 1-04-08 "Utilizing Vascular A and policy 1-05-01 "Infection Dialysis Facilities" on 10/1/20 emphasis on the need for apprand disinfecting of vascular of Administrator or designee will everyday for 3 days, weekly o weeks, and then this will be in monthly infection control and cont pg 3	receives y Plan of under the (110); il Governance other receive plans. B provides to see that ained to infortable of a on station has an area was an of the nent area ill separation medication is space as a will be placed nination. (CSS) into y #1-03-11 out? on the need to olood ers. Facility monitor team is agoing forward nates on policy coess Clamps. Control for 10 with opriate cleaning amps. Facility Il monitor team in each shift. Il monitor team is no policy coess Clamps. The control for the printer cleaning amps. Facility Il monitor team in each shift. Il monitor team is no each shift and in the printer cleaning amps. Facility Il monitor team in each shift and in the printer cleaning amps. Facility Il monitor team in each shift and in the printer cleaning amps. Facility Il monitor team in each shift and in the printer cleaning amps. Facility Il monitor team in each shift and in the printer cleaning amps. Facility Il monitor team in each shift and in the printer cleaning amps. Facility Il monitor team in the printer cleaning amps. Facility Il monitor team in the printer cleaning amps. Facility Il monitor team in the printer cleaning amps. Facility Il monitor team in the printer cleaning amps.	QJ

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Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks and then this will be each shift x 3 weeks and then this will be included in monthly infection control audit going forward. Results of audit will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. Further remaining Body will meet mouthly x 3 to ensure compliance with POC. Further remaining Body on less than remi- hard a supply of paper towels available at insurious findings include: A review of the facility's policy "infection Control The findings include: A review of the facility's policy "infection Control Tag Votte. The governing Body on less than remi- annually. The Facility administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. The Governing Body will meet mouthly x 3 to ensure compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than remi- annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	DEPARTME	nt of Health An	ID HUMAN SERVICES				DWB NO. 0	PROVED 938-0391_
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Continued From page 2 O. The facility failed to crisure that patient used disjects were adequately refrigerabled to inhibit beneficial growth before reprocessing. -Cross refer to 494.40(b)(1) Reture of Humodistyrars and Boodines - Tag V0331 E. The facility failed to more than any maintain indigerator temperatures to inhibit plantials indigerator temperatures to inhibit potential indicated growth in stereor reprocessand (reuse) dislipycars. -Cross refer to 494.60(b) Physical Environipositing V0403 F. The facility failed to more that patients had a supply of paper towels reveilable at handwashing tinks in the patient treatment area. -Cross refer to 494.30(a)(1)(b) Infaction Control-Tag V0140. A sufficient number of sinks with warm water and sonp should be available to facilitate hand washing. This ETANDARD is not met as syldenced by: No reviewed onable on 10/26/2014. Based on facility paley roview, observations and staff interview, he facility tailed to ensure that patients that insufficient control and the patient treatment that patients had a stupply of paper towels available at handwashing tinks in the patient treatment area. -Cross refer to 494.30(a)(1)(b) Infaction Control-Tag V0140. A sufficient number of sinks with warm water and sonp should be available to facilitate hand washing. This ETANDARD is not met as syldenced by: No reviewed onable on 10/26/2014. Based on facility paley roview, observations and staff interview, the facility tailed to ensure that patients that patients that patients that patients are also ply of paper towers available at handwashing almost in the patient treatment that patients and the patient treatment that patients are also placed by the patient treatment that patients are also placed by the patient treatment that patients are also placed by the patient treatment that patients are also placed by the patient treatment that patients are also placed by the patient treatment that patients are also placed by the patient treatment that patients are also placed by the			Language of the second		\$21	H RHARON ARTY		
D. The facility failed to cristura that patient used dialyzets were adequately refrigerabled to inhibit becterial growth before reprocessing. -Cross refer to 494.60(b)(1) Retarts of Hamodialyzets and Bloodines - Tag V0331 E. The facility failed to monitor and maintain prifingation temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) clinityzets. -Cross refer to 494.60(b) Physical Emirotiment-Teg V0403 F. The facility failed to monitor and maintain prifingation temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) clinityzets. -Cross refer to 494.60(b) Physical Emirotiment-Teg V0403 F. The facility failed to ansure that patients had a supply of paper towels available at handwashing clinks in the patient number of sinks with warm water and samp should be available to facilitate hand washing. This STANDARD is not met as evidenced by: No reviewed organity policy review, observables available at handwashing attributed in a supply of paper towels available at handwashing attributed in patients and control audit policy review, observable in the patient in the patient hand a supply of paper towels available at handwashing attributed in a supply of paper towels available at handwashing attributed in monthly infection control audit going forward. [V 114] A sufficient number of sinks with warm water and samp should be available to facilitate hand washing. This STANDARD is not met as evidenced by: No reviewed organity policy review, observable and addressed as necessity improvement Management Meetings (QFAM) and addressed as necessity improvement Management Meetings (QFAM) and addressed as necessity improvement manually. The Facility administrator (FA) representing the GB will be responsible for casuring implementation and ongoing compliance with this FOC. The Governing Body unless than semi-namually. The Facility administrator (FA) representing the GB will be responsible for casuring implementation and ongoing compliance with this FOC.	(XQ ID PREFIX TAG	CACH DEFICIENC	Y MUST BE PRECEDED BY MULL	PRE	TX	IEACH CORRECTIVE ACTION SH CROSS REFERENCED TO THE AFT	iction Dilld BE Ropriate	HOTTE FOLGO BING
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		VD HUMAN SERVICES MEDICAID GERVICES				FORM	11/15/2010 PPROVED 0931-0391
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(V 114)	for Dialysis Facilities" (revision data 03/2010) revealed "The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination must be available at each sink." Observation on 03/23/2010 of 1300 in the patient treatment area revealed that a paper towel dispenser located for the patients to wash their access sites at the exit area had no ovaliable paper towels for use after hendwashing. The chastration revealed that the paper towels were located in a machine with a cancer to dispense the towels. After weathry france was observed by a patient and surveyor, it was noted that the sansor was too working and no paper towels were available.		₹	114	Paper towels in the dispenser we replaced and threaded properly, towel dispenser at patient prep a battery powered hands free style dispenser. The dispenser was fo inoperative. Replaced batteries verified operation 10/14/10. Fa Administrator or designee will team everyday for 3 days, weekshift x 3 weeks, and then this wincluded in monthly infection of going forward. Results of audit reviewed in Quality Improvem Management Meetings(QIFM) addressed as necessary. FA is for ongoing compliance with it	rea is a mond to be and cility monitor dy on each fill be control audit s will be cent M) and responsible	10/18/10.
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₹V 120)	personnel open the completed and check includes inspection contemination of the and pressure sensitive and distintent service and distintent to brack (200-800 commercially available to the production of the analysis of the	machine efter the bealment is ix for contamination. This		120}	V120 The Clinical Services Specialist	(C22) in-	
	This STANDARD Not reviewed one staff interview, the and inspect control protectors in 2 of disjusts machines blood singed executions. The findings inches a review of the findings inches realized "Extern the state of the secution of the state of the secution of the secu	patients. le not met as evidenced by: the on 10/28/2010. policy review, observations and a facility staff falled to change aminated external transducer 2 observed patients whose a were observed to have well or onal transducer profectors #1,11).			The Chinical Services Specialists serviced the tearmates on polising Transducers Protect 10/07/2010 with emphasis on the change and inspect the externation for the presence of blood or sale of the presence of blood or sale external transducer protector in replaced whenever blood or sale observed in contact with the part of the transducer protector. Facility Administrator or designee will team everyday for 3 days, we shift, and then this will be into monthly infection control and forward. Results of audits will be used in Quality Improvement Man Meetings (QIFMM) and add necessary. FA is responsible compliance with POC.	cy #1-0-11 ors" on he need to handucers line every ment. The hine is laine is laine is laine is laine is laine of lifty I monitor ekly on each luded in lift going Il beir reviewed lagement ressed as	10-7-10

	PETCHENCIES	A MEDICAID SERVICES [X1] PROVIDENSIPPLERICIA [DENTIFICATION NUMBER:	4'	LDN3	ONETRUCTION	COMPLE	
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	der oksupplier Baet plalysis			12141	address, city, state, sip code Bhasion amity Rlotte, NC 28205		
CAN ID REPIX TAG	<i>REACH DEFIC</i>	A CH FRC INDAMIANO INCOMPAJIONI MENCA PARE DE ENSCÉDEO EN LAT LA ELYLEPTEM DE DENCIENCIED	PRE	MX G	PROMOER'S PLANOF CORRE (EACH CORRECTIVE ACTION SH CROSS PREFERENCED TO THE API DEFICIENCY)	ollo be	BLPS FULL Exp Exp
/ 120) C	Continued From	page 8	9	120)			
1	rallem in station mailem at catema enimanne de ca 1610 thought 1610	in 09/22/2010 of 1608 for the PT during four revealed the Ill manaducer protector was noted ted with blood. Chair valion at 145 revealed that no staff member anged the transducer protector.					
1	patent in stello patient's extern to be contenion 1610 through 1	on 0012212010 at 1810 for the nail of the self of the					
	facility's regists area revealed bloody transdu	on 09/22/2010 at 1650 with the condition in the patient realment that the staff should change the cons and chark the back of the machine is not					
(V 122)	staff on D3/22/ transducer pro changed and bloody. 494.30Xs14Y/	with the facility's administrative 2010 at 1865 revealed that the obscious should be immediately chacked by staff when they become in IC-DISINFECT COLIPARTITEN PROTOCOL		(V 122)			
	The facility in standard inferior implementing (4) And maint with applicab public health (ii) Ctention	uci demonstrate that it follows	d				

DEPARTMENT OF HEA	LTH AF	id Human Services	•	. :			11/18/2010 \PPROVED 0938-0391
CENTERS FOR MEDIC STATEMENT OF DEFICIENCES AND PLAN OF DOWNEOTION	HHE A	(XI) PROVIDENGUPPLERICUA IDENTRICATION NUMBER:	ł	antypyf Indho	CONSTRUCTION	(XX) DATE SURV COMPLETED	'
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NAME OF PROVIDER OR SUPP	JER			STREE	et aodresa, city, etate, zip code 14 eharon avity		
DHARLOTTÉ EAST DIAL	制料				LARLOTTE, NC 29205	a and a second	·
With the state of	BUITER	atement of deficiencies Ly Must be preceded by Fucl Leo Dentipying Information)	PR	d LFIX AG	PROVIDENTS PLAN OF CORRECT EACH CORRECTIVE ACTION BHOW OROSE-FEFERENCED TO THE APPR OROSE-FEFERENCED TO THE APPR OROSE-FEFERENCED TO THE APPR OROSE-FEFERENCED TO THE APPROVINCED TO THE	1086	DVAY COMPATION COMPATION
(V 122) Continued F	txh pa(e 9	1	/ 122)	• · · · · · · · · · · · · · · · · · · ·		
Not reviewed the pattern of the capture of the pattern of the patt	I one tide I one	ind met as evidenced by: on 10/20/2010. Illoy review, observations and actiny failed to ensure that tendend infection control ring equipment surfaces with milions in the patient and actiny failed to ensure that tendend infection control ring equipment surfaces with milions in the patient and place the patient and place the patient in the model yellow the patient and the epitophate of sherps conteiners and the epitophate elronglin after adured, after spills of blood, y, and efter each beatment. Any act with visible blood or body a promptly with a well wrung cut is total of stx (6) such beath puge and dielycete powder (white in a total of stx (6) such beath puge and dues noted on the cut. To 09/22/2010 at 1013 in the man dues noted on the cut. To 09/22/2010 at 1013 in the one acceptable of at 1605 teverled populs) scattered on the cut. To 09/22/2010 at 1605 teverled on mar patient stations #4 and a further revealed times trash in trestment area that were full in the interestment area that were full in trestment area that were full in the interestment area that were full interestment area that were full in the interestment area that were full interestment are			The CSS in-serviced the team on importance of maintaining a clea environment and ensuring trash; up from the floor and blood stain blood stains are cleaned when the Caris will be replaced by 10/15/removed the existing soap disperson mounting brackets and replaced disposable bottle-type dispense. The CSS in-serviced the teams policy 1-04-08 "Utilizing Vasc Clamps" and policy 1-05-01 "I Control for Dialysis Facilities" 10/1/2010 with emphasis on the appropriate cleaning and distinguished the control for Dialysis Facility Adm designee will monitor team even days, weekly on each shift x3 then this will be included in minfection control audit going I Results of audits will be revied Quality Improvement Manage Meetings(QIFMM) and addressessary. FA is responsible compliance with POC.	is picked is and ity occur. 2010; insers and with is, insers and with is, insers on ular Access infection on ie need for fecting of inistrator or eryday for 3 weeks, and nonthly forward weed in ement issed as	10-15-10

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		ID HUMAN SERVICES MEDICAID SERVICES		**		FOR	D: 11/18/2010 N APPROVED D. 0038-0391
STATEMENT	COUNTENT OF DELICE NOTES	(X1) PROVIDER/SLIPPLIER/CLIA IDENTIFICATION NUMBER:	W DRING	oing Fabre C	(X3) date su comple	· (報)	
l be street Miller		342227	a. Vane) 	Alde and the second sec	301	R 16/2010
Ī	EDVIDER OK BURPLIER TTE ELAST DIALYSIS			1204	ADDRESS, CITY, STATE, ZIP CÓDE BHARCH AMETY PLOTTÉ, NG 28205	•	
LVE LHELIX (Xe) ID	(EACH DEPOSENC	ATEMENT OF DETICIENCIES Y MAIST BE PRECEDED BY FULL THE COMMENT OF DETICIENCIES	ID PREFI TAG	x	MOVIDER'S PLAYOF CO BACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEPICIENCY)	BHOLA.O BE	DONE TO CONTRACT OF CONTRACT O
(V 122)	Confinued From pag and overflowing with		₹V 1	22) .		-	
	that two automated (dispensers in the far handwashing winks of caked mated buildup	ility's service area at insignated as dean had observed directly under the rved evidence of cleaning the					
	09/22/2010 revealed free from cluder and supplies. The infant tresh should be close	e facility administrator on I that the cree epould remain diffy bulkup eround ow also revealed that the med up by the stall. No to why the areas were not				,	
	patient insument an ciamps used for pat were located in a co dicinfectant and has clamp heads. The c	9/22/2010 at 1020 in the se reversed that vascular scores sites chains of 1:100 bloach of the chains of the chains of the chains and the chains of the chain		And the state of t		•	
	09/22/2010 at 1215	e facility administrator on revealed that the damps I level of fileson solution villy policy,		-			
	patient treament a selde the needle si treite set seldet arew tricks boold	19/22/2010 at 1015 in Eus tra revealed blood stains on namps container located directly salyaing in station #16. The ocaled on top of the sharps E Arrough 1155 without staff			•		

observed to clean the stains.

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		ND HUMAN SERVICES		i	FOR	M APPROVED
STATEMENT	3 FOR MEDICARE & IT DEFICIENCES CORRECTION	MEDICAID SERVICES (XI) PROMPERSUPPUDENCIA DENTIFICATION MANIER:	1'''	HE CONSTRUCTION	(X3) DATE SI. COMPLE	
1100 T = 0000	***************************************	907837	A BUILDING	paperature property and the second	.	R 26/2010
	OVIDER OR SUPPLIER	aran ang agastapatitista ang aran anan agastapatitista ang at	1	neet addrees, city, syaye, zip code 204 shardh abaty	NEW TOWNS THE PARTY OF THE PART	4970
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(V 122)	Confinued From pag	x 11	(V 122)			
(V 186)	D9/22/2010 at 1210 a should be deaned w possible.	facility administrator on evented that the blood stains then they occur or econ as ADSORP-MONITOR, TEST	(V 195)			
	Testing for free chlor chlorine should be p each treatment day treatment and again petient whit. If there	tion: monitoring, jesting freq ine, cirloramine, or total erformed at the beginning of prior to patients initiating prior to the beginning of each are no set patient shifts, riormed approximately every		:		
		g of free chionne, chicramina, uid be recorded in a log				
	chlorine can be about N.N-dieftyl-p-pheny test kite or dip-end-monitore can be use concentrations. Why must have sufficient resolve the maximu 4.1.1 (Table 1) [whitreght, Bamples should be been operating for energysts should be obtorown to term part assessed promp not assessed promp	-				
1	This STANDARD I	s not mat as evidenced by: on 10/26/2010.				ļ

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DEPART	MENT OF HEALTH AN	ID HUMAN SERVICES				FORM A	11/16/2010 APPROVED 0838-0391_
CENTER	18 FOR MEDICARE &	VEDICAID SERVICES [V1] PROMODENDE PROBROLIA	OCS M	X.TIPLE	CONSTRUCTION	VILLE BLACK COX	EA .
Statement And Plan C	of Demouncher Correction	DENTIFICATION NUMBER:	ABU			COMPLETED	ļ
(Barrello de			B. WIN			Ř	1
		302527	R' MIN	Liberton	please of the second	10/28	2016
NAME OF F	ROVICER OR SUPPLIER	. '	,	STREET	et address, city, state, of occe		
					4 SHARON ARLYY		
CHARLO	DALE RYBL DIYLARIZ	A company of the second strick delication	angereep-weep-bab-bab-bab-bab-bab-bab-bab-bab-bab-ba	CH	MALOTTE, NO 20105	ALTERA	000
(X4) (D FREFIX TAG	mer ann a puri Merentia. W	FRO (DENTIFICADED BY MAIL TANGET BE FREGEDED BY MAIL FATEMENT OF DEFICIENCIES	cii Errq VAY	PIX	PROVIDERS PLANT OF CORRECT (EACH DORRECTIVE ACTION SHOW CROSS-REFERENCE) TO THE APPR DEFICIENCY)	JE STORE I	EXTREMESOR BYTAS
ler v)	Continued From pag	pe 12	ίΛ	185}			
	chlorine tosting log facility falled to ensiste the fortist that feat machine that test members had been a daily basis processed of children for the findings included a review of the facility basis processed on a daily basis processed on the completed. A review on 09/22 Total Chlorine tosting a revealed that the chooks and 1740. The residual of documented Chilometer for the revealed that the revealed tha	cility's policy "Daily Water nittle Monitoring" (revision data "Total Chilorine teating is dorse for to the first patient treatment house and all activities that year quality water one around the first patient water one around the first patient water one around the first patient to document way a house. The review portace of 0.540, 0.540, 1.345 when teating at 0.500, 0.540, 1.345 when teating at 0.500, 0.540, 1.345 one a time of 0.945 on the log but of any results, initials or a Chilorine leading. The review of 0.945 teating of Chilorine water of 0.945 teating of Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 on the log but of 0.945 teating for Chilorine water of 0.945 teating for 0.94			V196- The CSS in-serviced the teamma importance of completing the witotal chlorine monitoring every policy 2-07-04 "Daily Water To Chlorine Monitoring" and document on the appropriate log. FA/desibe checked daily for 7 days the on going. Color blindness testif completed on the 2 RN's cited found that they did have testing are in teammates files. Color b testing will be done on all new annually there after. Facility A will spot check 25% of teammonthly for 3 months and annuafter. Results of audits will be Quality Improvement Manage Meetings (QIFMM) and addrancessary. FA is responsible compliance with POC.	ater system 4 hours per stal amenting ignee will a weekly ng was and it was g and results lindness hires and dministrator nates file mully there areviewed in ement essed as	10-18-10

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		nd Human Bervices Medicaid Services					M APPROVED O. 0938-0391
STATEMENT C	covisioned the Debiciencies	CAL) PROVIDENCE PARENCE A IDENTIFICATION NUMBER:	1''''	LEXNE	ECCHSTRUCTION	(X3) DATE BI COMPLE	TED
		342827	Jr. VAI	Ø		10	R 20/2010
	OVIDER OR SUPPLIER	·			et address, city, state, 21p code		- Adams Abroham
CHARLOT	TE EAST DIALYSIS	1		CI	HARLOTTE, NO 20205		populari de la composição
(XI) ID PREFIX TAG	(EACH DISTRIBUTION	ATEXIENT OF PRECEDED BY PULL 14 MUST BE PRECEDED BY PULL LEO EDENTIFYING INFORMATION)	PREI TA	FDX]	PROVIDERS PLAN OF CORRES PAR PORTOS PROSPERS POR THE APPR CROSS PROPERS POR TO THE APPR DEPORTOS	UL5 解	DYLE OCHLEDS) NO
(V 1 9 5)	Continued From pag record.	6 13	Įγ	196)			
	Bysism Total Chlork 09/2010) revealed the 09/2010) revealed the "Lamona StAWY Te chlorine teating in the abo revealed that the "Hobling the Octa-S light enters the back test tube color stance read the ppor value that matches color 1. A review of the nurse the octa- registered nurse dis system for total chil review revealed the	iy's policy "Dally Water he Monitoring" (revision date hat the facility usex the het Kit Colorimeter's for the het water system. The policy he stell instructions include hide Viewer extent match the contine compension. Match the contine Octa-Side and on the Octa-Side and on the local-Side and of the test tube eample." Addity's personnel file for stell color revealed that the itent is the facility's water when needed. The of the registered ruses falled to led color blindness testing					
	runse #3 on 09/29/ registered runse di system for folial chi review revenied th	actify's personnel file for staff 2010 revealed that the disertine facility's water often which needed. The at the registered nurse falled to that color blindness testing					
	facility ediministrati numen did not hav blindrens tasting it interview revealed numera did not hav interview also reve check the water so	OBJESTADIO as 14(th with the or revealed that these staff of any denomented color interpretation of the The more sean as to why these staff e any testing done. The call these number do staff of chicken and should stiff to enque that each number		٠			

DEPARTA	MENT OF HEALTH AN	: ID HUMAN SERVICES VEDICAID SERVICES			the state of the s	CHENO	PPROVED 1838-0391
	r Diriciencies	DAI PROVIDENTE PLEAGUA DEMTHICATION HUMBER	(XZ) MI		сонятнистюн	COMPLETED R	÷7
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ì	CYUURI CR SUMPLER TE BABT DIALYSIS		Series - A (Series construction	370	et address, city, state, zip code III sharch abity Larlotte, no. 20206		·
PRETIX TAG	(FACH DEFICIENC	Vietoval of Deuglynghe Vietoval of Deuglynghe Vietoval of Deuglynghe	qi EERS N.T.	אוי	PRECADER'S PLAN OF COHRECT (EACH CORRECTIVE ACTION SHOU CROSS-REPERENCED TO THE APPR DEHCIENCY)	ND BE	PALE CONTACTION (272)
(V 198)	Continued From pay		\$V	198)			
(ree v)	can read the color in 494.60(b)(1) REPROCESSING-1 HANDLING	ransportation &	(v	331)	· · · · · · · · · · · · · · · · · · ·		
	transportation shall manner meintensim the dislyzer is dish externally. To inhib first cannot be reproduced the reproduction and prolonged delays in the recommend and documented in the recommend and documented in this STANDARO Not reviewed ontaining tension tempor interview, the fact created dislyzers we inhibit bacterial of the findings included the finding included the processed with designated reuse dislyzers must be reproduced to the province of the processed with the province of the province of the province of the province of the processed with the province of th	and dialyzers during do so in a clean and assitury istanciand Precautions until lected both internally and indicated both internally and indicated both internally and indicated by the responsible party. In ol allowed to freeze. Other handling issues (such as in reprocessing) not described an reprocessing) not described and practice shall be validated by the responsible party. In not mat as evidenced by; is not mat as evidenced by; is not mat as evidenced by; is not 10/26/2010. Indicy review, observation, return log review and shall lift failed to maure that patient it adequately refrigerated to both before reprocessing. de: chilly policy "Reuse of Dialyzers" 2009) revested "Dialyzers" are in two (2) hours or stored in a terrigerator to reland bactorial at begun. Refrigerated			Upon inspection, it was determine frigerator was unable to maint temperature within acceptable lifeuse refrigerator has been replayerified to be within acceptable 09/29/10. The CSS in-serviced teammates on Policy 6-01-08 R Dialyzers with emphasis on dia in reuse refrigerator including it temperature required to be mained to be the mained to be the construction of a single temperature to be recorded was reviewed. Facility Administrativill review the log everyday if weekly on each shift x3 weekly on each shift x3 weekly on each shift x3 weekly on the construction of a single will be reviewed in Quality in Management Meetings (QIFM addressed as necessary. FA if for ongoing compliance with	am mits. The need and limits as of the cuse of lyzer storage the ntained eit and s out of range, gle s also tor or designee tor 3 days, s, and then the the charge esults of audits nprovement AM) and s responsible	

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, i		342827	B. WIN	ia <u>· </u>		10	R VZB/2010
	OADER OR BUPPLIER TE BAUT PIALYBIB			\$204	ADDRESS, CITY, STATE, ZIP CODE EHLAROH AMITY		
CVH TO PREFIX PAGE	T YEARING	ATENSENT OF DEFICIENCIES BY MUST BE PRECEDED BY PLAI LEC DENTRYMO NU ORMATION	PREF TAI	=ix	PLOTTE, NO 28206 PROVIDENS PLAN OF CC (SUCH CORRECTIVE ACTION CROSS REFERENCED TO THE DETAGRACY	N BHOULD BE Eapproproate	PATE TAND (KS)
(V 331)	Confirmed From pag Febroshalt*	e 15	ΙV	331)	-	Andrew State of the State of th	The state of the s
	treatment area rave patient used dinivative interpretation used for the interpretation used for the interpretation of the conservation of the conservation of the interpretation at the conservation and was or times.	agrees F. "An interview during 1105 with a patient dialysis confirmed that the 6 degrees F and it should not tall member revealed that the refrigerator had been elevated a not able to give specific dates					
	ceron revealed temperature limits degrees F." The revealed that the temperature check documented temperature documented factures for the ceroses F. On the temperature was F. Review of the observation) teves	(2010 of the refrigerator log for that the festility's refrigerator elected by 150 degrees F to 48 eyiew of the Cerzo10 log daff had documented in alimpia that the companies of a simple perature. Review for 05/01/2010 plation by stall of the mature to be a range of 32-38 corrected by 150 degrees of Cerzo10 date of alimpia as 32-42 degrees log for Cerzo2010 (date of saled that the temperature arranges as 30-48 degrees F.					
	patient treatment	the registered muse in the erea on 08/22/2010 at 1166 refrictrator has constantly been					

		NO HUMAN SERVICES MEDICAID SERVICES				FORM	11/16/2010 APPROVED 0898-0381
etaterant c And man of	F DEFICIENCIES CORRECTION	CT) PROVIDERMUPLERALA DENTPACATION NUMBER	(XZ) MI A. BUSI		COMPTRUCTION	COMPLETE	ÆY D
		342627	e wa	3 <u>.</u>	Walled the second secon	10/28	
	Overe or supplier Te east dialysis		,	340	t address, chi'i, state, 214 cope 4 Bharth austy aflotte, NC 28706		
(Ya) 40 Presen Pag	(EACH DEPROENC	Atenent of Devicencing of Must be Preceded by Pull LBC (Dentuy) ng Informatich)	PREF YAG	X	Provident PLAH OF CORRECT (EACH CORRECTIVE ACTION SHOU GROSS-HEPERENCED TO THE APPR DANNIGHCY)	KDHE]	DATE.
(v 331)	é concern with the to interview coveraled "E in litet refrigerator, th 50s."	mpetalure rendings. The Everythre we put hot distyzans as tempetature goas in the	N.	131}	e e e e e e e e e e e e e e e e e e e		y by gamegya, dan
(V 340)	09/22/2010 at 1210 aware of the elevate febroessing storage revealed that the street the elevated temporal temporal components.	ZER GERM=90%	{Y	a40)			
	consignit capa district applicable, the heart in applicable, the heart in the germicide solutions in the heart in the concentration. The parts of chemic be districted and the districted caps. The with dilute black, with dilute black, with dilute black, with districting the heart germicide approved.	emicidal procedure: = 90% fectad needlalyzer shall be filled with needlalyzer shall be filled with at least 90% of the prescribed ally distributed with new processor and per capped with new processor and per chapted with new processor and per chapted for next are captured for the first the chemical used for by the FDA as a daintectant selly affect the materials of the		*	V340- The CSS in-serviced reuse teams policy 6-04-03 Cleaning and Dis of Reuse Supplies with emphasis need to fully immerse the caps b germicide surface level. Facility Administrator will monitor subm caps per policy for 7 days then cweek for 2 weeks, then monthly of audits will be reviewed in Quality of audits will be reviewed in Quality of a contract Management Meetings.	infection on the clow the nersion of nece a Results ality	10-15-10
	dialyzer. This STANDARD is Not reviewed oneits Bessed on facility poster knerview, the faculty feath reuse of	not met as evidenced by: on 10/28/2010. Ilicy review, observations and acklity's reuse staff failed to labyzer obps were cleaned and apriete immersion in a assembling of the			(QIFMM) and addressed as nec FA is responsible for ongoing c with POC.	essary, ompliance	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PRINTED: 11/15/2010 FORM APPAOVED OMB NO. 0938-0391

CONTESC	EOR MEDICARE	& MEDICAID SERVICES			ACCOUNTY OF THE PROPERTY OF TH	OMB NO.	A250-A5A1
CHATEMENT OF C	DEFICIENCIES	(X1) PROADER/EUP/UEVOLIA DENTIFICATION NUMBER:	1 .		NOTESTRENCE	COMPLETED CONTRACTOR	
WAT LINE OF C	STATE OF THE STATE	342627	a Built 8. Wine			10/28/	2018
	Ander or supplier E EAST DIALYSIS			3254	PADORES, CITY, STATE ZIP CODE SHANON ANTY URLOTTE, NG 28205	·	
(XI) ID PREFIX TAG	HELULAKUR HELULA	STATEMENT OF DEFICIENCES ENCY MUST BE PRECEDED BY FULL OR LOC IDENTIFY ING INFORMATION)	IĎ PREH TAG	x T	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION RHOL CHOSS-REPEACHCED TO THE APPR DEHICLENCY)	LD HH CLI	prite constitution constitution
{V 340}	Disinfection of Reduced OB/2003) reduced and dising countries for a mind dayeate portical tabular may be defined as a minutes but no gueta, " Observation on a reprocessing for caps and portice solutions review of the dasignated observation revices the dasignated observations of the immersed byte. An interview of facility's rause is contained with the dasignation of the dasignation of the immerse of the imme	de: cility's policy "Cleaning and uses Supplies Poscy" (origination realed "Reuse supplies will be a field "Reuse supplies will be a field with a 1% perseate acid intum of 30 minutes. Elood and so, benter adepters, extension suffected for a period of 30 rester than 24 hours prior to except than 24 hours prior to except than 24 hours prior to except than 24 hours priorestably pa used for puttent reprocessed laced in two 1% perseated in thin plastic containers tocated in the same for thinfaction. The said that the cape in both a disinfactant were not fully a second for the containers with the capation was during a line as present in the reprocessing OUZZIZOTO at 1820 with the exhibition revealed that the cape should have the cape should have the cape should have the cape evel of the disinfaction surface. Interpret were not below the		940) (V 400)	V400-Physical Environment Members of the Governing Body have met to review the Statemer Deficiencies (SOD) and formula following Plan of Correction (Plandards under the Conditions Infection Control (V110); Physi Environment (V400); and Gove (V750 that are not met as well a standards, contain specifics of collans. The facility will ensure provides oversight and has syst place to see that the facility is and maintained to provide a safunctional and comfortable emand an effective infection cont is in place. The facility has be diligently working on correcti issues cited since the survey, alarm has been installed as readition the physical plant issued require more time as they are dependent upon permits and a varilability as well the fact the work will have to be comnon-operational hours. These been evaluated by an architect to move forward is in place. time frame to complete is 9-request your consideration in particular issues.	at of the the COC). The of of oct ical smance as other corrective that the GB terms in equipped fe, vironment rol program icen ing all the The fire quired, *In ues will also evendor iat much of pleted during e issues have et and a plan Estimated 12 weeks. We	12-31-10 for Fire system 12-31-10 for additional physical plant work
		DN is not met as evidenced by: inglip on 10/26/2010.					

)EPARTM	ENT OF HEALTH AM	ID HUMAN SERVICES		•	•	PRINTED: 1 FORM A OMB NO. D	PROVED
ATEMENT OF	FOR MEDICAPE, 6.1 PEROIENCIES EXPRECTION	MEDICATO SERVICES [XII] PROMEDISTRIPLENGUA IDENTIFIDATION NAMER:	OCH MI A. BIJIL		Е СОИВТЯЛСТЮИ	COMPLETED	
th (Dail of)	and hither state.			• •	E	R	
		343521	B. WIN	3,		10/28/2	510
we of the	SVIDER OR SUPPLIER	A - Marie Carlos Ca			PET ACCRESS, CITY, STATE, 20 CODE		
CHARLOT	tr rast dialysis			- "	HARLOTTE, NC 28205		
DAG TAG	CEACH DEFICIENC	THE POST OF DEMICIONCIES Y MUST BE PRECEDED BY FLUL THE POST OF DEMICIONCIES AND THE POST OF THE PO	10 PREP TAC		PROVIDERS PLAN OF CORS DEACH CORRECTIVE ACTION SH CHOSE HEFERENCED TO THE RP DENCERNLY)		odi CDALATION PALE
{V 400}	Continued From page 18 Based on observations as referenced in the Life			400	determined that this refrigerator to maintain temperature within a	was unable acceptable s been	
	Stafety Report of a c	omplaint investigation 10, facility policy review,			replaced and verified to be with limits as of 09/29/10. The CSS	in acceptable	
	Spiritualists of the seven	sistor tamparature log review	}		the teammates on Policy 5-01-C	18 Rouse of	
	Looser a trait interviews	il was defermined that the			Dialyzers with emphasis on dia	lyzer storage	9-30-10
	facility falled to mail	nialn a physical environment	1		in tense refrigerator including t	he {	
	that darrested the	potential risks to the health	1		temperature required to be main between 36-50 degree Fahrenh	eit and actions	
	and salety of patie	nia, vialitors and stall. Tha	1		to take if temperature is out of	range. Proper	
	facility falled to her	1		documentation of a single tem	perature to be		
	wt cini galbissid enti	o sebatuto atticka	1			acility	
	compartments for	facility that is approximately	1		A desirator or designee will	review the log	
	7600 square feet if	sker, falled to ensure that an	ì		everyday for 3 days, weekly o	n cach shift x3	
	euteldeisch nathera	operalist light located next to as in operation; falled to hold	}		weeks, and then the log will be daily by the charge muse on a	n on-going	
	the delle at move	scied (tiles furget Astalud	1		bacin Becalts of audits will be	e reviewed in	
	red mine at drawle	lates in blace of only	1 -		Ownier Improvement Manage	ement Meetings	
•	Interviduo staff on	the fire chills; falked to ensure	-		COTELATAD and addressed as D	ecessary. FA 18	
	an effective eman	ancy avacuation route for the	1		responsible for ongoing comp	oliance with	
	facility's patients,	the abulant of enalisiv ban flat	1		POC. * Since the Facility is approx	imately 7.600	ļ
	alternative fire exil	route from incide the patient	- {		sq. fl. in size, the required Sn	noke	
	treatment area in !	the event of the one fire exit	1		Compartmentalization will b	e accomplished	1
	blooked by first an	ed falled to monitor and maintain			by extending the existing no	n-rated partitions	1
l	educat totaledular	ranting to highly botanital	- 1		to the Roof Deck, as indicate	ed in the attached	ł
1	pacientel growin is	stored reprocessed (rause)	- Į		Sketches. This will provide	me minimuni	
1	Chalyzons. The chi	milative effect of these systemic	1		1,140 S.F. in either compare the minimum exiting require	ments. New 1	*12-31-
ļ	propints resulted	in the facility's inability to and safety of palients, staff and	١.		Hour Smoke/Fire Partition	and 20 Minute	for
	visitors at the dist	Bill suith a fundative our and	1		Fire Reted Doors will be ins	stalled at key	addition
1	Attributed the stan settlet	I min terminals	}	_	language in order to provide	the needed	physica
ł	The findings Inch	ntec	1.		pathway from exterior wall	to extenor wall.	plant w
1			1		Each door will also include system, 1 Hour Fire Rated	a passage rawn Frame, and Closes	r .
1	A. The facility fall	ed to have a amoke berrier	1		device*		
1	coparating the bu	Highing has two sebatate amoke			l		1
1	compartments to	a facility that is approximately			This emergency battery op	erated light was	1
	7600 square fact	in size; failed to ensure that an			13V gottstagg base have con-	fied by an outside	10/07
1	emargancy balls	ry operated light located next to			vendor 10/07/10. This will ensure it is in working ord	os momoreo to	
1	the re-use mam	was in operation; failed to hold	İ		facility audits. cont . pg 20	o amme monum)	1
	THE CITIES OR LINEOU	pacted times under varying	1		racinty anons. com . pg 20	·	

PRINTEO: 11/16/2010 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO. 0938-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES OCT) DATE SURVEY OCO, MAKTIPLE CONSTRUCTION (A1) PROVIDER/SUPPLIER/CHA STATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION HUMBER: A. SHIBLUDER a. Who 10/26/2010 342537 STREET ADDRESS, CITY, STATE, 21P CODE NAME OF PROVIDER OR SUPPLIER 3204 SHARON ARITY CHARLOTTE EAST DIALYSIA CHARLOTTE NO 28205 PROVIDERS PLAN OF CORRECTION

(MACH CORRECTIVE ACTION SHOULD BE

CROSS-REFERENCED TO THE APPROPRIATE

DEFICIENCY) ELIMATAL STATEMENT OF PERIODERS IN FULL HIGH AT FULL HIGH AT STATEMENT OF PERIODERS IN FULL HIGH AT THE ATTEMPT OF PERIODERS IN FORMATION OF THE ATTEMPT OF (XA) ID PREFIX TAG PREFEX {V 400} (V 400) Continued From page 19 V400 cont. *The current Patient Station #7 will be *12-31-10 conditions each quarter in place of only relocated. A minimum 5'-0" portion of the incorriding staff on the fire drills; and follod to for Treatment Chase will be demolished to lanoitibba remove alorage in the front cornidor of the facility provide a clear path to a New 3'-0" Exit Only physical next to the libby at the aids exit door. Door with Panic Hardware. A minimum plant work 5'-0"ADA Accessible Sidewalk will be -Cross refer to 494.60(a)(1) Physical installed to connect this new door to the Environment Pire-Salety and Life Salety Codeexisting parking area. After installed the emergency evacuation plan will be updated to Teg V0417 reflect the exit routes. B. The facility failed to ensure an effective 10-1-10 emission of contract of the facility's Fire drill was conducted on 10/1/2010 and will be conducted quarterly at mexpected evitamenta na ebuicini ot erotletv bno flate, etnestaq times by the Facility Administrator or fire exit route from helds the patient treatment. designee. These fire drills will be documented area in the avent of the time fire exit passageway and evaluated in QIFMM. was blocked or unpassable. Storage items have been removed from the corridor and relocated to the records storage ~Cross ruler to 494.60(d) Physical Environment area as of 09/30/10. Route will be monitored Tag VAAAA daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility 09/30/10. Administrator or designee. The Governing Body will meet monthly x 3 C. The facility falled to monitor and maintain refrigerator temperatures to inhibit potential to ensure compliance with POC. Further compliance to the POC will be reviewed bacterial prowth in stored haused distyzers. during monthly QA meetings and reported to the Governing Body no less than semi--Cross refer to 494.60(b) Physical Environment annually. The Facility administrator (FA) Ten V0408. representing the GB will be responsible for N 403) 494.60(b) PE-EQUIPMENT (V 403) ensuring implementation and ongoing MAINTENANCE-MANUFACTURER'S DPU compliance with this POC. The dialysis facility must hyderrent and maintain gridulani) irrangiupa ila latt atuana ol margara s emergency equipment distyris mechines and equipment, and the water treatment evetern) and ent nity samples in before one banking manufacturar's recommendations. This STANDARD is not met as evidenced by:

Not reviewed one is an 10/26/2010.

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		AD HUMAN SERVICES MEDICAID SERVICES				FORM	11/16/2010 APPROVED 0938-0391
STATEMENT	OF DEFICIENCIES CONRECTION	(X1) PROVIDERUSUPPLIENCUA IDENTIFICATION IN MERC	,	latipl Lowg	ECONSTRUCTION .	CONTRACTOR	р
		342827	g, var	iG	The same of the sa	10/25	, /2010
	REPUBLIC TEAN STORES		,	\$2	PLY Address, City, State, 219 code Coa sharch awity Harlotte, NC 25205		
DAO (D) PREFIX TAG	CACH CEFICIENC	rec Identilareamalicae A mirel be lafeceded ea latit Viènell de debiciencies	FREE TAI	₩	PROVIDENCE FLAX OF ORBIGORY (EACH CORRECTIVE ACTION SIXX CROSS-REPERENCED TO THE APPR DESIGNAL	TION ULD BE IOPENITI	COMPLETION COMPLETION
{V 403}	Continued From pag Based on facility poli	, encilevrásko, walvar vo	₹V	403)		·	
	refrigerator temperations refrigerator temperator manifalm refrigerator potential bacterial gradially particular at task for exposure in bacterial growth in the findings include. A review of the facility reprocessed within the designated rouse regrowth while reprocessed. The refrigerator uses atorage is maintaine including reprocessed. The refrigerator uses atorage is maintaine including reprocessed. The refrigerator uses atorage is maintaine including reprocessed. The refrigerator in the pure for the store resured to inhibal potential in observation revealed the guase storage. The momentum revealed of the refrigerator in the pure storage in the guase storage. The refrigerator in the pure storage in the storage of the refrigerator in the pure storage of the refrigerator of th	use log review and statifiated to monter, and temperatures to inhibit temperatures to inhibit temperatures to inhibit temperatures to inhibit temperatures to inhibit and temperatures of characters. To policy "Reuse of Characters" (a) temperature of Characters and Characters are temperatured in a fingerator to retard bectarial send for up to 36 hours prior to the contaminated dialyzer of between 38-50 degrees. Corontaminated dialyzer of between 38-50 degrees. Corontaminated dialyzer of between 38-50 degrees.			V403 Upon inspection, it was determine refrigerator was unable to maintatemperature within acceptable lineruse refrigerator has been replace verified to be within acceptable I o9/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Rediginary of the maintage of the Policy of the Policy of the Policy in reuse refrigerator including the temperature required to be maintaged to take if temperature is out of redocumentation of a single temperecorded was also reviewed. Fact Administrator or designee will reveryday for 3 days, weekly on weeks, and then the log will be redaily by the charge nurse on an basis. Results of audits will be requality Improvement Managem (QIFMM) and addressed as necresponsible for ongoing compliance.	in nits. The ded and inits as of the case	9-30-10

DEPARTM	ENT OF HEALTH	AND HUMAN SERVICES & MEDICALD SERVICES	AMIL AMIL AMIL AMIL AMIL AMIL AMIL AMIL		·	FOR OMB N	0; 11/16/2010 M APPROVED OL D998-0391
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Q1 (b)Q XF-GAN EMT	PALLACE WALLA DEFI	A STATEMENT OF DESCRIPTIONS A STATEMENT OF DESCRIPTIONS A STATEMENT OF DESCRIPTIONS	ID PREFIX TAG	Ť	PROVIDER'S PLAY OF (SACH CORRECTIVE ACTO CHOSS TISTERRANCES TO TO DESIGNED.	on should be Heapphophate	DATE (ESTILITAN EXP)
(V 403)	Continued From	PRGP 21	[V4I	03)	and the state of t	And the second s	
'	An Interview duti	ng the observation of 1105 with					
	the temperature	ere stall mamber revealed thet was 50 degrees F and that the					
	temperature shi	ould not be that high. The ctaff	1		•		
	member reveals	d that the temperature in the bean elevated for a while and			•		
	was not able to	ive specific dates or times.				•	1
	A senten as NOT	22/2010 of the refrigerator log for					
	09/2010 reveals	d that the facility's retrigarator				•	
	termeratura lim	lia should be "35 degrees F to 45					
	degrees F." The	raview of the log for 09/2010 e staff had documented			•		ŀ
	temperature ch	acks as ranges instead of a single	1			•	
	documented to	reportations. Review of 09/01/2010					
		iontation by the staff that this persture to be a range of 32-38	-				
	decrees F. On	09/07/2010 the range of the					
	temperature wa	as documented as 82-42 degrees	1	1			1
	F. Review of in	e log for OB/22/2010 (data of Vexted that the temperature		ŀ			
	reading was do	сипентой ва 30-48 фергоса F.					
	&m Interview or	1 09/22/2010 at 1350 with the		-			
	facility adminis	trator revealed that the	<u> </u>				
1	tamparaturas :	of the retirementary about be	1				
	monitored ava	ry day and that the exact rould be documented. The		1			
1	Interview 6130	revealed that the raveo elorage					}
	refricerator sh	ould not be greater than 50 degrees					
}	F. The interview	w further revealed that the too used a further reveal to the total and the further revealed to the further revent revealed to the further revealed to the further revealed to					
•	containing me	dications, and that the limits on the]				
	log ware set fr	or medication storage, instead of					
{V 40		ighest degree of 50 F. EMERGENCY	n	/408)			
(A 40)	PREPAREDN	ess-procedures	,				
	1	acility must implement processos			•		
1	i trè mailes il	Married Lettries is calcinicativities becommonwed	(1	1		i

PRINTED: 11/15/2010

FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN BERVICES DMB NO. 0938-0391 CENTERS FOR MEDICAGE & MEDICAID SERVICES (XX) DATE SURVEY pcz) MULTIPLE CONSTRUCTION . ONI PROVIDENCIA PRIENCIA STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION EDENTHICATION NUMBER A. BUILDING 10/26/2010 342637 STREET ADDRESS, CITY, STATE, OP COCE HAVE OF PROVIDER OR SUPPLIER TTURA MUHAHE MEET CHARLOTTE EAST DIALYSIS CHARLOTTE, NO 24205 PROVIDERS IN AN OF CORRESTION GROWN BY STREET WAS ACTION GROWN BY STREET WAY TO THE APPRICAMENTAL BEACH WAY TO THE APPRICAMENTAL BROWN BY THE BROWN BY THE REGULATORY ON LSC IDENTIFYING INFORMATION)
REGULATORY ON LSC IDENTIFYING INFORMATION) CHORD MEFIX DIDTERDACY V408- *The current Patient Station #7 will be IV 4083 Continued From page 22 (V 40B) relocated. A minimum 5'-0" portion of the and procedures to manage medical and non Treatment Chase will be demolished to medical emergendes that are likely to threaten provide a clear path to a New 3'-0" Exit Only the health or cately of the patients, the staff, or Door with Panic Hardware, A minimum 5'-0"ADA Accessible Sidewalk will be the public. These emergencies include, but are installed to connect this new door to the not limited to, fire, equipment or power failures, existing parking area. After installed the cate-telated ewaldsirces' major arobby emergency evacuation plan will be updated to interruption, and natural dissalars likely to occur reflect the exit routes. in the facility's geographic area. A copy of Certificate of Occupancy has been requested from the city of Charlotte, original 10-13-10 This STANDARD is not mot as evidenced by: architect and general contractor. Going forward any fire inspections will be kept on Not reviewed onsite on 10/26/2010. file in the facility. FA is responsible for Based on phaervallons, fire safety reports raview ongoing compliance with POC. and sleft interview, the facility falled to ensure an effective envergency evacuation routs for the *The facility has been diligently working on facility's patients, staff and visitors to include an correcting all the issues cited since the survey. alternative fire exit route from Inalda the patient The fire system has been installed as required. treatment area in the event of the one fire exit. The physical plant issues will require more *12-31-10 parabactway was blocked or unpossable. time as they are also dependent upon permits for and vendor availability as well the fact that additional The andings include: much of the work will have to be completed physical during non-operational hours. These issues plant Observation on 09/22/2010 at 1015 during four of have been evaluated by an architect and a plan work the faulity's patient heatmand area revealed that to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request the facility had a total of spacen (16) total stations your consideration in these particular issues.* for hamodialysis treatments. The facility hamodialysis station locations were against the four (4) waits of the patient treatment area. The observation of the facility's fire entery ememoney evacuation route revealed that the facility had one emergency exit landing directly into a hallway from \$10 patient treatment area. The exit toute los off of the pribatel rejective or it is aller such a of facility's lobby area and main con doors. The observation further revealed that there was no other exit location or emergency executation found in the patient restment area. Observation revealed that only one (1) exit rotte/ogress

KOKW Crist 3201/pg-(ta) bakanna Asiapiw Obsopia

Event ID WED112

FROM D: DOISE

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)EPARTM	ENT OF HEALTH A)	O HUMAN BERVICES	•		PRINTED: 11/ FORM APP OMB NO. 09	ROVED
	DEPICIENCIES	MEDICARD SERVICES (XI) PROMOGROUPPLEACHA IDENTIFICATION NO MEEN	V and dans (XXI attribute	COMELMICTION	COMPLETED	
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	PADER OR EUPPLIER TE BAST DIALYGIS	And the second s	22	et address, city, state, 29 code 14 sharch auty 14.pl.otte, hg. 28208		
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(V 408)	visitors and staff. No observed in the part observed in the part facility's registered area revealed that way out of the part individual about it, but way out would be indicating by point interview revealed fine drills to use the to evercuse that the interview revealed fine drills to use the to evercuse that the interview of the local was blocked. A review of the local fire inspecting at the facility and at the facility and an interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the interview on I facility administration of the III facility administ	a treatment area for patients, or other doors or exits were lent treatment area. 22/2010 at 1110 with the rouse in the patient treatment into the three was only one ent treatment area at the extremely area at the lent treatment area at the extremely the that area (staffing to the case exit) thereof in a case (staffing to the case exit) there treatment in a case at the treatment area at the treatment area at the treatment area at the treatment area at the treatment area at the interview also leadily administration did not that to do if that one fire exit in with fire or other objects. Colline merchall reports on lead that no report could be produced by when any fire merchall or one was done at the facility to facility. In aniety inspections were a facility in the aniety inspections were leadily. The exiting are not fined or produce a fine in county/city report for any past in the facility after aniety. The ed that the facility a fine aniety. The ed that the facility a fine aniety. The	(V 408)	1. The fire system has been install required. 2. The Server Room's Plywood we removed. The currently non-rates be upgraded to Minimum I Hour Partitions, in accordance with the sketches. This will allow the I Feating to run behind the plywood material once reinstalled. 3. Since the Facility is approximate, in size, the required Smol Compartmentalization will be a by extending the existing non-repartitions to the Roof Deck, as the attached Sketches. This will minimum I,140 S.F. in either cas well as the minimum exiting requirements. New I Hour Sm Partition and 20 Minute Fire R will be installed at key location provide the needed pathway fit wall to exterior wall, Each do include a passage latch system Rated Frame, and Closer devident the Corridor by upgradic extending the existing non-rathe roof deck as a minimum Resistant assembly. The Dot Bio Hazard Storage room an will be upgraded to a minimum door with a minimum I hour and Closer devise.	will be if Walls will Fire Rated to attached four Fire d finishing mately 7,600 the cocomplished ated indicated in I provide the compartment compartment compartment for the fire compartment for the fire compartment for the fire compartment for the fire compartment for the fire compartment for the fire compartment for the fire compartment for the fire compartment for the fire compartment for the fire for t	*10-22-10 for Fire system
ĮV4	unable to produ	the actual risk and the staff were on this document during the sefery-life safety	fA v	cont pg 25		

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CE	TERS	FOR MEDICARE & DEFICIENCE OHRECTION	VIEDICATO SERVICES ONI PROVIDENBUPPI ENICIA IDENTIFICATION RIMBER:	OX21 LAV		онетистон	COMPLETED	
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i) Pi	WILL TAG	SUMMARY E	LY BRANK, O'S DEWCENCIES TY MYRL BE ALECEDED BY LAIT TY BRANK, O'S DEWCENCIES	OI PREF VAT	EX	PROVIDER STANIOF CORRECTION OF CORRECTION OF COMPACTION OF CROSHER STATES OF CROSHER CORRECTIONS OF CROSHER CORRECTION OF CROSHER CO		DELE CONNECTION CON
	V 417)	acction, by Februar must comply with a 2000 edition of the Netional Fire Protein incorporated by roll this chapter). This STANDARD Not reviewed ones the chapter 8:30 AM noted: 1) The Server Rollman of the server area. 2) Facility is appreciated area. 2) Facility is appreciated area. 2) Facility is appreciated area. 2) Facility is appreciated area. 3) The facility in self dossing nor it self dossing nor it self obsing nor it self of the re-use the self quarter in held at unexpect conditions. 6) There is stort lobby to the self edit.	ted in paragraph (e)(2) of this y e, 2009. The dialysts racility philosolic provisions of the Life Safety Code of the olden Association (which is being as \$403.744 (a)(1)(1) of the not met as evidenced by: the on 10/28/2010. It not met as evidenced by: the on 10/28/2010, allon on Thursday 9/30/10 and 11:00 AM the following was come is lined with a phywood the walls which does not comply fire resistance rating for the months banks apparating the amove banks apparating the separate smoke compariments as Bio Nazard Storage room is not ine-rated. Cy battery operated fight located to phone of holding fire drills being shed times under varying age in the front confider max to the each door, partially blocking the paragraph of the Services.	€V		1	y an outside onto your or	*12-31-10 for additional physical plant work
,	₽v4	92(), 1630 (494.70(a)(12))	PA-RECEIVE SERVICES		[V 46	(23)		

DEPARTM	ent of Health An	ID HUMAN SERVICES MEDICAID BERVICES			and the state of t	OMB NO. 0	PROVED 930-0391	
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CHARTOL	IN BART DIALY SID			CH	ARLOTTE, NC 28209 PROVIDENCE PLAN OF CORRECT	nhu l	ØØ	
(MA) 10 PREFIX TAG	restriu needrieks	the Bealthang Infragration) Can hore he beschoo ba eint Valenfa of Dengleholer	PREF	ax.	PACH CORRECTIVE ACTION BHOV CHORS - REFERENCED TO THE APPR DETICETION	1088 1	DATE	
(V 463)	Continued From par The patient has the		. 2	483)			•	
	This STANDARD Not reviewed ones Host reviewed ones Host reviewed ones Host reviewed ones Income, patient interdisciplinary to the potient's plan patient records (P The findings inclu A review of the fa Association of the fa Association of the patient or the patient or the patient or the patient of the clinical record of the clinical record of the familiary of the familiary of the familiary of the familiary of the familiary of the state of the	olicy review, clirical record arview and what interview, the slide the patient in the facility's am annual meeting involving of cars for 2 of 7 nearpled atlant #1,8).			V463- Policy #1-01-07 Patient Assess Plan of Care" was reviewed wi interdisciplinary team (IT) with the need to include the patient designee in the development of care unless the patient declines will be given a written and ver to the care plan meeting as car become due. Patients will be a invitation and note if they will patient declines the invitation care a member of the IDT will them and ask for their signan- If the patient refuses to sign, noted in the record as well. I will audit all plans of care co 3months and then 10% of the quarterly. Results of audits in Quality Improvement Ma Meetings (QIFMM) and add necessary. FA is responsibl compliance with POC.	in the in the plan of patient of the plan of Each patient bal invitation e plans sked to sign attend. If the plan of 1 review with ure on the plan, this will be A/designee mpleted x one completed will be reviewengement tressed as	10-18-1	

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	1	offells various	HANT THAT STORTED LINE WHAT		}			
	-last	A PRINCIPAL WALLERY	withour Mo described regularity was				!	
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	TE)	deled that the	pallent had not been invited by her plan of ears mostlings. The					
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PRINTED: 11/15/2010 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES ONB NO. 0838-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES COMPLETED bal milital t companion (XI) PROVIDENSUPPLERALIA IDENTIFICATION MANDER: STATEMENT OF DEFICIENCIES AND PLAN OF CORPECTION a REMIDING 10/28/2010 B.Wha 842827 STREET MEINESS, CITY, STATE, ZE COOR NAME OF PROVIDER OR BUPPLER VIEW HUNANG HIST CHARLOTTE, NC 28208 CHARLOTTE EAST DIALYSIS PROVIDERS PLAN OF CORRECTION (EACH CORRECTIVE AUTION BROULD BE CROSS OF TREASURED TO THE APPRICATION PATELLEGROOM FTAG SCHWART STATEMENT OF DEFICIENCIES (FAUN DEFICIENCY MUST BE PRECEDED BY FULL REGILLATORY OR LSC (DEMINYING (N° OFMATICA) PACTIX (X4) P DEFICIENCY PREFIX V750 Members of the Governing Body (GB) have (V SD2) Continued From page 29 met to review the Statement of Deficiencies (V 502) nursing staff administrated a PRN medication to (SOD) and formulate the following Plan of the patient without any documentation for the Correction (POC). The standards under the reason why administered and the resesphenism Conditions of Infection Control (VI10); of the medication effectiveness. The review Physical Environment (V400); and Governance (V750 that are not met as well as revealed that on 09/20/2010 at 1807 the patient other standards, contain specifics of nodecibem and beneficialistic asw corrective plans. The facility will ensure that "Acelaminophen 650 milligrams" by mouth, No the GB provides oversight and has systems in other documentation was found regarding the place to see that the facility is equipped and administered medication and/or the affectiveness maintained to provide a safe, functional and of the medication. An interview on 09/29/2010 bi comfortable environment and an effective 1400 with the facility administrator revealed that infection control program is in place. the patient chould have had documentation from Eliminated the use of a medication cart and the nursing staff for the reason that the PRN the medication station has been relocated. A medication was administared and the 10-18-10 designated clean area was created for medication prep on one of the island nurse effectiveness of the medication. stations in the treatment area 09/29/10. A 8. A raview on 09/23/2010 of the clinical record plan is in place to also install separation barriers 12" in height will also be installed for patient sit revealed that the patient was around the medication prep area to further admitted to the facility on 07/21/2009 for chronic hemodialysis. A review of the patient healment designate this space as a clean area. The Clinical Services Specialist (CSS) inphesis for 08/19/2010 revealed that the facility serviced the teammates on policy #1-03-11 numling staff administered a PRN medication to "Changing Transducers Protectors" on the patient without any documentation for the 10/07/2010 with emphasis on the need to teason why administered and the resessant with change and inspect wet and/or blood of the medication affectiveness. The review contaminated external transducers . Facility revealed that on 08/18/2010 at 1443 the patient Administrator or designee will monitor team was administered the medication 'Loperamide everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in (and diames madication) 2 milligrams by morth-We often documentation was found regarding the monthly infection control audit going administered medication and/or the effective head forward. The CSS in-serviced the teammates on policy of the medication. An interview on 09/23/2010 at 1-04-08 "Utilizing Vascular Access Clamps' and policy 1-05-01 "Infection Control for 1400 with the facility administrator revealed that the patient should have had documentation from Dialysis Facilities" on 10/7/2010 with the nutring staff for the mason that the PRN emphasis on the need appropriate cleaning medication was administered and the and disinfecting of vascular clamps, cont. pg effectiveness of the medication. 484.140/bX3XI)-(II) PG-CHARGE NURSE-12 MO (V 686)

NURSING+3 MO DIALYSIS

(V 689)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PRINTED: 11/16/2010
FORM APPROVED
OMB NO. 0988-039]

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i i			1		explosives are produced; whether the chemicals or explosives are	manufactured.	AIOW
1					hand or handled imder co	Doingons broom	-mg [
1	the state of the s	MADERIOR IN RUILER DRUMING SERVER	ľ		flammable flyings; and oth	er situations of	1
-	Later marketing	Patient aim renen in allema kum	1		similar hazards."		
1	structure book t	BRIDGE TO SHOULD BE WASHING OF THE PARTY OF	1		cont pg 34		
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TENDER OF	FOR MEDICARE & DEFICIENCIES ORMECTION	AEDICAID SERVICES AND PROVENCIUM PROVENCIA PROVINCIA PROVINCIA PROVINCIA PROVINCIA PRINCIPA PROVINCIA PRINCIPA	OCO MLETIP	TE OCHELBROLKW	CCARPTELED (X2) DALE ETMAKA		
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{V 750}	the health and unfor sunf. The facility fail separating the build compartments for a 7800 square feet in hazardous storage construction and special for distinction and special for distinction and special for distinction and special first to not fine diverying conditions inservicing staff or storage in the from the color of the distriction strate for its infective streetgen facility's patients, alternative first and treatment stress in biocked by fire; alternative first and treatment stress in biocked by fire; alternative first and treatment stress in biocked by fire; alternative first and treatment stress in biocked and growth in distyzers.	creased the potential flak to y of patients, visitors east ed to have a expose barrier log into two experies employed facility that is approximately facility that is approximately state failed to have a stee failed to have a stee failed to have a stee failed to have a stee failed to have a stee failed to have a stee failed in the facility operated light of the second was in operation; failed to engarcy battery operated light re-use room was in operation; the unexpected times under each quarter in place of only each quarter in place of only the facility next to the facility next to the facility next to exclude the facility next to be extended to an aurocan experience for the statif and visitors to include an industrial of the one fine extitute to Whible potential in eluced reprocessed (reuse):	{V 750	V750 cont *The Storage Room is cla Hazard area in accordance 6.2.2.2 Due to this, NFP/ will require this area as w Closet to be upgraded to t Hour Fire Resistant Ratin accomplished by upgradi Non-Rated Partition and the attached Sketches. The Governing Body wi to ensure compliance wi compliance to the POC during monthly QA me the Governing Body no annually. The Facility representing the GB wi ensuring implementatic compliance with this P	with Section 8.4.1 ell as the Janitor's he Minimum 1 g. This will be ng the existing Doors according to 11 meet monthly x 3 th POC. Further will be reviewed stings and reported to less than semi-administrator (FA) ll be responsible for m and ongoing	*12-31-10 for additional physical plant wor	

ENTERS	FOR MEDICARE &	ND HUMAN SERVICES MEDICALD SERVICES PROVIDENSIA PROVIDENSIA PROVIDENSIA PROVIDENSIA PROVIDENSIA PROVINCE	CCC) MULTIFLE A PLAIDING B. WANG	E CONSTRUCTION 101 - CHARLOTTE EAST DIALYSIS	OMB NO	: 11/15/2010 APPROVED 0938-0391 0938-0391 NEY R
		342527		ey adoness, city, state, 210 code		
	ADEN DU BANANEU		22	OF GIFTMON WINLA		
TTOJANK	e evel diversing	1144		AND OTTE, NO 20206	RECTION	1 (X45
CXA) ID PREFIX TAB		r (bg dialland de belgengign) Range de bregenen ea attr Range de bregenen ea attr	PREFIX TAG	(EACH CORRECTING ACTION) CROSS-HIMPOTHICEUTO THE A DEPICIENTY	CALLE GE	SOMMETICH DATE
(K 014)	416.44(b)(1) LIFE	BAFETY CODE STANDARD	[K 014]			
	interior limith on w	allo and ceillings of exto, i, and extracces furnishing are es Class A. B. of Cl.				
lk 02	Bared on observing the between 8:30 AM noised. 1) In the server in plywood, February wall or eleganters in this compliance with Clares C, shall be from NPPA 256. Surface Burning Materials." 416.44(b)(1) Lill Hazardous are: the building by fire realstance with partitions in with partitions.	is not met as evidenced by: alicin on Thursday 6/30/10 I and 11:00 AM the following was coun the wells were covered with y is to insum that the walls are in NFPA 101 Chaptel "10.2.3.1 celling finish that is required to Code to be Class A, Class B, or a classified based on test results to Exterified based on test results control Method of Test of Characteristics of Building FE SAPETY CODE STANDARD ce teparated from other parts of fire barriers have at least one hour rating or such areas are enclosed end doors and the area is provided alto sprinklar ayarem. High hazard ided with both fire barriers and me 39.3.2, 39.3.2	{K a	228)		
łk.	Haspid on obs between 8:30 noted. 1) The facility	IND Is not met at evidenced by: anvalion on Thursday 9/30/10 AM and 11:00 AM the following was than a Bio Hazard Storage Room also hazard Storage Room also hazard Storage Room the sale has esti closing or fire raised. LIFE SAPETY CODE STANDARD		((152)		

Any dehoarch statement there will an asymptet (*) dehotes a deficiency which the instantion may be consisted from connecting providing it is determined that other are deficiently with the instantion of provided the frequency which the frequency which the frequency which the frequency which provided the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the frequency which the instantion is a state of the frequency which the instantion is a definitely and the frequency which the instantion is a definitely with the frequency which the instantion is a definitely with the frequency which the instantion is a provided that the frequency which the instantion is a definitely with the frequency which the instantion is a provided that the frequency which the instantion is a provided that the frequency which the instantion is a provided. For purple, the frequency which the frequency which the instantion is a provided. For purple, the frequency which the frequency which the instantion is a definitely with the frequency which the frequenc

	efficiencies	AEDICAID SERVICES (XI) PROMDERSUPPLIERICIA DENTY KATION MUSER	0(2) M. A. HURL		onethidatoh On-Charlotte east Dialysis	COMPLETED BY THE STRVEY	
		342527	BL VVK			10	26/2010
	nder or Buttler I Kant Dialysia			22042	addrese, city, state, 219 code Harion assity LOTTE, NG 28206	11.532	
(XOD) PREFIX TAG	INCH MERITIEN	TATEMENT OF DEPLICATIONS Y MUST BE PROCEEDED BY PULL LEG EDENTIFYING INFORMATION	PRED TAI	'IX	PROVIDERS FLATOF CORR (EACH CORRECTIVE ACTION B) CROSS-REFERENCES TO THE AF DEPOSITEORY)	KON D BE	CONSTRUCT CONSTRUCTS
	other, are provided	ge 1 called remote from each for each floor or fire section of .4.1, 21.2.4.1, 7.5.1.4	(K	032)			
(K 045)	Besed on observal between 8:50 AM inded. 1) There is storage tobby that exite to 418.44(b)(1) LIFE Emergency Illumin	is not met as evidenced by: ion on Thursday 9/30/10 and 11:00 AM the following was in the front confider next to the the cide exit door. SAFETY CODE STANDARD action is provided in abcordance 20.2.9.1, 21.2.9.1		K 048}			
lk osc	Based on obtain between 8:30 AN incled. 1) The battery of by the re-use root of 416.44(b)(1) LIF. Fire drills are he verying condition.	is not met as avidenced by: allon on Thursday 9/30/10 and 11:00 AM the following was estated emergency ights located an did not operate when tested. E SAFETY CODE STANDARD id at unexpected times under is, at least qualitary on each shift. In at least qualitary on each shift. It of estatinished routins.		{K 050}			
	Based on obee between 8:30 A	D is not mat as evidenced by: vailon on Thursday 9/30/10 M and 11:00 AM the following was ->ervices the stati on the chils				·	nuation shoot find

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TPUENT OF	OBENCIENCES DESCRIBACIES	DONTE CATION NUMBER	a Building	IN - CHARLOTTE EAST DIALYSIS	COMPLETED
	*	343877	B MMAS	And the state of t	10/30/2010
	MIDER OR SUPPLIER	American March Mar	33	et adonerb, chy, state, zip code ra bikaron assty Harlotte, ng 28206	
MAHLOI		the state of the s		AND METO OF AN ACTIONS	CON CANADA
CCA) IP PREFIX TAB	AND PERSONS	STATEMENT OF DUPICIONICES INCY MUST BE PRÉCEDED BY FULL OR LSC IDENTIFYING INFORMATION	PHEFIX TAD	CHOST HEREKEN ZET DY THE API	DOLD BE I Wasterin
(K 050)	Confinued Fram	1968 2	JK 050)		
	lq ni rahaup risee	ece of holding fire drills at under very an conditions.	2440		
(K 115)	418,44(b)(1) LIFE	SAFETY CODE STANDARD	K 115]		
	Mile and that its	h care facilities ere divided inlo se compenmente with smoke t lesset 1 hour live resistance			
	rating. Doors in s	intoke harriers are equipped with Doors are constructed of not leas a soil bonded core wood or			
	asid Jaskylupe.	n panels are provided and are of Brilled to 1,296 eq. inch per .1, 20,3,7.2, 20,3.7.3, 21,3.7.1; .			
	Based on obus between 8:30 /	O le not med as evidanced by: O'LOEKE VADEURIT no not not make O'LOEKE VADEURIT MA COST I bow M.			
	and the facility separating the	a approximately 7600 ag. ft. la alxe doea not have a amoke banler bulkkng into two amoke			
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DEPARTMENT OF HEALTH AND E	TUMAN	VICES RE/MEDICAID CERTIFICATION REFORMEDICATION TE CIVIL TA	RANSMITTAL		acilny ID: 001554	
C/\AD	DICAF	EMEDICAID CERTIFICATION OF THE STATE OF THE	STATE SUF	EVEL AGENCY		
PAI	RT 1 - 1	3. NAME AND ADDRESS OF FACILITY	γ		4, TYPE OF ACTION	2. Recertification
ICAREMEDICAID PROVIDER NO		3. NAME AND ADDICTION OF THE CAST DIALYS!	IS	•	1. Initial 3. Terminativa	4. CHOW
342627	1	(L4) 3204 SHARON AMITY		(L6) 28205	5. Valldation	6. Complaint
2.STATE VENDOR OR MEDICAID NO.	1	(L5) CHARLOTTE, NC			7. On-Site Visit	9. Other
(I.2)		7. PROVIDER/SUPPLIER CATEGOR	Y <u>09</u>	<u>)</u> (1.7)	8. Full Survey Affer	· Complaint
5. EFFECTIVE DATE CHANGE OF OWNERS	HIP	of TITE	09 ESRD	13 PTIP	L	DIGDATE (L35)
/O Ts	(L34)	01 Hospital 05 LAB	10 NF	14 CORF	FISCAL YEAR END	ING DATE (123)
6. DATE OF SURVEY 10/01/2010	(L10)	03 SNF/NF/Distinct 67 X-Ray	II IMR	15 ASC 16 BOSPICE	12/31	,
8. ACCREDITATION STATUS: —	, (1210)	04 SNF 08 OPT/SP	12 RHC		i	
0 Unaccredited 1 TJC 2 AOA 3 Other			C:			
11. LTC PERIOD OF CERTIFICATION		10, THE FACILITY IS CERTIFIED A	S A	nd/Or Approved Waivers C	of The Following Requir	ements
		A. In Compliance With	_	2. Technical Personn	el6. Scope of7. Medical	20141001
From (a):		Program Requirements Compliance Based On:		3 24 Hour RN 4, 7-Day RN (Rural)	SNF) 8. Parient K	oom Size
To (b):	/T 101	1 Acceptable POC		5. Life Safety Code	9, Beds/Ro	om .
12. Total Facility Beds Hotors 16	(L18)	1		•		
14	(L17)	X B. Not in Compliance with Prop Requirements and/or Applie	ram :d Waivers:	* Code: B*	(L12)	
13. Total Certified Bells States	(/ · · /	Reduitements		FACILITY MEETS		
MACON			į.		(1.15)	
14. LTC CERTIFIED BED BREAKDOWN	.0.01	TE ICF IMR	\	186) (e) (1) or 1861 (j) (1)	•	,
18 SNF 18/19 SNF	19 Sì	Nr	1	•		
·	(L3	o) (LA2) (LA3)				
(L37) (L38)	110	2)	TADATE			
(L37) (L36) 16. STATE SURVEY AGENCY REMAR	KS (IF AP	PLICABLE SHOW LTC CANCELLA !!	 ,			
				18. STATE SURVEY AC	ENCY APPROVAL	Date.
e Attached Remarks		Date:		N. SIAILUONIA	γ _	1 1. A.
17. SURVEYOR SIGNATURE		10/26/2010		Clar C	-bylling 11	12/2010
(Kolph miss)	AV	10/26/2010	(L19)		TE STATE AGEN	RCY
1) Copie Title		BE COMPLETED BY HCFA	REGIONAL	LOFFICE OR SING	LESTAILMOL	~F.A. 35723
PART	П-ТО	20. COMPLIANCE W	ALL CLAIT	21. 1. Statement	of Financial Solvency(He p/Control Interest Disclos	ure Stat (HCFA-1513)
19. DETERMINATION OF ELIGIBILI	ŢΥ	RIGHTS ACT:		3. Both of U	e Above.	•
_X 1. Facility is Eligible to Pa	nicipate		•			
2. Facility is not Eligible	•	T 01)		1		
Z. Pacini, is not a		(L21)		26. IERMINATION.	ACTION:	(T30)
	73.1.70	AGREEMENT 24. L'TC AG		VOLUNTARY	ነበ .	INVOLUNTARY
22. ORIGINAL DATE		GDINING DATE ENDING	3 DATE	01-Merger, Closure		05-Fail to Meet Health'Safety
OF PARTICIPATION	ממ	New termination of the control of th		02-Dissatisfaction W/	Reimbursement	06-Fail to Meet Agreement
01/30/2003	л	(L25)		03-Risk of Involuntary	Termination	OTHER
(L24)		TERNATIVE SANCTIONS		04-Other Reason for V	lithdrawal	07-Provider Status Change
25, LTC EXTENSION DATE:	77, AL	Suspension of Admissions				00-Active
		. (1,747	}		•	
(1.27)	B.	Rescind Suspension Date:		1		
		(1.4)		30. REMARKS		
		29. INTERMEDIARY/CARRIE	er no.	50. KEIVIMICKS		
28. TERMINATION DATE:		00101				
·		•	(1.3	311		
	(L	28)				
		52. DETERMINATION OF A	PPROVAL DA	TE		
31. RO RECEIPT OF CMS-1539				33) DETERMINA	TION APPROVAL	
	a	.32)			•	
the state of the s				•		

DEPARTMENT OF HEALTH AND HUMAN "" "VICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE ...EDICATO CERTIFICATION AND TRANSMIT: ..L PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY IIv WB31

Facility 11), 601554

ertification survey was conducted onsite September 22-October 1, 2010. As a result of the survey in conjunction with a Life Safety Code survey an immediate jeopardy C&T REMARKS - CMS 1539 FORM eruncation survey was conducted onsite deptember 22-october 1, 2010, its a result of the survey in confidence with a Lite dately code survey at infinitely was indentified on October 1, 2010 at 1130. The II was no removed during the recertification survey Condition level deficiencies were identified in 494.180 Governance, 494,30 Infection Control and 494,60 Physician Environment, Standard level deficiencies were also identified in 494,40 Water and Dialysate Quality, 494,50 Reuse, 494.80 Patient Rights and 494.140 Personnel Qualifications. A plan of correction was requested

An onsite follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the 11 at 1250 based on compliance with a fire alarm system An onsite rollow up was conducted at the facility October 20, 2010. The State Agency recommended removal of the D at 250 based on compnance with a fire ataim space. The CMS Dallas regional office was notified of the recommendation THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 in place. The CMS Dallas regional office was notified of the recommendation THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 the place. The Civis Danas regional office was nother of the recommendation are communities contained in the plan of correction not completed during follow up survey(RM).

PRINTED: 11/02/2010 FORM APPROVED OMB NO. 0938-0391 SERVICES DEPARTMENT OF HEALTH AND HUN. (X3) DATE SURVEY CENTERS FOR MEDICARE & MEDICAID SERVICES (X2) MULTIPLE CONSTRUCTION COMPLETED (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES IDENTIFICATION NUMBER: A, BUILDING ANT PLAN OF CORRECTION 10/26/2010 B. WING 342627 STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AMITY NAME OF PROVIDER OR SUPPLIER CHARLOTTE, NC 28205 CHARLOTTE EAST DIALYSIS (X5) COMPLETION PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE SUMMARY STATEMENT OF DEFICIENCIES CROSS-REFERENCED TO THE APPROPRIATE DATE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL (X4) ID TAG DEFICIENCY) REGULATORY OR LSC IDENTIFYING INFORMATION) PRÉFIX TAG {√ 000} i INITIAL COMMENTS {\\ 000} \! An onsite follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the IJ at 1250 based on compliance with a fire alarm system in place. The CMS Dallas regional office was notified of the recommendation. THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended. to be in compliance based on the plan of correction not completed during follow up survey. {V 110} {V 110} 494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: {V 114} {V 114} 494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. This STANDARD is not met as evidenced by: {V 117} 494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP {V 117} AREA; NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare (X6) DATE TITLE LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined to other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 d following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continue If continuation sheet Page program participation.

FORM CMS-2567(02-99) Previous Versions Obsolete

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AND HUM	IANS ICES	TRAN	ISMITIAL	ID: WB31 Facility ID: 001554
ARTMENT OF HEALTH AND HUM MEDIC	IAN S ICES ARE/MEDICAID CERTIFICATION TO BE COMPLETED BY THE ST	ATE SURVE	Y AGENCY	
PARTI	TO BE CUMPLETED			4, 424
3 / (1)	3. NAME AND ADDRESS OF FACILITY (L3) CHARLOTTE EAST DIALYSIS		1	1. Initial 2. Recertification 4. CHOW
EDICAREMEDICAID PROVIDER NO.	(L4) 3204 SHARON AMITY		acoung .	3. Termination 6. Complaint
342627 ALE VENDOR OR MEDICAID NO.	(L4) 3204 SHARON AND (L5) CHARLOTTE, NC	(I.	s) 28205	7. On-Site Visit 9. Other
ALC VENDOR OR THE	(L5) CHARLOTTE, TO CATEGORY	09	(L7)	8. Full Survey After Compinint
EFFECTIVE DATE CHANGE OF OWNERSHIP	7. PROVIDER/SUPPLIER CATEGORY	ESRD 13 P	TOP .	
	01 Hospital	NF 14 C		FISCAL YEAR ENDING DATE: (L35)
(19) DATE OF SURVEY 10/01/2010 (134		IMR 15 A		12/31
ACCREDITATION STATUS:(L10	04 SNF	rec 169	OSPICE	
1 TJC	(14 PIX.			<u>-</u>
2 AOA	10. THE FACILITY IS CERTIFIED AS:	. 10	Amound Waivers Q	The Following Requirements:
LTC PERIOD OF CERTIFICATION	A In Compliance With	· And/O	2. Technical Personnel	
From (a):	Program Requirements		24 Hour RN	/. Michigan States
To (b):	Compliance Based On:		4. 7-Day RN (Rural S	9. Bods/Room
	1. Acceptable POC	· · -	5. Life Safety Code	
2 Total Facility Bene Stations	X B. Not in Compliance with Program	tamera * Coo	ie: B* '	(L12)
3. Total Cortified Book Stations 16	X B. Not in Compliance with Program Requirements and/or Applied V	Varvers.		
3. Total Cormical Scale / 12 11 01 >		15. FA	CILITY MEETS	~ . C)
14. LTC CERTIFIED BED BREAKDOWN		1861	(c) (1) or 1861 (j) (1)	(L15)
	9 SNF ICF IMR			
18 SNF 18/19 SNF		1		•
(L37) (L38)  16. STATE SURVEY AGENCY REMARKS (I	(L39) (LA2) (LA3)			ife Safety Code survey, an immediate jeopardy (II) cies were identified in 494.180 Governance, 494.30 alysate Quality, 494.50 Reuse, 494.80 Patient Right
494.140 Personnel Qualifications. A	F APPLICABLE SHOW DIC CITY of the September 22-October 1, 2010. As a result 0. The IJ was no removed during the recertific refronment. Standard level deficiencies were all olan of correction was requested.  Date:	18.	STATE SURVEY AG	ife Safety Code survey, an immediate jeopardy (11) cies were identified in 494.180 Governance, 494.30 alysate Quality, 494.50 Reuse, 494.80 Patient Right ENCY APPROVAL Date:
17. SURVEYOR SIGNATURE		ļ	3	
// // // // // //	10/11/2010		1	(1
Koff Mies R	10/11/2010	(L19) EGIONAL O	1	(1
PART II.	TO BE COMPLETED BY HCFA R	(L19) EGIONAL O	FFICE OR SING	CLE STATE AGENCY
PART II -	TO BE COMPLETED BY HCFA R	(L19) EGIONAL O	FFICE OR SING	GLE STATE AGENCY of Financial Solvency (HCFA-2572) (Control Interest Disclosure Strat (HCFA-1513)
PART II -	TO BE COMPLETED BY HCFA R 20. COMPLIANCE WIT RIGHTS ACT:	(L19) EGIONAL O	FFICE OR SING	GLE STATE AGENCY of Financial Solvency (HCFA-2572) (Control Interest Disclosure Strat (HCFA-1513)
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PART II -  19. DETERMINATION OF ELIGIBILITY  X 1. Facility is Eligible to Participa  2. Facility is not Eligible	TO BE COMPLETED BY HCFA R  20. COMPLIANCE WIT RIGHTS ACT:  (L21)	EEMENT	FFICE OR SING  21. 1. Statement 2. Ownership 3. Both of th	CLE STATE AGENCY  of Financial Solvency (HCFA-2572)  //Control Interest Disclosure Strat (HCFA-1513)  e Above :  ACTION: (L30)
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### SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

ting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, scarching existing data sources, gathering and Imag nurses for the consecuent of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and intuining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including agestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction oject(0838-0583), Washington, D.C. 20503.

Provider/Supplier Number	Provider/Supplier No CHARLOTTE EA	ame ST DIALYSIS			**************************************
342627  Type of Survey (select all that apply)	A Complaint Investigation B Dumping Investigation C Federal Monitoring D Follow-up Visit M Other	E Initial Certification F Inspection of Care G Validation H Life Safety Code	I J K L	Recertification Sanctions/Hearing State License CHOW	
Extent of Survey (select all that apply)	A Routine/Standard Survey (all p. B Extended Survey (HHA or Long C Partial Extended Survey (HHA D Other Survey	g term cate radius)			

#### SURVEY TRAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

	Please	enter the worklo	ad information for			On-Site	Travel	Off-Site Report
Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	Hours 6pm-12am (G)	Hours (H)	Preparation Hours (I)
			0.50	0.00	1.00	-0,00	4,00	0.50
1. 14819	09/22/2010	10/01/2010	0.50	0.00	19.00	0.00	13,00	10.50
2. 15546	09/22/2010	10/01/2010	1.00	0.00	4.00	0.00	1.50	0.50
3. 26594	09/22/2010	10/01/2010	0.50	0.00				
4.					:			
5.								
6.				<u>:                                    </u>				
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8.								
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10.								
11.								
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14.				<u> </u>	Total RO	Supervisory Revi	ew Hours	0.00

Total SA Supervisory Review Hours.....

1.00

Total SA Clerical/Data Entry Hours,...

0.50

EventID: WB3111

Total RO Clerical/Data Entry Hours.....

0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

# SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

blic porting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and information, send comments regarding this burden estimate or any other aspect of this collection of information, send comments regarding this burden estimate or any other aspect of this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, and information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and existing data necessary.

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342627  Type of Survey (select all that apply)	A Complaint Investigation B Dumping Investigation C Federal Monitoring D Follow-up Visit	E Initial Certification F Inspection of Care G Validation H Life Safety Code	I Recertification J Sanctions/Hearing K State License L CHOW	
Extent of Survey (select all that apply)	M Other A Routine/Standard Survey (all B Extended Survey (HHA or Lo C Partial Extended Survey (HH D Other Survey	4++D -		

## SURVEY TEAM AND WORKLOAD DATA

	Please	enter the worklos		On-Site	On-Site	leutification number On-Site	Travel Hours	Off-Site Report Preparation
Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	Hours 12am-8am (E)	Hows 8am-6pm (F)	Hours 6pm-12am (G)	(H)	Hours (1)
					3.00	0.00	5.00	2.00
Team Leader ID	10/26/2010	10/26/2010	1.00	0.00	1.00	0.00	0.00	0.00
1. 15546	10/26/2010	10/26/2010		0.00	1.00			
2. 13743	1072072				:			
3.					na de la companya de la companya de la companya de la companya de la companya de la companya de la companya de			
4. 5.								
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13.					Total R	O Supervisory Re	view Hours	0.00

Total SA Supervisory Review Hours.....

Total SA Clerical/Data Entry Hours....

0.50

Total RO Clerical/Data Entry Hours.....

0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

OCT-69-2019 15:81

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FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES OVE NO. 0838-0391 CENTERS LOS MEDICYAE Y MEDICYLO BELANCES CONTRETED CONTRETED DESI SELTIPLE CONSTRUCTION DATE DESCRIPTION PLANSES. STATEMENT OF DEFICIENCIES EMCKIN A AND PLAN OF COPPECTION 10/01/2019 n.wwa 362527 etreet receible cut, state, of coca FLUE OF PROMOEN ON SUPPLEA STAM SHARON ASSTY CHARLOTTE, NG 28205 CHARLOTTE EAST DIALYSIS PETATERAN PARAMETRIS PRAH OF CONFECTION PARAMETRIS PRAH OF CONFECTION PETATERAN PETATERAN COMPLETION CLARACY STATIONAL OF DEFICIENCES (PACH DEFICENCY MAST BE PRESENTED BY FIXA REGULATION ON LSC CENTRY NO WE CHARACTOR IO PAEPA TAG V110-Members of the Governing Body (GB) have Continued From page 1 V 110 met to review the Statement of Deficiencies blood linged external transducer protectors; falled (SOD) and formulate the following Plan of to ensure their stell implemented standard Correction (POC). The standards under the Infection control precentions by dearing Conditions of Infection Control (VII0); earlyment experse with renoved of been from Physical Environment (V400); and Governance floors in the petiem treatment area, expropriate (V750 that are not met as well as other clearly and drivinging of vactorial champs used standards, contain specifics of corrective plans The facility will ensure that the GB provides in patient beginneds and deaning blood string oversight and has systems in place to see that from work surfaces during patient hamoscopies the facility is equipped and maintained to treatments; tailed to ensure that passent used provide a safe, functional and comfortable deliyaers were adequately relitigated to inhibit environment. Eliminated the use of a pacterial growth before reprocessing; and total medication cart and the medication station has to ensure that perferts had a supply of paper been relocated. A designated clean area was COMBIN SANTIEURE AL LIGHTER BUYER PARTIE DE LA LA DE created for medication prep on one of the island petent ventuent erea. The cumulative effect of nurse stations in the treatment area 09/29/10. A these systemic problems restated in the facility's plan is place to install separation barriers 12" in thereth to exists as busiefou of dreath payour height around the medication prep area to further designate this space as a clean area. control practices for distysts patients. Plexiglas barriers will be placed to prevent. potential cross contamination. The Andreas Include The Clinical Services Specialist (CSS) inserviced the teammates on policy #1-03-11 A. The facility failed to ensure that a clean croa 10-15-10 "Changing Transducers Protectors" on was designated to prevent polential 10/07/2010 with emphasis on the need to cross-contamination of madicalians/supplies and change and inspect wet and/or blood tot stell to prepare, harkie and store medications contaminated external transducers . Facility Administrator or designee will monitor team to be administered to patients. everyday for 3 days, weekly on each shift.3 -Cross refer to 494.30(=X1XI) Interdion Control weeks, and then this will be included in monthly infection control audit going forward. Tag V0117 The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for B. The facility staff taked to change and inspect conteminated external transducer protectors in 2 Dialysis Facilities" on 10/7/2010 with of 2 observed pedents with wet at blood inged emphasis on the need for appropriate cleaning external transducer protectors. and disinfecting of vascular clamps, Facility Administrator or designee will monitor team -Cross refer to 494.30(s)(1)(1) Infection Control everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in T#g V0120 monthly infection control audit going forward. O. The facility failed to ansare that pish cont pg 3 implemented standard infection curring

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The CSS in-serviced the teapolicy 1-04-08 "Utilizing V Clamps" and policy 1-05-01 Control for Dialysis Faciliti with emphasis on the need cleaning and disinfecting of Facility Administrator or demonitor team everyday for each shift x3 weeks, and the included in monthly infectioned in Quality Improvement Meetings (2) addressed as necessary.  for ongoing compliance of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of	the spicked up to and blood occur. Carts 10; removed the mounting isposable bottle minutes on ascular Access 1 "Infection ies" on 107/20 for appropriate f vascular clamestignee will -3 days, wackly then this will be overment plfMMM) and FA is responsible.	10-15-10 3- 3- 10 ps. y on
f. b. Observation on 03/22/2010 at trush (paper wrappers) ecationed on treatment area floor near patient sta	the patient none E4 and				ndrusten sheet Page 1

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Observation further revealed three track cens to the beginn negations are a first water trail end overflowing with trastr 1. C. Observation on 00022/2010 at 1516 revealed that but maternaled (GO10 Brand) step disparises in the facility a service area at handwashing sinks designated as dean had caked mated builded observed directly under the Chapmann. No observed evidence of alexaning the departed was observed. An Interview with the facility administrator on DSV222010 revealed that the cree should remain from cluster and dirty buildup pround supplies. The interview also revealed that the tresh should be cleaned up by the staff. No reason was given as to why the Bress wave not desped by the staff. 2. Observation on 02/22/2010 at 1020 in the buttely parament star taxasley that asserted clarife frend for batters Americal access again word located in a container of 1:100 bleach disprocured and had visible clotted blood on the clamp heads. The consideration further revealed that the clamps were not fully submorted in the disimertant bleach. An interview with the facility exeministrator on CBIZZZOJO et 1215 revosled bisi the clamps should be below the lavel of blesch solution according to the facility policy. 5. Observation on OBY22/2010 at 1015 in the patient treatment area revealed blood strong on top of the needle charps container located directly peride the patent dayzing in staken #16. The

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PRINTED: 10D602010 FORM APPROVED OMB NO. 0938-0391 DEPARTMENT OF HEALTH AND HUMAN SERVICES CH DATE ELEMEN CENTERS FOR METHCARE & METHCAID SERVICES KA MATIFIE CONSTRUCTION COURTELED ON PROVIDERS SPLENOUS STATEMENT OF DOPPER LESS AND PLAN OF COARECTION A THE COURT 1010112019 STREET ADDRESS, EITY, STATE, AP CORE 3435EF Alex Havines for HAVE OF PROVICER OR BUPPLER CHARLOTTE, NO 28805 DESCRIPTION OF CONFECTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPTION ENGINEERS DESCRIPT PEN PENETRANO PENE CHARLOTTE EAST DIALYOR ESSAYON ON THE DESILATION HEADWALCH INVOINTELECT MAD IN MECCHES IN LITT ATTRIBUTED AND IN MECCHES IN THE HOFIX TAG PREHIA V 198 Continued From page 14 V 196 टेश्प एकछत् क्षेत्र प्रत्ये प्रज्ञान्त्रहरू V 33 REPROCESSING-TRANSPORTATION & 494,50(b)(1) V 331 HANDLING V331 11 Reprocessing Upon inspection, it was determined that this 11.1 Transportation and handling refrigerator was unable to maintain Persons handing used dialysays during manaportation what do so in a closur and sanitary temperature within acceptable limits. The reuse refrigerator has been replaced and 9-30-10 manner meintaining Standard Processions until verified to be within acceptable limits as of the displace is displaced both recitally and 09/29/10. The CSS in-serviced the teammates externally. To inhibit bacterial growth, then your on Policy 6-01-08 Reuse of Dialyzers with that carnot be reprocessed within 2 house should emphasis on dialyzer storage in reuse pe replicate and any approach to please Capies. refrigerator including the temperature manabattation and handling leaves (such as required to be maintained between 36-50 prolonged dolays in reprocessing) not described degree Fahrenheit and actions to take if in this mecommended practice whell be validated temperature is out of range. Proper documentation of a single temperature to be and dominated by the serious bary. recorded was also reviewed. Facility Administrator or designee will review the log This STANDARD is not met an evidenced by: everyday for 3 days, weekly on each shift x3 Based on facility policy review, observation, weeks, and then the log will be monitored telification terripotesture log review and staff daily by the charge muse on an on-going interview, the tectiny falled to ensure that patient basis. Results of audits will be reviewed in READ GENERAL MAN EGACINED LONG HALLE POP PORTION TO COMMENT AND MANUAL PROPERTY OF COMMENT AND ASSESSMENT OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF T Quality Improvement Management Meetings Inhibit becashal growing belong reprocessing (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with The andings include: POC. A review of the fectily policy "Reuse of Diplyzons" (revision data 00/2009) revealed "Dialysers are tebloceased within two (S) trains on stored in a designated rouse refrigurator to relaid backerial growth rank reuse is begun. Resignated distyzers may be stored for up to 36 hours prior to boing raprocussed. The religerator used for contemporal delycor द्रोपानुस कि तास्ताधाना क्रिक्स विद्या वस्तु कर If construction shirts Page 16 of 24 Fehigitica."

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Physical Environment Pine Finders and Life Safety Code-Tag VU417  B. The facility failed in ensure an effective emergency exacuation route for the facility's patients, staff and visitors to include an alternative fill exit foots from inside the patient treatment fill exit foots from inside the patient treatment was blocked or unpassable.  -Cross raise to 494.60(d) Physical Environment.			Fire drill was conducted on I be conducted quarterly at any the Facility Administrator or fire drills will be documente. OIFMM.  Siorage items have been rencorridor and relocated to the area as of 09/30/10. Route daily for 7 days then week monthly for 3 months by F Administrator or designee. The Governing Body will ensure compliance with PC compliance to the POC widuring monthly QA meeting the Governing Body no learning I be a monthly. The Facility at representing the GB will ensuring implementation VACS compliance with this PO	o/1/2010 and wexpected times designee. 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This emergency battery operated light was Continued Floin page 24 repaired and operation verified by an outside V 417 2000 edition of the Life Ballety Code of the vendor 10/07/10. This will be monitored to National Fire Protection Association (which is ensure it is in working order during monthly incorporated by reference at \$403.744 (a)(1)(i) of facility audits. 6, Fire drill was conducted on 10/1/2010 and this chapter). will be conducted quarterly at unexpected times by the Facility Administrator or This STANDARD is not met as a videnced by: designee. These fire drills will be documented Based on observation on Thursday BRUV10 and evaluated in QIFMM. between 8:30 AM and 11:01 AM the following was 7. Storage items have been removed from the *17-31-10 corridor and relocated to the records storage additional area as of 09/30/10. Route will be monitored ttelon daily for 7 days then weekly for 2 weeks then physical 1) The facility did not have a five alarm system nor plant was there any pagely bemeled mucks detector monthly for 3 months by Facility work Administrator or designee. *The facility has been diligently working on found in the building. 2) The Server Room is fixed with a plywood correcting all the issues cited since the survey. interior linish on the wells which does not comply This report was received on 10-11-10 stating with the required his resistance relief for the completion dates could be no later than 10-18-10. The fire system was ordered the 3) Facility is approximately 7600 eq. n. in size and day of the survey. The installation of the fire system is subject to the availability of the door not prove a smoke painter, sectarated the vendor who is working with the facility to building Into two separate emoke comparing the 4) The facility has His Hazard Storage room is not expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that sell closing not fire-inted. 5) The entergency battery eparated light located meets local code on 10-22-10. In addition the next to the re-use morn was not operational when physical plant issues will require more time as they are also dependent upon permits and 6) The techny inservices the stall on Fire Critis vendor availability as well the fact that much each quarter in place of holding Fire draw being of the work will have to be completed during Neid at unexpected times under varying non-operational hours. These issues have been evaluated by an architect and a plan to 7) There is storage in the front comider results the move forward is in place. Estimated time frame to complete is 9-12 weeks. We request labby to the able and door, partially blacking the V 463 your consideration in these particular issues. 494.70(a)(12) PR-RECEIVE SERVICES V 463 OUTLINED IN POC The passent has the right to-(12) Facelya Dya racessary sarvices outined in

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TEDICARE & MEDICAID SERVICES CENTERS FC EPARTMENT OF HEALTH AND HUMAN. ID: OB2211 MEDICARE/MEDICARD CERTIFICATION AND TRANSMITTAL VICES Facility 10: 001554 PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY 4. TYPE OF ACTION: 6 (L8) 3. NAME AND ADDRESS OF FACILITY 2. Recertification (L3) CHARLOTTE EAST DIALYSIS MENCAREMEDICAID PROVIDER NO. 1 Initial 4. CHOW 3. Termination (L4) 3204 SHARON AMITY 342627 Œ 6. Complaint (L6) 28205 5. Validation STATE VENDOR OR MEDICAID NO. 9, Other (L5) CHARLOTTE, NC 7. On-Site Visit (LT) (1.2)7. PROVIDER/SUPPLIER CATEGORY 8. Full Survey After Complaint EFFECTIVE DATE CHANGE OF OWNERSHIP 13 PTIP no RSRD 05 HHA 01 Hospital FISCAL YEAR ENDING DATE: 14 CORF (L35)10 NF (1.9)OF LAB 02 SNEINFIDeal (1.34)04/5/2009 15 ASC DATE OF SURVEY 11 IMR 07 X-Ray 12/31 03 SNF/NF/Distinct (L10) 16 HOSPICE 12 RHC . ACCREDITATION STATUS: AR OPTISP 04 SNF I JCAHO 0 Upaccredited 3 Other 2 AOA 10. THE FACILITY IS CERTIFIED AS: And/Or Approved Waivers Of The Following Requirements: LTC PERIOD OF CERTIFICATION __ 6. Scope of Services Limit X A. In Compliance With 2. Technical Personnel Program Requirements 7. Medical Director From (a): 3. 24 Hour RN Compliance Based On: 8. Patient Room Size 4: 7-Day RN (Rural SNF) To (b); X 1 Acceptable POC 9. Beds/Room 5. Life Safety Code (L18) 2. Total Facility Beds B. Not in Compliance with Program (L12)Requirements and/or Applied Waivers: A1* * Code: (L17) 13. Total Certified Beds 15. FACILITY MEETS 14. LTC CERTIFIED BED BREAKDOWN (L15) 1861 (c) (1) or 1861 (j) (1): IMR. ICF 19 SNF 18/19 SNF 18 SNF (LA3) (L42) (1.39)(1.38)(L37)A complaint investigation was conducted onsite at the facility April 15, 2009. As a result of the investigation, a standard level deficiency was found in 494.30 infection Control. A 16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE): plan of correction was requested. Refer to intake #NC00054102. 18. STATE SURVEY AGENCY APPROVAL Date: RVEYOR SIGNATURE (L20)06/01/2009 (L19) PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY 1. Statement of Financial Solvency (HCFA-2572) 2 Ownership/Control Interest Disclosure Stant (HCFA-1513) 20. COMPLIANCE WITH CIVIL 19. DETERMINATION OF ELIGIBILITY RIGHTS ACT: 3. Both of the Above : 1. Facility is Eligible to Participate 2. Facility is not Eligible (1.21)(1.30)26. TERMINATION ACTION: 24. LTC AGREEMENT 23. LTC AGREEMENT INVOLUNTARY 00 22. ORIGINAL DATE VOLUNTARY ENDING DATE 05-Fail to Meet Health/Safety BEGINNING DATE 01-Merger, Closure OF PARTICIPATION 06-Fail to Meet Agreement 02-Dissatisfaction W/ Reimbursement (1.25)03-Risk of Involuntary Termination OTHER (L41) (1.24)27. ALTERNATIVE SANCTIONS 07-Provider Status Change 04-Other Reason for Withdrawal 25. LTC-EXTENSION DATE: 00-Active A. Suspension of Admissions: (1.44)B. Rescind Suspension Date: (1.27)(1.45)30. REMARKS 29. INTERMEDIARY/CARRIER NO. 28. TERMINATION DATE: 00000 (L31)(1.28)32. DETERMINATION OF APPROVAL DATE 31. RO RECEIPT OF CMS-1539 DETERMINATION APPROVAL (1.33)

(L32)

nent of Health and Human re/Medicald/CLIA Complaint Part I - To		1131 21	3. Date	Complaint Rece	ived
1. Medicare/Medicaid F	acility Name and Address CHARLOTTE EAST DIALYSIS 3204 SHARON AMITY		1 10	30609 M DD Y Y	
3 4 2 6 2 7	CHARLOTTE, NC 28205	f Complaint			6B. Total Number of Complainants
4. Receiving Component  1 State Survey Agy.  1 2 RO	5. Date Acknowledged  0 3 2 7 0 9 3	1 Resident/Patie	nt Family 4		011
1 Resident Abuse 2 Resident Neglect 3 Resident Neglect 3 Resident Rights 4 Patient Dumping 5 Environment 6 Care or Services 7 Dietary 8 Misuse of Funds/ Property 9 Certification/Unanthonized Testing	10 Proficiency Test 11 Falsification of Records / Reports 12 Unqualified Personnel 13 Quality Control 14 Specimen Handling 15 Diagnostic Erroneous Test Results 16 Frand/False Billing 17 Fatality/Transfusion Fatality 18 Other (Specify)		pleted following  Substantiated  Unsubstantiated  Unable to Verify	7.C. Number per Alle	of Complainants gation  1 0 1 2 3 4 5
19 Life Safety Code	20 State Monitoring				
8. Action (if multiple actions, 1 linvestigate within 2 Investigate within 3 Investigate within	2 Working days 6 Other 4 45 working days 7 None	(Specify) Letion (Specify)			
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12. Proposed Actions Taken by S  1: 0 4  2: 3: 1.	A or RO  1 Recommend Termination (23-day) 2 Recommend Termination (90-day) 3 Recommend Intermediate Sunction 4 POC (No Sanotion) 5 Fine 6 Denial of Payment for New Admi 7 License Revocation 8 Receivership  14. Parties Notified and	ssions 11 Directed P 12 Limitation 13 Suspension 14 Revocation 15 Injunction 16 Civil Mon	nitor 1 DC 1 of Certificate 1 of Certificate 1 of Certificate	8 State Onsite Mo 9 Suspension of P 20 Suspension of A 11 None 21 None 22 Other (Specify) 23 Emforcement Ac 23 Moultain	art of Medicare Payments
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Any deficiency statement ending with an actorisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nutring homes, the findings stated above are disclosable 90 days of the safeguards provide sufficient protection to the patients. (See instructions.) Except for nutring homes, the above findings and plans of correction are disclosable 10 tollowing the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility: if deficiencies are cited, an approved plan of correction is requisite to continued program participation.

, CHAR EAST APR-24-2009 FRI 02:43 PM DAV PRINTED: 04/15/2009 FORM APPROVED OMB NO. 0938-0391 DEPARTMENT OF HEALTH AND HUMAN SERVICES (X3) DATE SURVEY COMPLETED CENTERS FOR MEDICARE & MEDICAID SERVICES (X2) MULTIPLE CONSTRUCTION (X1) PROVIDERISUPPLIERICLIA STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A BUILDING 04/15/2009 B. WING 342627 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 3204 SHARON AMITY CHARLOTTE, NC 28205 PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE CHARLOTTE EAST DIALYSIS (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) ID PREFIX TAG (X4) ID DEFICIENCY TAG V 147 Continued From page 1 V 147 of a patient's central venous catheter dressing 7 1. An in-service on Central Venous of 16 hemodialysis treatments (Patient #1). Catheter changes and initiation of The findings include: treatment was Completed on 4-15-09 by the vascular Review of the facility's policy "Central Venous Access Manager with attendance all Catheler (CVC) Care" (revised on 04/2009) pct's and RNs revealed that the purpose of the care was to reduce the risk of infection in the patient and to 2. Teammates will be observed by RN reduce trauma to the catheter and exit site while or Facility Administrator to assure minimizing blood loss. The policy review also 5-15-09 company guidelines are adhered to. revealed that cuffed catheters with well-healed Teammates will be observed on 3 exit sites may not require a dressing but still require examination and cleaning of exit site each occasions. treatment 3. Bi-weekly meetings between RN's A clinical record review on 04/15/2009 for patient and Facility Administrator will be held #1 revealed that the 32 year old patient had his to discuss any concerns or issues first dialysis treatment at the facility 12/30/2004. pertaining to any patient or teammate. The review revealed that the patient had "CVC right side femoral catheter" used for his hemodialysis treatments at the facility. The review of the patient's post treatment flow sheets on the 4. Teammates and RN's are instructed to dates of 03/10/2009, 03/26/2009, 03/28/2009, document any event that is a variation 04/04/2009, 04/07/2009, 04/11/2009 and from company policy and procedure 04/14/2009 revealed that no staff either changed the patient's CVC dressing or documented and/or any Physicians order cleaning of the patient's dressing after his hemodialysis treatments. No documentation was 5. MD was fully aware of pt's refusal of found in the patient's clinical record where the dressing changes. On several MD visits, facility's administration or the patient's physician was made aware of the patient not having his MD verbalized to pt, the importance CVC catheter cleaned after each hemodialysis of dressing changes performed in-center by RN treatment. Staff interview on 04/15/2009 at 1010 with the facility's administrator revealed that he was not aware of the patient refusing catheter care after the 7 missed changing or cleaning of the exit site.

Facility ID: 001554

If continuation sheet Page 3 of 3

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Event ID: 082211

FORM CMS-2567(02-99) Previous Versions Obsolets

## SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

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blic reporting barden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data intaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection intaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection intaining data needed, and completing and reviewing the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data received in the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching exists and the collection of information is estimated to average 10 minutes per response, including time for reviewing instructions and the collection of information in the collection of information in the collection	aperwork Reduction
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rovider/Supplier Number	Provider/Supplier N CHARLOTTE E.	Name AST DIALYSIS		-
142627 Type of Survey (select all that apply)	A Complaint Investigation B Dumping Investigation C Federal Monitoring D Follow-up Visit M Other	E Initial Certification F Inspection of Care G Validation H Life Safety Code	I Recertification J Sanctions/Hearing K State License L CHOW	•
Extent of Survey (select all that apply)	A Routine/Standard Survey (all ) B Extended Survey (HHA or Lor C Partial Extended Survey (HHA D Other Survey	IR Jeim Cue Land		

## SURVEY TEAM AND WORKLOAD DATA

	Please	enter the worklo		On-Site	On-Site	dentification number	TIETOL	Off-Site Report Preparation
nveyor ID Number (A)	First Date Arrived (B)	Last Daie Departed (C)	Pre-Survey Preparation Hours (D)	Hours 12am-8am (E)	Hours 8am-6pm (F)	Hours 6pm-12sm (G)	Hours (H)	Hours (I)
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Total RO Clerical/Data Entry Hours.....

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Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

FORM CMS-670 (12-91)

EventID: OB2211

Facility ID: 001554

DEPARTMENT OF HEALTH AND HUMAN SERVICES	OMB 0938-0360
ENTERS FOR MEDICARE A MICEIONIS APPLICATION/NOTIFICATION AND SURV	EY AND CERTIFICATION REPORT
PART I - APPLICATION - TO BE COMPLETED BY	2. Provider Number
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Varita tast	,
3. Street Address N. Sharen Antry	
4.CIV OC MECK LENBI	VC-
T. ZIP Code	
6. State 2520 S	10. Fiscal Year Ending Date
8. Telephone No. (20) 531-8122	(2/3//10
	Telephone No.
11. Name/Address/Telephone Number of Authorized Official  Address:	OTTE NC-26205 (204) 531-1550
3204 10. Duality Demarks Se	ection [see item 27])
12. Type of Application 2. Sympassion to new location 2. Only	nge of ownership
1. Initial 5. Expansion in current location 6. Char	nge of services/operations
	☐ Not for Profit ☐ Public
13. Ownership (v2)	Yes, hospital provider number
14. Is this Facility Hospital-Based (check one) (v3) Tes 15 No "	(V4)
The No If	Yes, SNF provider number
15. Is this Facility SNF-Based (check one)	(Ve)
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o. Is this facility owned and/or managed by a multi-facility organization. (Address:	14600 98401
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20. Germicide (v₁z) (check all that apply)  □ 1. Formalin □ 2. Heat □ 5. Other (specify) □ 5. Other (specify)	
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(V13) Total Patients = (V14) Hemodialysis + (V15)	Stations)
22. Number of Stations (check all that apply and include isolation stations under Total 5	Hemodialysis Training
Total Stations = (V17) V Territorial (V17)	Yes No
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23. Does the facility have Isolation stations?  24. Total Number of Patients (enter number of dialysis facility patients treated on each shift to B, MONDAY  B, MONDAY  C. 3	TUESDAY  D. WEDNESDAY  TUESDAY  D. WEDNESDAY
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25. Total Number of patients followed at home (vzo)	

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artment of Health and Human Heart Medicaid/CLIA Complaint Form	eted by Component First Receiving Complaint (S/	3. Date Complaint Received
	and Address	
1. Medicatestatean	E EAST DIALYSIS	030609
Identification Number CHARLOTT	DON AMITY	MMDDYY
	RON AMTY TTE, NC 28205	
342627 CHARLE		6B. Total Number
	6A. Source of Complaint	4 Anonymous of Complainants
4. Receiving Component 5. Date Acknowle	edged 1 1 Resident/Patient Family 2 Ombudsman	5 Other 011
1 State Survey Agy-	2. 1	Employ
1 2 RO   U 3 Z		
MMD	Dir	c Commission to
	7.B. Findings (To be completed fo	7.C. Number of Complainants per Allegation
Allegations 7.A. Category  10 Proficient 1 Resident Abuse	have tigation)	, 517
1 1016 2 Resident Neglect 11 Palancan	Reports Ol Substan	ntiated 2
2 3 Resident Rights 12 Thomalifi	ed Personnel Musub	stantiated/ 3
3 S Environment 13 Quality C	control "   Tinable	c to Verify
6 Care or Services 14 Specimo	ic 4	5
J Distary Erroneo	us Test Results 5	
Property	alse Biling Transfirsion Fatality	
9 Certification/Un- 17 Fatality/ anthorized Testing 18 Other (	Specify)	
aminorized vesses		
19 Life Safety Code 20 State N		
Action of multiple actions, indicate earlies	t action) S Referral (Specify)	
1 Investigate within 2 Working only	od - Antion (Specify)	
7 Tovestigate within 10 working day	S	
3 Investigate within 45 working day	78	
4 Investigate during next onsite	Completed By Component Investigating Complain	nt (SA or RO)
Part II - To Be	Completed By Composite 11.	Findings (Under 7B Above)
9. Investigated by	10. Complaint Survey Date	
1 State Survey Agency	0 4 15 0 9	
2 RO	MMDDYY	
		The second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of the second of th
12. Proposed Actions Taken by SA or RO	9 Provisional License	17 TA & Training for Unsuccessful PT 18 State Onsite Monitoring
1 Recom	mend Termination (23-day) 10 Special Monitor	10 o part of Medicare Paymonis
F-F-7	mend Termination (90-day) mend Intermediate Sanction  10 Special Model  11 Directed POC  12 Limitation of Certific	An a of An Agential Cartering
2: 3 Recon 4 POC (	No Sanction) 13 Sugression of Certifi	icate 27 Other (Specify)
- Ll	of Payment for New Admissions 14 Revocation of Certification 15 Injunction	ficate 23 Enforcement Action
7 Licen	se Revocation 16 Civil Monetary Peni	alty 15. Date Forwarded to CMS RO or
8 Recei	vership	Date   15. Date Forward to Carallel   15. Modificated SA (MSA)
	14. Parties Notined and Dates	4 1 6 0 9 Medicaid SA (A2567) (Attach HCFA-2567)
13. Date of Proposed Action	1 Facility 2 Complainant 2. 2	<del>[* 4 * * *</del>
,	3. Representative 3.	M MD DY Y
041509	4 Other (Specify)	
M MD D Y Y	Taking Final Close-Out	Action (RO/MSA)  18. Date of Final Action Sign
Part III - To Be C	ompleted By Component Taking Final Close-Out	dion of Certificate 18. Date of Pulsa Action 519
16. Date of CMS/MSA	17. CMS RO/MSA ACTION	nsion of Certification
Receipt	8 Revoc	cation of Certificate
Kecah	9 Injun	Advantary Penalty
	I None TA8	& Training For Unsuccessini P1
MMDDYY	2 Termination (23-day)	cellation of Medicare Approval
	3 Termination (90-day)	er (Specify)
and the second second		orcement Action
		Page 1 of
	CMS RO	1000

END STAGE RENAL DISEASE APPLICATION/N	OTIFICATION AND SURVEY AND CERTIFICATION REPORT
PART I - APPLICATION	N - TO BE COMPLETED BY FACILITY  2. Provider Number
. Name of Facility	
Pavila East Charlotte	
3. Street Address N. Sharon Amity Rd.	
4. City	5. County
Charlotte	MECKIENBUIG
6. State	7. ZIP Code
NC	9, Facsimile No. 10. Fiscal Year Ending Date
8. Telephone No.	(704) 531-8122 12/31
(104)531-1900 11. Name/Address/Telephone Number of Authorized Official	()//
11. Name/Address/Telephone Name:	Address:
7 01 - 5 - 01 00 370U M	7
10 Type of Application/Notification: (V1) (check all that a	apply and specify in Remarks section (see term 27)
1. Initial 2. Expansion to new	position to the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the same of the sa
4. Change of location 5. Expansion in curre 7. Other (specify) 6 was a UT	
	For Profit Not for Profit Public
13. Ownership (V2)	(V3) Yes No If Yes, hospital provider number
14. Is this Facility Hospital-Based (check one)	(V4)
	(V5)☐ Yes ☑ No If Yes, SNF provider number
15. Is this Facility SNF-Based (check one)	(Ve) [ [ [ [ [ (ve) ] ] ] ] [ [ [ (ve) ] ] ] [ [ (ve) ] ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ] [ (ve) ]
	Yes TVbb #Ves name and address of parent organization
<ol><li>16. Is this facility owned and/or managed by a multi-facility organ</li></ol>	nization? (v7) Yes No If Yes, name and address of parent organization Address:
Name:	
• .	(in Romarks section (see item 271)
(VB) 17. Services Provided: (VB) (check all that apply and specify	y in Remarks section [see item 27])
(VB) 17. Services Provided: (Ve) (check all that apply and specify	ansplantation 4. Home training. 3. Home suppose  Hemodialysis Hemodialysis
(VB) 17. Services Provided: (VB) (check all that apply and specify	ansplantation
(VB)  17. Services Provided: (Vs) (check all that apply and specify  1. Hemodialysis   2. Peritoneal Dialysis   3. Tra	ansplantation 4. Home training. 3. Home suppose  Hemodialysis Hemodialysis
(VB)  17. Services Provided: (VB) (check all that apply and specify  1. Hemodialysis	Ansplantation HemodialysisHemodialysisPeritoneal DialysisPeritoneal DialysisPeritoneal Dialysis
(VB)  17. Services Provided: (Vs) (check all that apply and specify  1. Hemodialysis	Ansplantation HemodialysisHemodialysisHemodialysisPeritoneal DialysisPeritoneal DialysisPeritoneal Dialysis
(VB)  17. Services Provided: (Vs) (check all that apply and specify  1. Hemodialysis	An Applantation  Hemodialysis Hemodialysis Peritoneal Dialysis  V(10)  Yes No  1. Manual  2. Semi-Automated  3. Automated  In 2. Heat  3. Gluteraldehyde  4. Peracetic Acid Mixture
(V8)  17. Services Provided: (V9) (check all that apply and specify  1. Hemodialysis	An Applantation  Hemodialysis Hemodialysis Peritoneal Dialysis  V(10)  Yes No  1. Manual  2. Semi-Automated  3. Automated  In 2. Heat  3. Gluteraldehyde  4. Peracetic Acid Mixture
(V8)  17. Services Provided: (V9) (check all that apply and specify  1. Hemodialysis	Ansplantation  Hemodialysis Hemodialysis Peritoneal Dialysis  V(10)  Yes No  1. Manual  2. Semi-Automated  3. Automated  Im 2. Heat  3. Gluteraldehyde  4. Peracetic Acid Mixture  (specify)
(VB)  17. Services Provided: (Vs) (check all that apply and specify  1. Hemodialysis	An Anomal A. Home Training.  Hemodialysis Hemodialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Automated 3. Automated 3. Giuteraldehyde 4. Peracetic Acid Mixture (specify) Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis
(VB)  17. Services Provided: (Vs) (check all that apply and specify  1. Hemodialysis	An Anomal A. Home Training.  Hemodialysis Hemodialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Automated 3. Automated 3. Giuteraldehyde 4. Peracetic Acid Mixture (specify) Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	A. Home Training.  Hemodialysis Hemodialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis No  1. Manual
(VB)  17. Services Provided: (Vs) (check all that apply and specify  1. Hemodialysis	An Anomal Partition Hermodialysis Hermodialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis    Wis   Yes   No
(VB)  17. Services Provided: (V9) (check all that apply and specify  1. Hemodialysis	An Anomal Talling.  Hemodialysis Hemodialysis Hemodialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	Ansplantation  Hemodialysis Hemodialysis Hemodialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis Peritoneal Dialysis No  1. Manual
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	An ansplantation    4. Home Training.
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	An Annual
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	An Home Training.  Hemodialysis Hemodialysis Peritoneal Dialysis
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	Ansplantation    4. Home Hailing.
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	Ansplantation  Hemodialysis Hemodialysis Peritoneal Dialysis  Peritoneal Dialysis Peritoneal Dialysis  1. Manual 2. Semi-Automated 3. Automated  In 2. Heat 3. Gluteraldehyde 4. Peracetic Acid Mixture (specify)  modialysis + (v1s) Peritoneal Dialysis  isolation stations under Total Stations)  modialysis + (v1e) Hemodialysis Training  (v1e) Yes No  ity patients treated on each shift for full week prior to submission of this form)  AY C. TUESDAY D. WEDNESDAY  3 4 1 2 3 4 1 2 3  4 1 2 3 4 1 2 3
17. Services Provided: (vs) (check all that apply and specify  1. Hemodialysis	Ansplantation    4. Home Hailing.

26, Staffing	(V21) Pegistered Nur	rse	_ (V22) [	Licensed Practical Nu	ırse
(list full-time equivalents)	(V23) Social Worker	.25	(V24) [	3 Dietitian	25
,	. (vz5) 🗹 Technicians	7.00		Others	75
27. Remarks: (Use this space		nts for Items 1–26)			
or the second	<del></del>				
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				true and correct to the	
understand that incorrec rescinded, under 42 C.F	t or erroneous statements R. 405.2100 and 405.218	may cause the Requ			
understand that incorrec	t or erroneous statements	may cause the Requ 30, respectively.		al to be denied, or facilit	
understand that incorrec rescinded, under 42 C.F	of or erroneous statements P. 405-2100 and 405.218	may cause the Requ 30, respectively.	est for Approv	al to be denied, or facility  Date  NISTRAFOR  4	y approval to be
understand that incorrec rescinded, under 42 C.F	t or erroneous statements .R. 405.2100 and 405.218 PART II TO	Title  D BE COMPLETED	est for Approv	al to be denied, or facility  Date  NISTRAFOR  4  AGENCY	y approval to be
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understand that incorrect rescinded, under 42 C.F. Higherter of Authorized Official 9. ESRD Provider Number	t or erroneous statements .R. 405.2100 and 405.218 PART II TO	Title  D BE COMPLETED	Est for Approv	al to be denied, or facility  Date  NISTRAFOR  4  AGENCY	y approval to be
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