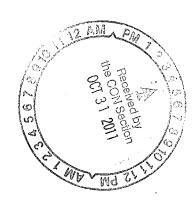
COMMENTS BY RENAL ADVANTAGE, INC. REGARDING PROJECT I.D. NO. F-8746-11 FILED BY DVA HEALTHCARE RENAL CARE, INC. D/B/A CHARLOTTE DIALYSIS CENTER ADD TWO STATIONS



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 two dialysis stations to its Charlotte Dialysis Center ("Charlotte"). This is based on Charlotte's 85% 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 its Charlotte Dialysis Center.

DaVita states that it now has 109 in-center patients at Charlotte. It projects 119.5 Mecklenburg County patients by the end of Year 2. *See* application, pages 11 and 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. There is no substantiation for these growth projections. 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. All that DaVita provides is numbers; it does not provide a need methodology, and there is simply no way the Agency can assume that Charlotte's growth will track the Mecklenburg County AACR. In addition, this facility has recently been approved for a one station expansion. *See* application, page 3. This additional station had not been developed as of the time of the filing of the Charlotte CON application on September 15, 2011. It would be prudent to see how busy the new station is 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 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, 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 Charlotte application should be denied under Criterion 20.

IV. Conclusion

The DaVita 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)	
•)	
Project I.D. No. F-7861-07)	

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-189(b).		•					
This the day of	, 2011.						
				•			,

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

CERTIFICATE OF SERVICE

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

This 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.

The proposed project shall be consistent with applicable policies and need determinations in (1) 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

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 L8, 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.
- 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,² 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:

CONTY	OPERATE 2017	GYEIR 2012		20日 即計論	COUNTRY	OR TOTAL
	IN-CIR PIST	H HOWE LIST	IN CTRUPES	HOME ETS	THE YEAR LENGT	THE YEAR ZORIG
Cabarrus	70	0	76	. 0	100%	100%
Total	70	0	76	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 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:

- \Rightarrow 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 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 X1.085 = 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:

	010000000000			V VI VI	(601) (45) (41)	
	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
- \Rightarrow 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

 \diamond 246.7 x 0.139 = 34.288

ļ,

 \Rightarrow 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 x 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.

 $39.0 \times 0.085 = 3.315 + 39.0 = 42.315.$ "

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:

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	開	2012 REPROPERTY		ZUIZE EREFEREN	SECTION STATE OF THE SECTION OF THE	
	IN-CIR PIR	HOME PIS	The Street	HIL HOWR RISH	HILLE KAR THEA	IIIIII !! A.K. Z !! IIII
Cabarrus	91	0	9 8	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 X 1.085= 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 I, 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:

	(01-11) (01-15) (07-15) (15-15) (17-15) (15-15)		7 (13 7 W 154) 2 (13 7 W 154)		(1) (1) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4	
	In-Center	Home	In-Center	Home	In-Center	Home
	Patients	Dialysis	Patients	Dialysis	Patients	Dialysis
		Patients		Patients		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:

Cabacrus County Total Dialysis Patients Historical and Projected

						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 Projected

	110,000					
1		12/05	12/06	12/07	12/08	12/09
ı	No. Patients	45	47	53	5 5	109
i	% 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 Cabarus 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 CABARRUS COUNTY DISTYSIS PATIENTS LIBER					
	12/06	12/07	12/08	12/09	
Harrisburg DC**	_			49	
Copperfield DC	47	53	5 5	60	
Branchview*	44	. 51	5 0	_	
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 in-center 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 Cabarrus 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:

	川市YXXR 75-2011本部	申記文章 X 2 2 2 0 1 2 4 2
Population 65+	20,752	21,608
Home Dialysis Patients	7	7
In-Center Dialysis Patients	. 75	78

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

温和温和高州所得的作业思想的能够到到各种的现在时间到 PATTENTS 中心是一种种能够通过中的工程和用				
COUNTY	学业。 图	AR LUMBER BER	的語言語	AR 2 前時間
	IN-CENTER	HOME	IN-CENTER	HOME
		DIALYSIS	HARRISON LINE BARRIE	DIALYSIS
Cabarrus	65	7	67	7
Mecklenburg	10		11	
Total	75	7	78	7

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 Doman	. I live in the $_$	area.	I
understand from Dr. Doman that she will be se	rving as medic	al director of a new	dialysi s
center to be located in, which will b	e 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:

	Y YYYOO LITE	
Concord	Cabarrus	1
Harrisburg	Cabarrus	2
Charlotte	Mecklenburg	1
Huntersville	Mecklenburg	3
Total Cabarrus	3	
Total Mecklenby	Ą	

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 Cabarrus 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:

PROPERTY DE XPENSES AND NEE REVENUE	HILDRI YEARTH	OP YEAR 2
Projected Operating Costs	\$2,990,071	53,189,462
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:

PROPERTY BY EVEN SEASON FOR THE PROPERTY OF TH	OPVERS	TOP YEAR'S
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 PAYENCES AND THE REVENUE	OF WAR I	OK-YAVE Z
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:

	PROTECTED EXPENSES AND YET REVENUE 1 1 1	1077771	OF VEGE
٠,	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

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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.

HILL POSITION HILL	DOMET TEST TEST TEST
RN (dc)	3.0
Pt. Care Technician (dc)	8.0
Bio-Med Tech	0.5
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0_5
Social Worker	0.5
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	OFER TION	
THE DAYS THE			
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 Hou	3,120		
(we			

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:

		HESTYRVETE	TOTAL	TOTAL HEE ON	HRS/HRS 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:

		HEATTERS AND THE
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.

The state of the s	
HAMILIA STATESTALLING THE STAT	TOTAL BIES YEAR ?!
RN (dc)	1.5
RN HT (dc)	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:

	WEEKGY	Hours of Open	Winds Him		
Division	MORNING	ARTERMOON	LVENING	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				

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:

	#FIKS	His/YR/File	TOTALTEE Hours	TOTAL HRS. OR CPERATION	HRS/HRS OF
		2.080	5.304	(ANNUAL)	OPERATION IN
RNs 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:

	PANNET.	
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.

HIHEESTTOMING	TOTAL FILL 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
Dieticisa	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:

	YEKGY HOURS	THE PERSON NAMED IN COLUMN TWO IS NOT THE OWNER.	
Monday	HENVIORENCE 7	AFTERNOON 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:

	#CU\$	HRÄYKRUE	TOTAL FIRE	TOTAL HRS OF BOTTON	HRS HAS OF OPERATION
RNs	4	2,0 80	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:

SCHOOL STATE	TWESHEE		TOTUSA
	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.

I PSM MILL	TO AD ETR'S YEARS
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:

	WESTER V	Hours of Ope	EATTONIE III	
THE TOTAL STREET	MORNING	HAFTERNOOM	#EVENING#	TOTAL
Monday	. 4	4	4	12
Tuesday	4	0	0	. 4
Wednesday	4	4	4	12
Thursday	4	0	0	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:

		Hasiyayara		Total Hestor Operation	HRS/HRS OF
RNs	4.5	2,080	9,360	2,496	3.7
Techs	7.0	- 2,08 0	14,560	2,496	5.8
Total	11.5	2,080	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/SHIVE	M/W/M PATIENTS	T/TH/SA PATIENTS
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

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

(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:

TO THE COMPANY OF THE PARTY OF	
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, Cabarrus 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:

i Sidenti Avita Plavados	
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:

AS DITTELL PROVINCE	
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 VI.1(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:

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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 VL5(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 nursing 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.

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(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-3577-10, Harrisburg Dialysis Center, F-3581-10, Cabarrus County Dialysis, F-3584-10, 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.

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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.
- Cabarrus County Dialysis In Exhibit 7, the applicant provides an September 3, 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.

- -C- 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 II, pages 11 14, and 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.

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(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."
- 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 twelve-station 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.
 - -C- 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- Cabarras 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) vascular 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 VIL5, 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.

SMIFP 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

HARRISBURG DIALYSIS CONTER		市也研加研EX2时間開開
Projected Expenses	\$2,990,071	\$3,189,462
# Dialysis Treatments	10,530	11,388
Average Cost per Treatment	\$283.96	\$280.10

UNITEX A XERUS COUNTY DIALYSIS CENTER (IIIIIII IIIIIIII PYTER TIPIIII EREBIRIII PYZEIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII			
Projected Expenses	\$1,894,521	\$2,072,639	
# Dialysis Treatments	5,850	6,318	
Average Cost per Treatment	\$323.85	\$328.05	

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

BATETRE CENTER CONCORD THE BUT	WINE THE EXTENSION OF	
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 DIALYSIS CENTER PROPERTY OF THE				
Projected Net Revenue	\$3,393,664	\$3,625,976.		
# Dialysis Treatments	10,530	11,388		
Revenue per Treatment	\$322.85	\$318.40		

THE INCOMES AND SECURITY DIALYSIS CENTER BETWEEN THE PROPERTY OF THE PROPERTY			
Projected Net Revenue	\$1,995,824	\$2,248,536	
# Dialysis Treatments	5,850	6,318	
Revenue per Treatment	\$341.17	\$355.89	

通识时间 COPPERVICIO DIXLYSIS CENTERITY SPIRE EN INTERVAL IN INTERVAL INTERVAL INTERVAL IN INTERVAL INTERVAL INTERVAL INTERVAL INTERVAL IN INTERVAL INTER			
Projected Net Revenue	\$4,495,936	\$4,855,496	
# Dialysis Treatments	13,650	14,742	
Revenue per Treatment	\$329.37	\$329.36	

WHITE TO AND CENTER CONCORDANCIA HIS INDUSTRICAN AND THE PROPERTY OF THE PROPE			
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	CABARRUS	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 Dislysis 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:

- 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 semiannual 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

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- 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.

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.

(O4-6) (-41-1-	
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		4-0-,020
Generator & Other Fixed Equipment	\$147,500	-	
Dialysis Machines	10		\$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.

NC – TRC CA – WFU

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.

NC - TRC C - WFU

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 l	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:

April 8, 2009 Paula Quirin

PROJECT ANALYST: 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.

NC

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 semi-annual 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.

C

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		Opei	rating Year 2	Percent	Patients as a of percent of OTAL
·	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
			·			=
New Hanover	95	0	97	Ó	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.

C

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 facility qualifies under the 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.

NC

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.

C

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.

C

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.

C

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.

C

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;

C

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

C

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.

 \mathbf{C}

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.

C

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.

C

.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

- 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]
- 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.

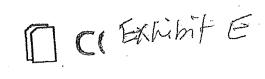
.2205 STAFFING AND STAFF TRAINING

- .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

P.02

RECEIVED NOV 2 9 2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid 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 & Medicald 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:

> Azzie 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:

1. 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 monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements.
- 4. The title of the person responsible for 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 Charlotta, North Carolina advising the public of your termination from the Medicare program. Please be advised that, under Medicara, 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

CCI

North Carolina Department of Health and Human Services





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 (II) 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

Azzic 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, R&SN Facility Survey Consultant Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief

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EPARTMENT OF HEALTH AND HUMAN SEPT CES

CENTERS FOR

DICARE & MEDICAID SERVICES

MEDICARE/M. CAID CERTIFICATION AND TRANSMITTA. PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY ID: WB31

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) inclaim stay vey was communicationance deputation 22-control 1, 2010. As a result of the stay of the condition level deficiencies were identified in 494.180 Governance, 494.30 actified 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 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 Dallas regional office was notified of the recommendation. THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance place. The CMS Dallas regional office was notified of the recommendation. 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	,	

olic reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and into 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. 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. 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.

ud.	aggestions for reducing the ballotte. Project (0938-0390), Washington, D.C. 20503.			(Y3) Date of Revisit
(1)	Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction A. Building		12/21/2010
	342627	B. Wing	Street Address, City, State, Zip Code	
lame	of Facility		3204 SHARON AMITY	
CF	ARLOTTE EAST DIALYSIS	`	CHARLOTTE, NC 28205	i designates previousiv
٠,			charatory improvement Amendments program, to s	show those deficiency should

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 stuly identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each equirement on the survey report form).

			(Y5) Date (Y4)	Item (Y5)	Date
Item	(Y5) Date (Y4	l) Item	(10) Date		Correction
Prefix <u>V0110</u> Reg. # 494.30		ID Prefix V0114 Reg. # 494.30(a)(1)(i) LSC	Correction Completed 12/21/2019	ID Prefix V0117 Reg. # 494.30(a)(1)(i) LSC	Completed 12/21/2010
Prefix <u>V0120</u> eg. # 494,30(a)(1)(i)	Correction Completed 12/21/2010	ID Prefix <u>V0122</u> Reg. # 494.30(a)(4)(ii) LSC	Correction Completed 12/21/2010	ID Prefix V0196 Reg. # 494.40(a) LSC	Correction Completed 12/21/2010
ID Prefix <u>V0331</u> Reg. # 494.50(b)(1)	Correction Completed 12/21/2010	ID Prefix V0340 Reg. # 494.50(b)(1) LSC	Correction Completed 12/21/2010	ID Prefix V0400 Reg. # 494.60 LSC	Correction Completed 12/21/2010
ID Prefix V0403 Reg. # 494.60(b)	Correction Completed 12/21/2010	ID Prefix V0408 Reg. # 494.60(d) LSC	Correction Completed 12/21/2010	ID Prefix <u>V0417</u> Reg. # 494.60(e)(1) LSC	Correction Completer 12/21/201
ID Prefix <u>V0463</u> Reg. # 494.70(a)(12) LSC		ID Prefix <u>V0502</u> Reg. # 494.80(a)(1) LSC	Correction Completed 12/21/2010	ID Prefix V0686 Reg. # 494.140(b)(3)(Correctio Complete 12/24/20
viewed By	Reviewed By		nature of Surveyor.	nes p	Date: /2/2// 20

epartment of Health and Human Services lenters for Medicare & Medicaid Services

Form Approved OMB NO. 0938-0390

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duction	on Project (0938-0390), Washington, D.C. 20503.			(Y3) Date of Revisit
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	342627		Street Address, City, State, Zip Code	
	e of Facility		3204 SHARON AMITY	
C	HARLOTTE EAST DIALYSIS		CHARLOTTE, NC 28205	show those deficiencles previously

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 Chrs-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 and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each equirement on the survey report form),

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Followup to Survey			Check for an	y Uncorre	cted Di	enciencies. Wa	s a Summary of to the Facility?	YES N

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, searching existing data sources, gathering and national statements and sources, gathering and reviewing the collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information. Scal comments regarding this burden estimate or any other aspect of this collection of information.

Provider/Supplier Number	Provider/Supplier Name CHARLOTTE EAST DIALYSIS	
342627 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 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.

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)	Off-Site Report Preparation Hours (I)
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Total SA Clerical/Data Entry Hours....

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Total RO Clerical/Data Entry Hours.....

Facility ID: 001554

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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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pressions for reducing the birtheri, to Clinical	
ojcct(0838-0583), Washington, D.C. 20503.	

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
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.

	Please	e enter the worklo	ad information for	r each surveyor. \	Jse the surveyors i	dentification number		l
urveyor 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)
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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

RECEIVED NOV 2 9 2010 ____

DEPART	MENT OF HEALTH A	yd human services	ļ				11/16/2010 APPROVED
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(A) DATE

PRINTED: 11/16/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED OMB NO. 0938-0381 CENTERS FOR MEDICARE & MEDICAID SERVICES DZ) MILITIPLE CONSTRUCTION (XX) DATE SURVEY OX 11 PROYIDIANGUPPLIENCULA IDENTIFICATION NUMBER: STATEMENT OF DEFICIENCIES COMPLETED AND PLAN OF CORRECTION A BUILDING R B. WHE 342827 10/26/2010 STREET ADDRESS, CITY, STATE, 21P CODE NAME OF PROVIDER OR SUPPLIES 2204 SHARON AMITY CHARLOTTE EAST DIALYSIS CHARLOTTE, NC 20206 PROVIDER IN PLAN OF CORRECTION (EACH CORPORTIVE ACTION BHOLED BE (AD) COMPLETION SUMMARY STATEMENT OF DEFICIENCIES (XA) (C) PREPIX TAG PREETX (PACH DEFICIENCY MUST BE PRECEDED BY PURITHER REGULATION) OR LEC HOENTRYNG MECHANISMS DAYE CAOSS-REFERENCED TO THE APPROPRIATE TAG V110-(V 110) N 110) Continued From page 1 Members of the Governing Body (GB) bave bapterial growth before reprocessing; and falled met to review the Statement of Deficiencies (SOD) and formulate the following Plan of to ensure that pallents had a supply of paper Correction (POC). The standards under the towels available at handwashing sinks in the Conditions of Infection Control (V110); patient treatment area. The cumulative effect of Physical Environment (V400); and Governance these systemic problems resulted in the facility's (V750 that are not met as well as other inability to suscess the provision of quality infection standards, contain specifies of corrective plans control practices for dialysis patients. The facility will ensure that the GB provides oversight and has systems in place to see that The findings include: the facility is equipped and maintained to provide a safe, functional and comfortable A. The facility feeled to ensure that a clean trea environment. Eliminated the use of a medication cart and the medication station has was designated to prevent potential cross-contemination of medications/supplies कार्य been relocated. A designated clean area was created for medication prep on one of the for staff to prepare, handle and store medications island nurse stations in the treatment area to be administered to patients. 09/29/10. A plan is place to install separation barriers 12" in height around the medication 10-15-10 -Cross refer to 494.5D(a)(1)(i) Infection Control prep area to further designate this space as a Tag V0117 clean area. Plexiglas barriers will be placed to prevent potential cross contamination, B. The facility staff falled to change and inspect The Clinical Services Specialist (CSS) inserviced the teammates on policy #1-03-11 conteminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to external transducer protectors. change and inspect wet and/or blood contaminated external transducers . Facility -Cross refer to 494.30(a)(1)(i) Infaction Control -Administrator or designee will monitor team Tag V0120 everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in C. The facility failed to ensure that staff monthly infection control audit going forward implemented standard intection control The CSS in-serviced the teammates on policy precautions by cleaning equipment surfaces with 1-04-08 "Utilizing Vascular Access Clamps"

Teg V0122

removal of trach from floors in the patient

beginnent area, appropriate clearing and

disinfecting of vescular clamps used in patient

treatments and cleaning blood stains from work

surfaces during petioni hamodialysis froziments.

-Cross refer to 494.30(a)(4)(ii) Infection Control -

cont pg 3

and policy 1-05-01 "Infection Control for

emphasis on the need for appropriate cleaning

and disinfecting of vascular clamps. Facility

Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in

monthly infection control audit going forward

Dialysis Facilities" on 10/7/2010 with

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PLAN OF CO	PRECTION	DENTIFICATION NUMBERS	A. RUA	DING	The state of the s	R	
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N 110)	Confinued Promi pag	10 2	N	110)	V110 cont. The CSS in-serviced	the team on	
to and	perminant i regir project	to existing that patient used	1			CIGRA 1	
Į.	distracts were eight Distracts were eight	untely refrigerated to inhibit		1	the importance of maintaining environment and ensuring trash from the floor. Facility Adminis	strator or	
ľ	baoterial growth bel	ore repressing.	1	1	IN monitor team evel	And And A	
1	Detailette Branktun			- 1	was a cach shift X3 W	ccks, and	
1	-Cross refer to 494	.50(b)(1) Respect	1	1	mo methoded in mo	nuny (
	Hemodialyzata and	Bloodines - Tag V0331	1	İ	Of 9mon tibur to	rwaru, i	
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1	E. The facility faller	l to monitor and maintain	1	1	refrigerator was unable to main temperature within acceptable	iam Smits The	
	wifings intereniiim	refingerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse)			the same hat been ten	aced and	
	bacterial growth in	1		to the beautiful accommon in this as P.			
	chalyzara.	1		The state of the company of the country of the coun			
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	-Cross refer to 49			I some and the terms rate	ecs, raper		
}	Tog V0403		- 1				
l .		d to ensure that patients had a	1		battery powered hands free st The dispenser was found to b	e monerative.	10-18-10
	F. The recent whe	Asie trailaple at paugnasipul a to atems inti bateurs um n	- 1		The dispenser was found to be Replaced batteries and verific	d operation	10-18-10
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{	Etike III the butter	(GERMIN) II FEAT	}		and the second of the	signee will	}
1	-Chron refer to di	4.30(a)(1)(i) Infection Comrol -			C TOT VShureira manager tot 3	OZYS, WEEKLIJ OK	1
l	Tag VD114	A TANK A	}		each shift x 3weeks and then	IDIS WILL DO	[
1/446	ANA SOUNT TYNIC	SINKS AVAILABLE	1	V 174	included in monthly infection going forward. Results of an	dite will be	1
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1	A sufficient numb	bns telew masw itilw skills to te			1 Afactions (1)11	· NA NA I BIDIU	
	son should be a	vallable to facilitate hand	- [I James and or meches Sarv. I'A	is responsible t	D)
	washing.		1		,ionce main	171	
1			- 1		1 m. Comming Rody Will 1	անան դուսասել չ հ	' [
					to ensure compliance with compliance to the POC wil	t he reviewed	1
1	This STANDARD) is not met as evidenced by:	1		during monthly QA meeting	es and reported	td
{	Mo reviewed care	lle on 10/26/2010.	1				
	M	antise made shannalisa and			as mu Tongilate and	נרגנו משמוחות	1
	Batan on tacilly	policy review, observations and profity falled to ensure that			1 Canada GR Will fi	e Lezponytote to	
}	WHYPER HAR	ribbly of babas rowers available at			anomine implementation	wa ongowe	
	प्रसामस्त्रक्षणात् श्री विभागमात्रकारात्र स्था	nks in the patient treatment free.			compliance with this POC	•	
	The Andinge inc	kidə;					
	erit to weiven A	lacility's policy "infection Control					

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FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO. 0938-0381 CENTERS FOR MEDICARE & MEDICAID SERVICES (XZ) MULTIPLE CONSTRUCTION (XX) DATE STEVEY (XII) PROVIDENSUPPLIENCUA IDENTIFICATION NUMBER: STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION COMPLETED EXICULTA, A R R. WHG 10/28/2019 342627 STREET ADDRESS, CITY, STATE ZIP CODE NAME OF PROVIDER OR BUPPLIER 2204 SHARON ANTY CHARLOTTE BAST DIALYEIS CHARLOTTE, NC 28205 PROMOBITE PLAN OF CORRECTION COLPUSTION SUMMANY STATEMENT OF DETICIONCIES DAD ID SECRIFICA NIET BE MECEMED BALLT SECRIFICA NIET BE MECEMED BALLT COMMENTS OF THE SECRIFICATION EACH CORVECTIVE ACTION SHOULD BE PREAX PRITIX DUTE CHOSSREPERENCED YO'THE AVAILUPINATE TAG CETTOLENOY N 114 (V 114) Continued From page 3 for Dialysis Facilities" (revision data 03/2010) Paper towels in the dispenser were revealed "The facility should have a sink available replaced and threaded properly. Paper towel dispenser at patient prep area is a for patients to wash their access sites prior to battery powered hands free style trealment and train hands after trealment. Scep dispenser. The dispenser was found to be and a supply of paper towels protected from 10/18/10, inoperative. Replaced batteries and contamination must be available at each sink." verified operation 10/14/10. Facility Administrator or designee will monitor Observation on 00/23/2010 at 1300 in the patient team everyday for 3 days, weekly on each troublent area revenied that a paper lovel shift x 3 weeks, and then this will be dispenser located for the patients to wash their included in monthly infection control audit appears sites at the exit area had no available going forward. Results of audits will be paper towels for use after handwashing. The reviewed in Quality Improvement Management Meetings (QIFMM) and observation revealed that the paper towels were addressed as necessary. FA is responsible achequit of totalog a diffuential management and belease for ongoing compliance with POC. the towels. After washing hands was observed by: a patient and europyor, it was noted that the censor was not working and no paper towels , eldelisva orew An interview with the facility's registered nurse during the observation on 09/23/2010 at 1300 revealed that the paper towel dispenser was not working. The interview revealed that paper towals would have to be obtained in a different fashion until the sensor was fixed. 484.30(6)(1)(I) IG-CLEAN/DIRTY;MED PREP (V 117) N 117} AREA:NO COMMON CARTS Clean areas should be clearly dealgnaled for the proparation, handling and storage of medications and unused supplies and equipment. Geen areas should be clearly separated from contemporated areas where used aupplies and equipment are translad. On not handle and alone medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handlad. hear our sisty resteologic each elettem realt

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[V 117]	(including visits contained individual patient dos area away from dialy apparately to each p	ė š kining dikusnis), preparė 198 in a class (cantralizaci) 1914 siutiona esid delivai 1916mi. Do not carry muhipia 19 sintiion to station,	(V 117)			
	madications to paties deliver medications i must be cleaned bet	•				
	This STANDARD is Not reviewed on site	not mel as evidenced by: on 10/26/2010.				٠,
	ciali interview, the fo clean area was desi cross-contervination	o patients.		V117 Eliminated the use of a medication the medication station has been re A designated clean area was creat	located.	
	The findings include: 1. A review of the facility's policy "insection Conjust for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and alongs of medications and unused supplies and equipment. Clean areas should be clearly separated from contemprated areas where supplies and equipment are handled."			A designated treal nate was to an medication prep on one of the isle stations in the treatment area 09/2 plan is in place to also install sept barriers 12" in height around the imedication prep area to further dethis space as a clean area. FA is responsible for ongoing cowith POC.	and nurse 29/10. A aration : csignate	10~18-10
	treatment area revo filled with medication along with syninges the hendwashing si their access sizes.	22/2010 at 1025 in the patient valed that a medication cart was and other unused supplies was located the chylogeness to wash for any was designated for and had a sign that was				,

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{V 137}	written as 'Patients' located at the base further revealed the was noted to preve medications and at An interview on OA facility's nursing at medications and at the cart was kept in medications and the confirmed that the get wet from public locations of the policy of the preview reve considered the policy of the preview reversaldered the policy of th	must wash access slies" and of the sink. The observation of the sink. The observation of the sink. The observation of water episches on the opplies. 12212010 at 1000 with the affirevaled that the patient mused supplies are stored on medice the handwesting sink, and start the staff has always are stored that the staff has always are stored stapplies in this location of. The interview slap hands, and staff washing hands, as and staff washing hands, as and staff washing hands, as and staff washing hands. The lacility administrator on the lacility administrator on the prevented that the supplies should be prevented from being that from people washing that		117}			

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	Lise external ver transcription of the transcription of the transcription of the transcription of the transcription of the transcription of the transcription of the transcription of the transcription of transcription of transcription of tra	NOT WETTED/CHANGED Inus and arianal pressure Uprotectors for each patient went blood contamination of the est pressure monitors. anaducer protector becomes welt, aloly and inspect the protector. If a the eide of the transducer was the mechane, have qualified					

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PRINTED: 11/16/2010 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES DMB NO. 0938-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES CONSTETED PT) PROVIDENCE PTENCLA IDENTIFICATION NUMBER: (XZ) MILTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES EMILITURE A AND PLAN OF CORRECTION R A. WANG 10/26/2010 342627 STREET ADDRESS. CITY, STATE, ZIP CODE name of provider or Bupplier 3214 BHARON AMITY CHARLOTTE, NO 28205 CHARLOTTS EAST DIALYSIS PROVIDERS FLANCE CERRECTION
FRACH CORRECTIVE ACTION SHOULD BE
CROSSRED TO THE APPROPRIATE CA) SIMMARY STATEMENT OF DEFICIENCES (EACH OPPICIENCY MUST BE PRECEDED BY PULL. REGULATORY OR LECTION THY INFORMATION ID Prefix pa) id Print Tag OFTE DEFICIENCY N 1201 (V 120) Confinued From page ? percount open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of blanch (300-800 mg/L free chlorine) or a commercially available, EPA-registered tubacculocidal germinino before reuse. Change filters/protectors between each pallent treatment, and do not reces them. Internal transduced filipps do put need to be changed The Clinical Services Specialist (CSS) inmuthery between patients. serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to 10-7-10 change and inspect the external transducers This BTANDARD is not met as evidenced by: for the presence of blood or saline every Not reviewed onette on 10/29/2010. 30 minutes during patient treatment. The external transducer protector is to be Based on facility policy review, observations and replaced whenever blood or saline is stall interview, the facility staff falled to change observed in contact with the patient side of and inspect contaminated external transducer the transducer protector. Facility protectors in 2 of 2 observed patients whose Administrator or designee will monitor distingly machines were observed to have well or team everyday for 3 days, weekly on each blood singed external transducer professors shift, and then this will be included in (Patient stations \$1,11), monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management The findings include: Meetings (QIFMM) and addressed as A review of the facility's policy "Changing Transductor Protectors" (revision date of 12/2009) necessary. FA is responsible for ongoing compliance with POC. rovealed "External transducet proteotors will be inspected for the presence of blood or saline every 30 minuse during patient treatment and included in the monitoring process. The external transducer protector will be replaced whenever blood or salars is observed in contact with the patient side of the transducer protector."

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Event ID: WHII 12

Facility ID; CO1534

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	pallent in station #1 pallent'a external tr to be contaminaled 1610 incough 1845	9/22/2010 et 1508 for the during tour revealed the meducer protector was noted with blood. Observation at revealed that no staff member ed the transducer protector.					
	patient in stellon illi patient's external to to be contermation 1610 through 1645	Delizazono et 1610 for tius il during taut revesied the consciuent protector was nuted with blood. Observation et trevesied that no staff membar and the transducer protector.					
	facility's registered area revealed that broody transducer	09/22/2010 at 1650 with the increase in the patient nextment that self should change the sund check that back of the a sund that the machine is not					
(V 122)	biall on Cal22/20* Iransducer protoc changed and che bloody. 494.30XaX4XIII IC	th the facility's administrative 0 at 1555 reversed that the tops should be immediately cked by staff when they become -DISINFECT		(V 122)			
	SURFACES/EQL The facility must standard infection implementing- (4) And maintain with applicable 6 public health pro- (8) Cleaning and	IPWRITTEN PROTOCOL demonstrate that it follows in control precautions by ing procedures, in accordance tale and local laws and accepted cadures, for the-1 distribution of contaminated at devices, and equipment.					

DEPARTN	IENT OF HEALTH A	ID HUMAN SERVICES	-			PRINTED: FORM / OMB NO.	11/18/2010 \$PPROVED 0928-0391
CENTERS STATEMENT OF FIND PLAN OF I	F DEFICIENCIES	MEDICAID SERVICES (X1) PROVIDERGUPLIBRICUA IDENTRICATION NUMBER:	V Grant	-	CONSTRUCTION	(XX) DATE SURV CONSTRUCTOR	EY .
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(X4) 10 PERFEX YAG	MACH MAWATINE	FEO INTELLIFICATION (MECHANIZAM) A WIRLA RE RECEDED BA LOTT A WIRLA RE RECEDED BA LOTT	PREFE TAO	×	PROVIDER'S PLAN OF COPPED GROSS-PEFEFSHOED TO THE APPR DEVICEMENT)	ad by Operate	CASA ETIPON DATK
(V 122)	Continued From pag	a 9	N1	22)	;		
	Not reviewed phelia based on facility per stall interview, the facility per stall interview, the facility implemented a preceditions by class removal of treath area, and dishifecting of vest moutments and classificating of vest moutments and classificating of vest included. A review of the facility revealed "Equipm transmitted included "Equipm transmitted and all work surfactions of completion of produced throughout the datases contaminated include are calculated and the contaminated contaminated area contaminated and the contamination and chalky." 1. b. Observation of the can had not contain and chalky. 1. b. Observation the can had not contain and chalky. 1. b. Observation the can had not contain and chalky.	licy review, observations and actiny failed to ensure that tenderd infection control in infection in the patient infection in the patient information in the patient in the			The CSS in-serviced the team on importance of maintaining a clear environment and ensuring trash up from the floor and blood stain blood stains are cleaned when the Carts will be replaced by 10/15/10 removed the existing soap dispermounting 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" 10/7/2010 with emphasis on the appropriate cleaning and distinguished designee will monitor team even days, weekly on each shift x3 then this will be included in minfection control audit going it. Results of audits will be review Quality Improvement Manag Meetings (QIFMM) and addrancessary. FA is responsible compliance with POC.	is picked is and ity occur. 2010; insers and with ins. instants on ular Access infection on e need for fecting of inistrator or eryday for 3 weeks, and boothly onward wed in ement	10-15-10
	#11 Observation	n kuther revealed three trash ni krealmant area that ware full		•		A D D	

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NAME OF PROVIDER OR BURPLER SYREET ADDREES, CITY, BTATE, 20 LODE 1201 BHARON ALKEY CHARLOTTE HAST DIALYSIS GHARLOTTE, NC 28265	-	
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(V 122) Continued From page 10 (vid overflowing with trach. 1. c. Obseyvation on 03/22/22/00 at 1618 revealed that two automated (GOJO Brand) soup dispenses in the facility's service suce at handwacking sinks designated as clean had carked rusted buildop observed directly under the dispensers. No observed avoidance of cleaning the dispensers was observed. An interview with the facility administrator on 03/22/2010 revealed that the crea should remain free from clutter and diffy buildup enound suppillus. The interview wish a revealed that the trash should be cleaned up by the stall. No reason was given us to why the press ware not cleaned by the stall. 2. Observation on 03/22/2010 at 1020 in the patient treatment area revealed that viscular clamps used for patient vascular access elles were located in a container of 11:00 beach disinfectant and two visite clotted blood on the clamps heads. The observation functor revealed that the disinfectant bloods on the clamps heads. The observation functor revealed that the distinfectant bloods that the damps should be below the level of inteach solvion according to the facility policy. 3. Observation on 03/22/2010 at 1016 in the patient within the stamps alread that the stamps alread distinguish at the stating to local in station with T. The blood stains were located the stating to the facility policy.		

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(V 122)	Confinued From pag	11	(V)	122)				1. Mod moracido mario e
(∨ 186)	DB/22/2010 at 1210 a should be disaused w possible.	facility administrator on everaled that the blood stains then they occur or soon as ADSORP-MONITOR, TEST	(v 1	195)				• .
	Testing for free chick chlorine should be p each treatment day the free treatment and again potent shall it there	tion: monitoring, lesting freq ine, chloramine, or total erformed at the beginning of prior to paliants initiating prior to the beginning of each are no set patient shifts, formed approximately every		The second secon	: : !			
		g of free chlonne, chicramina, uld be recorded in a log			•			and the same of th
	chlorine can be acco N.N-dicttyl-p-pheny test Kits or dip-and-	rine, chloráinine, or total omplished using the risna-diamins (DPD) based nad test strips, On-lina						
	concentrations. Whi must have sufficient resolve the maximu	ed to measure chloramine chever test system is used, it samplifylly and specificity to m levels described in [AAL#] ch is a maximum level of 0.1						
	Bamples should be been operating for enelysis should be	chawn when the system has at least 15 minutes. The parformed on-elle, eince Al decrease if the sample is dy.	,					
	This STANDARD i	s not met as evidenced by: e on 10/26/2010.		***************************************				

PRINTED: 11/16/2010

TOTO NO. 1040010F

FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO. 0838-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES (X3) DATE BURNEY (XS) HEATHER CONSTRUCTION IXI) PROMDENSUFFUERICULA STATEMENT OF DEPICION CHES ENTIFICATION NUMBER: AND PLAN OF CORRECTION A BUILDING SL WING 10/20/2010 342627 othert address, oity, state, of odde HAVE OF PROVIDER OR SUPPLIER SHARON ARITY CHARLOTTE, NO 20205 CHARLOTTE BAST DIALYER PROVIDER I PLAN OF CORRECTION (PACH CONNECTIVE ACTION SHOULD NO CROSS-REFERENCED TO THE APPROPRIATE DCD) Summary Statement of Deficerably (Each Edrichecy Milites Preceded by Fig. Regulatory or Lec (Dentifyer Information) DUSTO PREFIX TAG PROFIX TAG DEFICIENCY [V 198] Continued From page 12 (881 V) Based on facility policy review, the feptility's total anicate traing log review and staff interview, the facility falled to ensure regularly performed tasting V196to morefor the total chlorine in its water system The CSS in-serviced the teammates on the used in patient hampetialysis and falled to provide importance of completing the water system total chlorine monitoring every 4 hours per color blindness testing in 2 of 4 sampled staff policy 2-07-04 "Daily Water Total members that test the facility's water system for Chlorine Monitoring" and documenting 10-18-10 the presence of chlorine (Staif#1,3). on the appropriate log. FA/designee will be checked daily for 7 days then weekly The findings include: on going. Color blindness testing was completed on the 2 RN's cited and it was A review of the facility's policy "Daily Water. found that they did have testing and results System Total Chlorine Monitoring' (revision date are in teammates files. Color blindness 03/2010) revealed "Total Chlorine testing is done testing will be done on all new hires and on a daily basis prior to the first patient treatment annually there after. Facility Administrator and every four (4) hours until all activities that will spot check 25% of teammates file monthly for 3 months and annually there require use of dialysis quality water are after. Results of audits will be reviewed in completed." Quality Improvement Management Meetings (QIFMM) and addressed as A review on Del23/2010 of the facility's "Routing necessary. FA is responsible for ongoing Total Chlorine Teeting Log* for 02/15/2010 compliance with POC. revealed treatme facility stell falled to document Chiorine beding every 4 hours. The review revealed that for D2/15/20/10, the facility staff documented Chiteins testing at 0300, 0540, 1345 and 1740. The review further revealed that the facility staff wrote a time of 0945 on the log but failed to document any results, initials or eignatures for the Chilorina testing. The ravisw ravealed that the 0946 testing for Chlorine was not documented as completed. An interview with the facility's Biomed technician on 09/23/2010 at 1400 revealed that the total chlorine checks should be done every 4 hours with a 15 mirute extra window of time given. The inforview ravealed that some firms the nursing etan does not fully document on the water log

		ND HUMAN BERVICES MEDICAID SERVICES	1	and the state of t	FORM); 11/16/2010 1 APPROVED 1. 0938-0391	
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(V 195)	Continued From pag racord.	0 13	ĺν	196)			
	Bysiam Total Chloria 03(2010) revealed the "Lymona SL-MW To Chlorine teeting in its also revealed that if	iy's policy "Dally Water no Monitoring" (revision data nat the facility uses the nat Kit Colorimeter for the newter system. The policy ne stell instructions include lide Viewer oo their non-direct					
	"Holding the Octa-Side Viewer so that non-direct light enters the back of the comparator. Match the test tube color standard on the Octa-Side and read the porn value on the Octa-Side shadow that matches color of the test tube sample."						
	nurse #1 on 09/235 registered nurse dis system for total chill review revealed tha	sclisy's paracomel file for staff 2010 ravested that the 1 test the facility's valur ofte when needed. The n the registered ranse falled to led color biindness testing		•			
	rune #3 on 09/23/ registered hurse di system for total chi review revented the	active personnel file for stall 2010 reversed that the dust the facility's water often when needed. The at the registered purse taked to land color blindress teeling					
	facility edministrati nurses did not hav blindness tasting in interview revealed https://ex. interview.also.revo check the water of	DEPZ372D1Q at 1400 with the or revealed that these staff a key documented color in the peakonsel file. The no reason as to why these staff a key teading both. The called that these numbers do getern for children and should		٠			

PRINTED: 11/15/2010 FORM APPROVED

DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO D838-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES OCS) DATE GURNEY INTO PROVIDEROX PPIEROLIA

EPENTIFICATION PLANSER HOTOURTEHOOD SEPTEMBLE (SSG BTATEMENT OF DIPHOISINGES AND PLAN OF CORRECTION COMPLETED 化配准加热 10/26/2010 342627 STREET ADDRESS, CITY, STATE, 21P CODE NAME OF PROVIDER OR SUMPLIER DOOR SHAROON ASSITY CHARLOTTE BAST DIALYSIS CHARLOTTE, NC 28205 PROVADER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE PKLIA OCYMATELICAN GEAL Summary Statement of Depictancies (Each Deficiency Aust be preceded by Full Regulatory or Les (Dentifyring Information) ID PREPIX POXI VITORY DAT DEFICIENCY (V 198) Continued From page 14 {V 198} can read the color matches. tree vi 494.80(b)(1) (V 331) REPROCESSING-TRANSPORTATION & HANDLING 11 Reprocessing 11.1 Transportation and handling Persons handling used distyzers during transportation shall do so in a clean and sanitary manner melintaining Standard Precautions until V331 the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzara Upon inspection, it was determined that this that cannot be reprocassed within 2 hours should refrigerator was unable to maintain temperature within acceptable limits. The be refrigerated and not allowed to frozza. Other transportation and handling feates (such as reuse refrigerator has been replaced and verified to be within acceptable limits as of prolonged delays in reprocessing) not described 09/29/10. The CSS in-serviced the in this recommended practice shall be validated teammates on Policy 6-01-08 Reuse of and documented by the responsible party. Dialyzers with emphasis on dialyzer storage 9-30-10 in reuse refrigerator including the This STANDARD is not med see evidenced by: temperature required to be maintained Not reviewed onsite on 10/26/2010. between 36-50 degree Fahrenheit and actions to take if temperature is out of range.

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The findings include:

A review of the facility policy "Reuse of Dialyzers" (revision date 09/2009) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retaid batterial growth until reuse is begun. Refrigerated dialyzers may be stored for up to 36 hours prior to being reprocessed.

The refrigerator used for contaminated dialyzer

Based on facility policy review, observation,

rollingiator temperature log raview and siell

Inhibit bactorial growth before reprocessing.

Interview, the facility falled to ensure that petical

used dalyzers were adequately refrigerated to

Storaga is mainizined batward \$6-50 degrees

Everib:Whi12

resty fix for 654

Proper documentation of a single temperature to be recorded was also

reviewed. Facility Administrator or designee

weekly on each shift x3 weeks, and then the

will review the log everyday for 3 days,

log will be monitored daily by the charge nurse on an on-going basis. Results of audits

will be reviewed in Quality Improvement Management Meetings (QIFMM) and

addressed as necessary. FA is responsible

for ongoing compliance with POC.

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P.19

DEPARTMENT OF HEALTH AND HUMAN SERVICES GENTERS FOR MEDICARE & MEDICAID SERVICES STATISHENT OF DEFICIENCIES AND FLAN OF ODMESSTON 34227		0. Work	DMG	NETRUCTION	COMPLE	D: 11/15/2010 M APPROVED O, 6938-0391 MAEY MED R Z8/2010	
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(V 331)	treatment area rave patient used district religerator used for the thermometer raws 55 degrees Fu observation of the district ray the front of the front of the front of the front entire ray of the observation at one staff member temperature was a temperature in the	current at 1100 in the patient gled a total of seven (?) are inexte of the storage reuse atorage. Inepertion of yealed fluid the temperature himsheld at 1105. The control of the centigerator dudition relation was placed eligerator that was written as all the 55 degrees Fagrees F. "An interview during 1105 with a patient dialysis	**	391)			
	CO2010 revealed temperature limits degrees F. "The I revealed that the temperature characteristic documented temperature was degrees F. On Cotemperature was F. Review of the observation) revealed was documented to the content of the cotemperature was content of the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature with the cotemperature of the cotemperature with the cotemperature of the cotemperature o	/2010 of the refrigerator log for that the featity's refrigerator elected by "35 degrees if to 48 eview of the Cerzolio log staff had documented it a single teath had documented it is a single teather. Review for 09/01/2010 intellon by staff of the status to be a range of 32-38 excitation to the arange of the documented as 22-42 degrees log for 09/22/2010 (date of saled that the temperature immeniad as 30-48 degrees if. The registered mures in the teres on 09/22/2010 at 1155 or officerator has constantly been					

בוסוכנייו ועו חחז P.20

		ND HUMAN SERVICES MEDICAID SERVICES				FORM	11/15/2010 APPROVED 0898-0391
	F DEFICIENCIES CORRECTION	(KI) PROVIDERALIPLERICLA IDENTIFICATION NUMBER;	(XZ) MI A. BUSI	••	сомтистом	COLUMETE COLUMETE	ARY D
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NAME OF PR	OVIDER OR SUPPLIER	And the second s		FIRE	IT ADDRESS, CHTY, STATE, 219 COPE		Carre S III
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(Ya) di Profix Yas	(EACH DEPICIENC	rec dockarang in companion) A hatel ge byecstoto ba kait Vietesial ob dercipiene	PREPL YAQ		PROVIDENS PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOX CROSS PREPERSIES TO THE APPRI DANICIENCY)	RDBE	DATE
(V 331)	interview revealed "E in that refrigerator, th SOL"	mpetature readings. The verythre we put hot distyzars a tamparature geas in the	Na	81 }			1130000
(V 340)	UB/22/2010 at 1210 in aware of the elevate reprocessing storage revealed that the state the elevated temporary	ER GERM-90%	ĮV;	340)			-
	conclost capa diamini applicable, the her the germicide solution in hemodialyzer is concentration. The parts of chamic be dishilected and the dishilected and the with dilute bleach, with dilute bleach, with dishilecting the hermicide approved that does not advert dishyzer.	redialyzer shall be filled with an until the concentration in at least 90% of the prescribed all distributed dialyzers shall men papped with new or ecspa may be distributed for potalyzer, or with any other by the FDA as a distributed fill all distributed and the FDA as a distributed fill all distributed and the FDA as a distributed the			V340- The CSS in-serviced reuse teams policy 6-04-03 Cleaning and Disof Reuse Supplies with emphasis need to fully immerse the caps be germicide surface level. Facility Administrator will monitor submaps per policy for 7 days then oweek for 2 weeks, then monthly of audits will be reviewed in Quality of Management Mee (QIFMM) and addressed as nece FA is responsible for ongoing owith POC.	infection on the clow the hersion of mace a . Results ality tings essary.	10-15-10
	Not reviewed onsite Headd on facility po- staff kharylen, that snaure that reuse d	licy review, observations and scality's reuse stall failed to (alyzer caps were cleaned and apriote immersion in a assembling of the			,	N. Wangangan and A. Wangan	

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{V 340}	The findings include A review of the facility of Reuse day 2020 prevented and disinfer action for a minimal distriction for a minimal distriction for a minimal distriction on Deservation of Deservation of Deservation reveal (permisde) solution the dostational distriction of the dostational distriction of the dostation of the containers of the containers of the curface level. The when no staff was area. An interview on Of facility's reuse ten containers with the facility relevants that the trial theorytesy reveals in both containers	ity's policy "Cleaning and to Eupplies Policy" (origination and Policy" (origination and Precise Supplies will be care with a 1% periodic acid with a 1% periodic acid barrier adapters, extension barrier adapters, extension and than 24 hours prior to 22/2010 at 1006 in the facility's revealed that reprocessing used for patient reprocessing used for patient reprocessing yeardon for delinfaction. The statification for delinfaction. The statification was during a time present in the reprocessing present in the reprocessing allowed that the sape in both that he caps in both the caps in the reprocessing at the reprocessing allows the the caps in the reprocessing allowed that the sape in the delinfaction surface. Saled no reason as to why the sipers were rul below the		V 400)	V400-Physical Environment Members of the Governing Bodhave met to review the Statemer Deficiencies (SOD) and formula following Plan of Correction (P standards under the Conditions Infection Control (V110); Phys Environment (V400); and Gow (V750 that are not met as well standards, contain specifics of plans. The facility will ensure provides oversight and has sys place to see that the facility is and maintained to provide a stunctional and comfortable en and an effective infection cont is in place. The facility has be diligently working on correct issues cited since the survey, alarm has been installed as readdition the physical plant is require more time as they are dependent upon permits and availability as well the fact the work will have to be com non-operational hours. Thes been evaluated by an archite to move forward is in place. time frame to complete is 9-request your consideration in particular issues.	at of the the coordinate the coordinate the coordinate as other corrective that the GB terms in equipped fe, vironment real program ten mg all the The fire quired, *In ues will also vendor that much of pleted during e issues have et and a plan Estimated 12 weeks. We	12-21-0 for Fire system 12-31-10 for additiona l physical plant work
	This CONDITION Not reviewed one	l is not met as evidenced by: lite on 10/26/2010.)		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO. 0838-0391 CENTERS FOR MEDICARE & MEDICAD SERVICES CCO DATE SURVEY OCH MINTLINE COMELLINGLICH STATEMENT OF DEPOSENCIES AND PLAN OF CORRECTION (KI) PROVIDENSIPPLIENCIA IDENTIFICATION NAMES: COMPLETED AHILDHG B. WING 10/26/2010 342821 STREET ADDRESS, CITY, STATE, 20 CODE HAVE OF PROYDER OR SUPPLICE ALEEY HEMERIA WAY CHARLOTTE BAST DIALYSIS CHARLOTTE, NO 28205 PROVIDERE FLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSE-HETERENCED TO THE APPROPRIATE рај Срмучитон Бата Eunimany biatement of desiciencies (Each desciency wist be preceded by Fill Regulatory or loc destiny and hydrikhidin io Prefix Tag (中国) (1) TAG DENCIENCY V400 cont. Upon inspection, it was (V 400) **₹/ 400)** Continued From page 18 determined that this refrigerator was unable to maintain temperature within acceptable Based on observations as referenced in the Lile limits. The reuse refrigerator has been replaced and verified to be within acceptable Stafety Report of a completes investigation completed 00/30/2010, facility policy review. limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of observations, refrigerator temperature log review Dialyzers with emphasis on dialyzer storage 9-30-10 and staff interviews, it was determined that the in reuse refrigerator including the facility falled to maintain a physical environment temperature required to be maintained that decreased the potential risks to the besith between 36-50 degree Fahrenheit and actions and salety of patients, visitors and stall. The to take if temperature is out of range. Proper facility falled to have a empire barrier separating documentation of a single temperature to be the building into two separate smoke recorded was also reviewed. Facility compartments for a facility that is approximately Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 7600 square feet in size; falled to ensure that an emergency battery operated light located next to weeks, and then the log will be monitored daily by the charge nurse on an on-going the re-use room was in operation; falled to hold basis. Results of audits will be reviewed in the drills at unexpected times under varying Quality Improvement Management Meetings constitute each quarter in place of only (QIFMM) and addressed as necessary. FA is interviding staff on the fire thits; faith to entire responsible for ongoing compliance with an effective emergency evacuation route for the facilities patients, staff and visitors to include on POC. * Since the Facility is approximately 7,600 alternative fire exit route from incide the patient sq. fl. in size, the required Smoke fixe exit eno erit to tneve ent ni seat inemissit Compartmentalization will be accomplished plocked by fire, and falled to monitor and maintain by extending the existing non-rated partitions refrigarator temperatures to kilibil potential to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum bacterial growth in stored reprocessed (neuse) 1,140 S.F. in either compartment as well as chalyzors. The cumulative effect of these systemic the minimum exiting requirements. New 1 problems resulted in the facility's inability to *12-31-10 Hour Smoke/Fire Partition and 20 Minute ensure the health and safety of pallents, staff and for Fire Rated Doors will be installed at key additional visitors at the dialysis facility. locations in order to provide the needed physical pathway from exterior wall to exterior wall. plant work The findings include: Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer A. The facility falled to have a smoke berrier device* coparating the building grid out separate sunde compartments for a facility that is approximately This emergency battery operated light was 7600 square feet in size; feited to ensure that an repaired and operation verified by an outside 10/07/10 vendor 10/07/10. This will be monitored to emergency ballary operated light located next to ensure it is in working order during monthly the re-use morn was in operation; failed to hold facility audits. cont. pg 20 five drille of unexpected firmes under varying

PRINTED: 11/16/2010 FORM APPROVED OMB NO. 0998-0391 DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICARD SERVICES OCH DATE SURVEY

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	manufacturar's re-	perated in accordance with the commendations. is not met as evidenced by: iis on 10/26/2010,	- Annual Company of the Company of t	·			

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	refrigerator temperations refrigerator, the facility maintain refrigerator potential bacterial gradialyzers. This deficit patients participating at this for exposure to bacterial growth in the The findings include: A teview of the facility reprocessed within the designated rouse refrigerator used districts the refrigerator used to the facility reprocessed. The refrigerator used to the refrigerator used to the refrigerator used to the refrigerator in the parameter to inhibal potential brobservation feverated the reuse storage. The momental reveals of districts in the reuse storage. The momental reveals of districts of the reveals temperatures to inhibit with in stored reused entered reused entered program occident program occident program occident program occident program occident program occident program occident program occident program occident program occident program occident			Upon inspection, it was determine refrigerator was unable to maintain temperature within acceptable limit reuse refrigerator has been replace verified to be within acceptable limit objects. The CSS in-serviced the teammates on Policy 6-01-08 Reuse Dialyzers with emphasis on dialyz in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit to take if temperature is out of randocumentation of a single temperare recorded was also reviewed. Facil Administrator or designee will reveryday for 3 days, weekly on exwerts, and then the log will be madaily by the charge nurse on an orbasis. Results of audits will be requality Improvement Manageme (QIFMM) and addressed as neces responsible for ongoing compliant POC.	ts. The d and nits as of se of ser storage inted and actions age. Proper ature to be sity view the log ach shift x3 omitored n-going viewed in nt Meetings ssary. FA is	9-30-10	

PRINTED: 11/16/2010 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED OMB NO. 0958-0381 CENTERS FOR MEDICARE & MEDICARD SERVICES (X3) DATE SLAVEY (XX) MULTIPLE CONSTRUCTION AND PLAN OF OCERECTION
STATEMENT OF DEFICIENCES (X1) PROMPERATE PLICACLIA IDENTIFICATION NUMBER: A BURDING R 10/20/2010 342627 STREET ADDRESS, CITY, STATE, OF CODE NAME OF PROVIDER OR SUPPLIER TIME HURAHE FOR CHARLOTTE PAST DIALYSIS CHARLOTTE, NO 21206 PROVIDER'S FLAY OF CORRECTION
(SACH CORRECTIVE ACTION SHOULD BE
CROSS REFERENCED TO THE APPROPRIATE DATE (NETENN (NETENN) DUMLARY STATEMENT OF DEFICIENCIES ID PREFIX D(A)(D REGULATORY ON LSC IDENTIFYING WEOGNATION PREFIX TAG DENCHERCY Confinued From page 21 N 403) (V 403) An Interview during the observation of 1105 with ballett dialysis care stall mamber revenied that the temperature were 60 degrees F and that the temperature should not be that high. The staff member revealed that the temperature in the refrigerator had been alavated for a while and was not able to give specific dates or times. A review on D9/22/2010 of the refrigerator log for 100/2010 revealed that the ladility's retrigerator temperatura limita should be "35 degrees F to 45 degrees F.* The raview of the log for 09/2010 revealed that the staff had documented temperature chacks as ranges instead of a single documented temperature. Review of 09/01/2010 revealed decrementation by the staff that the refrigerator temperature to be a range of 32-38 degrees F. On 09/07/2010 the range of the temperature was documented as 32-42 degrees F. Review of the log for 09/22/2010 Ideas of observation) revealed that the temperature reading was documented as 30-48 degrees F. An interview on 09/22/2010 at 1350 with the facility administrator revealed that the temperatures of the retigerators should be monitored every day and that the exact temperature should be documented. The interview also revealed that the reuse signage refrigerator should not be greater than 50 degrees F. The Interview further revealed that the log used by the stall was meant for use for religerators containing medications, and that the limits on the ing were set for medication storage, instead of showing the highest degree of 50 F. 494.60(d) PE-EMERGENCY 你你叭 PREPAREDNESS-PROCEDURES

The dialysis facility must implement processes

PRINTED: 11/15/2010

DEPART	MENT OF HEALTH A	NO HUMAN BERVICES					FORM AF DIMB NO. D	
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1	the public. These e	morgancies include, but are				5'-0"ADA Accessible Sidewalk was installed to connect this new door	to the	
	not limited to, hig.	equipment or power failures	1 ,			and a norting area. After instal	led the	1
1	carb-related emen	sinces water amply	152	l		emergency evacuation plan will t	e updated to	
1	in the facility's Sec	THE REPORT WEST WAS IN ANY	*"			reflect the exit routes. *		- 1
1	in the pacitity 8ec	Bighilm wien.					has been	1
	· [1.			A copy of Certificate of Occupa- requested from the city of Charles	tte original	7
į	THE STANDARD	is not man as evidenced by	:			titant and neperal contractor.	Come	10-13-10
1	Not reviewed one	te on 10/26/2010.	1			forward any fire inspections will	be kept on	1
1	1					file in the facility. FA is respon	sible for	l
1	Based on phases	ulons, fire existy reports re-	new			ongoing compliance with POC.		
1	and stoff Interview	of the facility falled to ensure	n mil	1				
ĺ	affactive amorgo	not executation routs for the	.			*The facility has been diligently	v working on	
-	facility's patients.	staff and visitors to Incheso	ant I			and off the icenes cited St	nce the survey.	}
	allemanye ilio ex	it route from Inside the path the event of the one fire ex	n.			The fire custom has been instal	led as required.	}
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l	for hamorialvais	rentments. The facility				your consideration in these pa	TUCUM ISSUES.	
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1	four (4) walls of	the patient tradutions arou.	1110					
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CENTERS FOR MEDICARE & MEDICARD SERVICES TATEMENT OF DEPOSITION TO DEPOSIT OF DEPOSITION NUMBERS TO PROVIDENCE TO		A PUNL PRING	CONSTRUCTION	(X3) DATE SURVEY CONFLETED		
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(V 408)	visitors and staff. No observed in the part of the part facility's registared are revealed that way out of the part facility. The interview revealed that indicating by point interview revealed that the revealed that the revealed that the revealed that the revealed that the revealed that the revealed that the revealed that the revealed that the revealed that the facility and the transport of the conducted at the facility administrating and conducted at the revealed and conducted at	H incultural area for petionia, or other doors or exils were lent beatment area. 120/2010 at 1110 with the runs in the patient treatment that the their was only one ent treatment area at the ew revealed. "I have never of the ew revealed." I have never of the ew revealed. "I have never of the cone exit the ew revealed. "I have never of the cone exit the exit for the cone exit them." The limit to the cone exit the reatment area attents. The interview also accessful in the treatment area attents. The interview also facility administration did not what to do if thet one fire exit it with fine of other objects. The marchall reports on the marchall or on weather the report could be by when any fire marchall or on weather the facility to finy compliance. No ould be produced by the facility of the produced by the facility in a produced by the facility in a facility. 1 (actification of the produce of fine entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of the entering of t	(V 408)	1. The fire system has been instal required. 2. The Server Room's Plywood we removed. The currently non-rates be upgraded to Minimum 1 Hour Partitions, in accordance with the sketches. This will allow the 1 H Rating to run behind the plywoor material once reinstalled. 3. Since the Facility is approximate, it in size, the required Smole Compartmentalization will be a by extending the existing non-repartitions to the Roof Deck, as the attached Sketches. This will minimum 1,140 S.F. in either as well as the minimum exiting requirements. New 1 Hour Sm Partition and 20 Minute Fire R will be installed at key location provide the needed pathway fixed to exterior wall. Each dot include a passage latch system Rated Frame, and Closer devi 4. The Facility Bio Hazard Storage room will from the Corridor by upgradic extending the existing non-rate the roof deck as a minimum Resistant assembly. The Doc Bio Hazard Storage room an will be upgraded to a minimum	will be i Walls will Fire Rated e attached lour Fire d finishing mately 7,600 te eccomplished ated in I provide the compartment compartment soke/Fire anted Doors ans in order to orn exterior or will also and Hour Fire the in the facilities I be separated ing and ted partition to I Hour Fire to the facilities I be separated or will also orage room is orage room is orage room is orage room or or will also the facilities I be separated or and the corridor	*10-22- for Fire system
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(V 417)	acction, by Februal must comply with a 2000 ection of the National Fire Protein corporated by to this chapter). This STANDARD Not reviewed one Based on Charles and helwest 8:30 AM notes! 1) The Server Roundard interior finish on with the required area. 2) Facility is applicated and the server and there are building into two 3) The facility in self closing not the tested. 3) The facility in self-control of the re-united to t	ded in paragraph (e)(2) of this y e, 2009. The dailysts radity y e, 2009. The dailysts radity phileshis provisions of the Life Salary Code of the colon Association (which is colon Association (which is colon Association (which is colon Association (which is colon Association (which is not mot as evidenced by: It not mot mot as evidenced by: It not mot as evidenced by: It not mot mot mot as evidenced by: It not mot mot mot mot mot mot mot mot mot m	{V 417}	V417 cont. 5. This emergency battery operare paired and operation verified vendor 10/07/10. This will be measure it is in working order dufacility audits. 6. Fire drill was conducted on I will be conducted quarterly at times by the Facility Administratesignee. These fire drills will documented and evaluated in Control of the corridor and relocated to the storage area as of 09/30/10. Remonitored daily for 7 days the weeks then monthly for 3 mon Administrator or designee. *The facility has been diligen correcting all the issues cited survey. The fire alarm has be required. In addition the physwill require more time as the dependent upon permits and availability as well the fact it work will have to be comple operational hours. These iss evaluated by an architect an forward is in place. Estimat complete is 9-12 weeks. We consideration in these particulars and in the second of the secon	onitored to conitored ator or be conitored to conitored t	
N.	conditions. 6) There is startleby to the sky odf.	age in the front confider next to the is exit door, partially blocking that PR-RECEIVE SERVICES	ÍΛ	469)	•,	

PRINTED: 11/16/2010 FORM APPROVED

DEPARTMENT OF HEALTH AND HUMAN SERVICES CHAR NO. 0938-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES DOES DATE WITH ANY IXX) MULTIPLE CONSTRUCTION (X1) PROVIDER/GLEP/LIER/GLIA RTATEMENT OF DEFICIENCIES COMPLETED IDENTIFICATION NUMBER: AND PLAN OF COMPETION A. PAULDING R EL VONOS 10/26/2010 342827 BYRCET ADDRÉSO, CITY, GTATE, ZUP CODE NAME OF PROVIDER OR SUPPLIER 3204 SHAROM AMITY CHARLOTTE BAST DIALYSIS CHARLOTTE, NC 25209 PROVIDER'S PLAN OF CORRECTION [PACH CORRECTIVE ACTION BHOLLD BE CROSS REFUNEWED TO THE APPROPRIATE CHAPTETICAL STAG HECHTYLOUR ON TEO IDENTIFAIND IN CHANTLOW (EVOH DELYMENCA INTEL RE ENCOUNDED BA HAT THE STREET OF DESIGNED BY HAT 15 (run id Kraght Kraght Tag PREFFIX. DEPICIENCY (V 483) Confinued From page 26 (V 463) The patient has the right to-(12) Receive the necessary services outlined in the patient plan of care described in §494.90; This STANDARD is not met as evidenced by: Not reviewed anothe on 10/26/2010. Based on facility policy review, clinical record review, patient interview and sist interview, the facility failed to include the patient in the facility's interdisciplinary team annual meeting involving V463the patient's plan of cars for 2 of 7 nampled Policy #1-01-07 Patient Assessment and patient records (Patient #1,8). Plan of Care" was reviewed with the interdisciplinary team (IT) with emphasis on the need to include the patient/patient The findings include: 10-18-10 designee in the development of the plan of care unless the patient declines. Each patient A review of the facility policy "Patient will be given a written and verbal invitation Assessments and Plan of Care" (revision date to the care plan meeting as care plans 03/2010) revealed "The patient plan of care will become due. Patients will be asked to sign be completed by the facility's interdisciplinary invitation and note if they will attend. If team, including patient or personal representative patient declines the invitation the plan of and he signed by main members including the care a member of the IDT will review with patient or the patient's personal representative." them and ask for their signature on the plan. If the patient refuses to sign, this will be A raylew on 09/22/2010 of the open clinical noted in the record as well. FA/designee moord for patient #1 revealed that the patient was will audit all plans of care completed x admitted to the facility on 03/02/2008. The review 3months and then 10% of those completed quarterly. Results of audits will be reviewed of the clinical record revealed that an "Armus' in Quality Improvement Management Care Plant meeting was scheduled for Meetings (QIFMM) and addressed as Wednesday 03/03/2010 for the patient. A review necessary. FA is responsible for ongoing of the form inviting the patient was found in the compliance with POC. chnical record of the patient. The review of the form revealed that the facility's chelician signed the staff signature position and dated it 03/03/2010 but falled to obtain a patient signature that she would either attend or not aftend the meeting. The

PRINTED: 11/15/2010 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN BERVICES OMB NO. 0938-0391 CENTERS FOR MEDICAGE & NEDICAID SERVICES CO) DATE SURVEY DOD HALTIPLE CONSTRUCTION CON PROVIDENSIAPUEVOLA IDENTIFICATION NOVABERI COMPLETED STATEMENT OF DEPICIONCIES MINITURY A AND PLAN OF CORRECTION 10/20/2010 B. WING. 342627 OTHERT ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIES DZD4 SHARON AMIT CHARLOTTE, NO RESOL CHARLOTTE EAST DIALYEIS PROVIDERS PLAN OF CORRECTION GRACH CORRECTIVE ACTION SHOULD BY CROSS-REFERENCED TO THE APPROPRIATE DETICIENCY edurution BURNARY STATEMENT OF DEVICENCES (EACH DEFENENCY MEN'S BE PRECEDED BY FULL REGULATORY OR LBC (DESTITY 85 INFORMATION) cy XFEFIX (144) (1) (144) (144) (144) (144) (144) (144) (144) (144) (144) (1 (V 465) (V 463) Continued From page 26 space was not complated and taff islank but the staff member (distriction) had signed the staff eignature witness paction. No documentation was found where the patient received individualized care and a chance to perticipate in her plan of Cara maening. An interview with patient #8 on 09/22/2010 at 1040 during the facility tour and observation nevdeled that the patient had not been invited by the facility staff to her plan of care meetings. The interview revealed "I am usually teld they . happened, but the stall does not really invite me to attend. I would by to make it if possible. I usually sign the paper after the meeting happens." An interview with the facility administrator on 09/22/2010 at 1629 revealed that that this form should have indicated whether the pedent was going to attend or not, that the staff should not plan the form before the patient algread, and that V502-The Required documentation for the batteuts are runted to the Wesquits and narrally administration of PRN medication to include the reason given and effectiveness sign the form. 10-15-10 (V 502) 494,80(a)(1) PA-ASSEBB CURRENT HEALTH (V 502) of the medication was reviewed with RN's. Facility Administrator will monitor STATUS/COMORBIDS documentation of PRN meds once a week for 3 weeks then complete random audits The patient's comprehensive assessment must quarterly. Results of audits will be include, but is not implied to, the following: reviewed in Quality Improvement Management Meetings (QIFMM) and (1) Evaluation of current health status and addressed as necessary. FA is responsible medical condition, including co-mortal conditions. for ongoing compliance with POC. This STANDARD is not met as avidenced by: Hol raviewed onalts on 10/26/2010.

FORM CALESTOTICS OF PROVICE VERSOR COMMISS

Based on facility policy roview, clinical record

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Fundity to: 001854

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PRINTED: 11/15/2010 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO. 0838-0391 GENTERS FOR MEDICARE & MEDICAID SERVICES COMPLETED DOLINATE CONSTRUCTION (XI) PROVIDER/SUPPLER/11A DEHIFFICATION MANDER: STATEMENT OF DEFICIENCIES AND PLAK OF COMPECTION a bulldang 10/28/2010 B. Who 842827 STREET REPRESS, CHY, STATE, 21: COOR HAME OF PROVIDER OR SUPPLIER YTERA HUNAHS AUGC CHARLOTTE, NC 28208 CHARLOTTE EAST DIALYSIS PROVINCES PLAN OF CORRECTION

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CROSS ###IRPURICED TO THE APPRISHMATE. par Constitution Stag STRANKY STRYEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FILL REGIL ATORY OR LSC (DENTIFYING INFORMATION) XTERY DAY (学) DETICIENCY PREFIX V750 Members of the Governing Body (GB) have (V 502) Continued Prom page 29 met to review the Statement of Deficiencies (V 502) duraing staff administered 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 reassessment Conditions of Infection Control (V110); of the medication effectiveness. The review Physical Environment (V400); and Governance (V750 that are not met as well as rayealed that an 09/20/2010 at 1807 the patient other standards, contain specifics of was administered the medication corrective plans. The facility will ensure that "Acetaminophen 850 miligrame" by mount. 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 09/23/2010 bi comfortable environment and an effective 1400 with the facility administrator revealed that infection control program is in place, the patient exocid 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 ext bas beverainings any noticothem 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 plan is in place to also install separation 5. A raview on 09/20/2010 of the clinical record barriers 12" in height will also be installed for patient \$6 revealed that the patient was admitted to the facility on 07/21/2009 for chronic around the medication prep area to further hemodialysis. A review of the patient healment designate this space as a clean area. The Clinical Services Specialist (CSS) inahesis for 08/19/2010 revealed that the facility serviced the teammates on policy #1-03-11 nursing staff administered a FRN medication to "Changing Transducers Protectors" on the patient without any documentation for the 10/07/2010 with emphasis on the need to क्षित्रकार कार्य क्रुपार्था क्षेत्रकार कार्य क्षेत्र विश्वक्षक क्ष्या क्ष्य change and inspect wet and/or blood of the medication affectiveness. The review contaminated external transducers . Facility revealed that on Obviol2010 at 1443 the patient Administrator or designee will monitor team was soministered the medication "Loperamide everyday for 3 days, weekly on each shift.3 (anti ciames medication) 2 miligrams by moritiweeks, and then this will be included in the phier documentation was found regarding the monthly infection control audit going echninicianed medication and/or the effectiveness The CSS in-serviced the teammates on policy forward. 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 huleing staff for the meason 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. (人 688) 494.140(b)(3)(I)-(II) PG-CHARGE NURSE-12 MO 31 (C88) V) NURSING+3 MO DIALYSIS

PRINTED: 11/16/2010 FORM APPROVED

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DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO 0438-03:01 CENTERS FOR MEDICARE & MEDICARD SERVICES ATANAME ALTA (ET) DOST WITTING DOSTRACTES (KI) PROVIDENCIPALENCIA

PENTYICATION MUSER: STATEMENT OF CAPACIDACIES AND FLAN OF CORRECTION A HULDING R 10/28/26/0 342877 BIRDET AUDKEUR, CITY, STATE, DIP COLE NAME OF PROVIDER OR SUPPLIER STOL SHAROH ANALY CHARLOTTE, NO 28205 CHARLOTTE EAST DIALYSIS PROVIDERS PLAN OF CORRECTION (EACH CORRECTIVE AUTION SHOLLD BE CROSS-REPEARINGED TO THE APPROPRIATE pid) Piripiaten Patu Surrany higherent of denderges by fill regulatory or lec identifying nitcreation PREFIX TAG DXX ID DEFICIENCY) V750 cont. Facility Administrator or designee (V 686) will monitor team everyday for 3 days, Continued From page 30 **(√** 686) weekly on each shift x3 weeks, and then this The charge nurse responsible for each shift mustwill be included in monthly infection control (I) Be a repisioned nurse, a licensed practical nurse, or vocational nurse who meets the practice audit going forward. The CSS in-serviced the team on the requirements in the State in which he or she is importance of maintaining a clean 10-18-10 environment and ensuring trash is picked up employed: (8) Have at least 12 months experience in from the floor. Facility Administrator or providing nursing care, including 5 months of designee will monitor team everyday for 3 experience in providing nursing care to pallents days, weekly on each shift x3 weeks, and then this will be included in monthly infection on maintenance diabata; control audit going forward. Upon inspection, it was determined that this refrigerator was unable to maintain This STANDARD is not mot us avidanced by: temperature within acceptable limits. The Not reviewed origins on 10/26/2010. reuse refrigerator has been replaced and verified to be within acceptable limits as of Bessed on facility policy toviety and staff interview. 09/29/10. The CSS in-serviced the team on the facility falled to contensite a charge nurse for policy 6-01-08 "Reuse Policy" and reviewed each shift during homodialysis treatments. refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The The findings include: dispenser was found to be inoperative. Replaced batteries and verified operation. A review of the facility policy "Teammate Qualifications, Licensum and Adequals Facility Administrator or designee will monitor team everyday for 3 days, weekly on Teammete Staffing" (nevision date of 12/2008) *10-22-10 each shift x 3 weeks and then this will be revended "Cherge Nurse Standards: The charge included in monthly infection control audit for Fire unies tesboumple for each epill All pe a system going forward. registered nutses, licensed practical

PONIN CINE-2587 (CO-69) PHYXIIB VERBER CHICANA

amployed,"

nursely acadional nurse who meats the practice

An Interview on 09/22/2010 at 0900 with the facility administrator revenied first the facility does not criminally have a designated charge nurse during the hemodialysis beatments. The interview of engine quality and for ob avve paterns have an established charge nurse. All of the staff knows we have a mines that can handle things

and who to report problems to."

recubiomenta in each State in which he or she is

Breta (0:W80)12

FROMULT 101554

cont pg 32

The facility has been diligently working on

correcting all the issues cited since the survey.

The fire alarm has been installed as required.

A coupposition espect Lodge 31 of 24.

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HARLOTT	e fast dialysis	l l	Ci	ANNIOTTE NC 28209	rnos T	D(E)
and the same of th		TATELON OF GENCHAL	ø	PROVIDER'S PLAN OF CORRESPONDENCE AUTHOR SH		PYLE PUSITALITICAL PUBI
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				V750 cont. *The physical plant	issues will	
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	CONTRACT THE CONTRACTOR	have any formal or accidinate	l .	I avoid a relate to move it	Mann is in	}
	CHRIBE UNIBE			place. Estimated time frame to 9-12 weeks. We request your	consideration in	l
a swiffed		VERNANCE	(V 780	these particular issues.		1
(V 760)	Mary at 1 th and 1 th and 1		1	· ·		
		1	1	*The Server Room's Plywood	will be	1
	THIS CONDITION	le not mal as evidenced by:	ł	1 7th a merently DON-T	STECH AN WITH ALVEY	*12-31-
	Not reviewed one	He on 10/26/2010.	1	i - Joseph Annymin I D	Officerone	for
	Į	†		w www in accordance WIII	THE BUBOLION	addition
	Based on facility	policy review, observedone,	}	sketches. This will allow the Rating to run behind the plyy	wood finishing	physical
	Landimontal forms	aratura (DO REVICIA (1)(1) 3/144)		1 . * 3 roinctalle/i		ļ -
	I have demonstrated in Marca	E CHANDING DESTRUCTION OF THE PROPERTY OF	1	Since the Facility is approximately	mately 7,600 sq.	1
	A warmen from heady	WIFU IF INOVICE OVERSITY OF IT	Ì	l w r for the required SMO	65	
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ł	Infaction control	program; and fated to ensure	1	Deck as more	ed in the armon	~ .
1	that the feelity r	naintained a physical environment the potential risk to the health and		Sketches. This will provide 1,140 S.F. in either compar	tment as well as	1
1	that decreased	to, visitors and stall. The facility	1	mor pertina municipal	emens. Hen a	
1	salaty or pation	Bulloke periet sebicating the	l	Carolin/Fire Partingon	WILL YO YATERTOO	Ì
1	tations to they o	o soparata amoke comparimento	1	I 3d (little sygnet beard) he is	istalieg bi ved	
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1	aren Bland for 4 h	THE RESERVED COUNTY OF STATE O	1	Each door will also includ system, I Hour Fire Rated	Frame, and C)	ser
1	Programme and south	BU WALLEY MARKET (15) CHIMB AL	1	system, I Hour Fire Rates	i tumo,	
1.	1 the Harmon	PID BUDGED (MEDITALIS) IN THE TOTAL AND AND AND AND AND AND AND AND AND AND		device. The Facility Bio Hazard S	storage room is	ot
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PRINTED: 11/15/2010 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES OMB NO, DESILOSSI CENTERS FOR MEDICARE & MEDICARD SERVICES DOS) DATE SLEVEY DOD WATER COMPLETEDIN COMPLETED ON PROVIDENSUPPLIENCIAL (XI) PROVIDENCIAL (XI) PROVIDENCIAL PROVIDENCI STATEMENT OF DEFICIENCES AND PLAN OF CONFECTION A. DUKLDINO 40/28/2010 B. WAYG 342827 STREET ADDRESS, CITY, STATE, ZIP CODE Hame of Provider or Bupplich TIMA HUHAHE REST CHARLOTTE, NO 28208 CHARLOTTE PART DIALYERS CONSTRUCT CONSTRUCT CAN PROVIDERS PLAN OF CORPORTION (PAOH CORRECTIVE ACTION EMCALD RE CROSS-REFERENCIA TO THE APPROPRIATE DEPLEMENT) Bunmary Statement of Deficiencies (Each Deficiency Ment be Preceond by Pull Regulatory or Lec (Dehtifying Information) PREFIX OH) DO PREFEA TAG V750 cont. This emergency battery operated (V 750) light was repaired and operation verified by Continued From page 32 (V 750) blocked by fire; and failed to monitor and maintain an outside vendor 10/07/10. This will be monitored to ensure it is in working order rehigerator temperatures to inhibit potential 10/07/10 parterial browth in atored reprocessed (reuse) during monthly facility andits. Fire drill was conducted on 10/1/2010 and dialyzare. The cumulative affect of these will be conducted quarterly at unexpected systemic problems resulted in the locality's times by the Facility Administrator or inability to ensure sels and effective cone for all designce. These fire drills will be documented dialysis pediants, and the salety of stell and and evaluated in QIFMM. Storage items have been removed from the visitors. corridor and relocated to the records storage area as of 09/30/10. Route will be monitored The findings include: daily for 7 days then weekly for 2 weeks then A. For fliddings causing the Candillon for infection monthly for 3 months by Facility Administrator or designee. Control to be not mal, see V110 and its sesponeted tage. reprocessing; and falled to Please review the attached MSDS Sheet for ensure that a clean area was designated to 09/30/10 Renalin, Section 16 for Other Information. prevent palential cross contamination of The NFPA Flammability Classification for medicational supplies and for staff to prepare, this chemical is 0, thereby qualifying as a low handle and alore medications to be administered hazard in accordance with NPFA 101 Section to patients; tailed to change and inspect 6.22.2. contaminated external transducer protectors in 2 of S observed between with wat at plood linged NFPA 101 Section A6.2.2.4 for High Hazardous contents are described as the external transducer protectors; falled to ensure that staff empamanted standard injection control following "contents include occupancies where flammable liquids are handled or used biacamplies by deaning adribinary ampaces with 12-31-10 or are stored under conditions involving removal of treah from floors in the patient for possible release of flammable vapors; where additional treatment area, appropriate cleaning card grain dust, wood flour, or plastic dust, physical disinfacting of various clamps used in patient aluminum or magnesium dust, or other plant treatments and cleaning blood stains from work explosives are produced; where hazardous work surfaces during patient nemodialysis treatments; chemicals or explosives are manufactured, felled to create that patient used distyzers were stored, or handled under conditions producing adequately reliassated to inhibit backerial growth flammable flyings; and other situations of paloia sabinceagual and falled to autina first similar hazards." patients had a supply of paper towels available at cont pg 34 handwashing sinks in the palient treducent area. -Cross refer to 494.30 infection Control Condition: Tag V0110

MINING CHARLESTICK SET PHENICUS VERSIONS CHARGES

B. The facility falled to maintain a physical

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n contravion sheet Proge 33 of 34

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CI	TOMA	ie east dialysis			CH	ARLOTTE, NC 28205			
	CX4 ID PREFIX PAG	MANUAL PROPERTY OF THE PROPERT	TATERANT OF DURNINGES LY MUST BE PRECEDED BY FULL LEC IDENTIFYED RIPORMATION :	PROFE TAC	4X	PROVIDERS PLAN OF CORRECT CACH CORRECTIVE ACTION SHOULD BE THE APPROVIDER OF THE APPROVIDER OF THE APPROVIDERS OF THE APPROVINCE OF THE	1.D bbz }	DELE CONSTALION D(E)	
	(V 750)	Continued From pare environment that can the health and unfoil but he health and he health	is 33 creased the potential lisk to by of patients, visitors and led to have a smoke harder ling and two separate smoke facility that is approximately area that is 1 how in retering twelve, area that is 1 how in retering twelve, inhibited when storing twelve, inhibited of dalyzers); failed to regency battery operated light reuses from was in operation; the su unexpected times under each quarter in place of only the line drift; failed to minimize the exit door, failed to anaural and executed in the facility next to the stori and visitors to include and noute from inside the patient the event of the one fine exit maintain and talled to monitor and maintain and reprocessed (reuse).	W	760)	V750 cont. *The Storage Room is classified a Hazard area in accordance with S 6.2.2.2. Due to this, NFPA 101 St will require this area as well as the Closet to be upgraded to the Mini Hour Fire Resistant Rating. This accomplished by upgrading the e Non-Rated Partition and Doors a the attached Sketches. The Governing Body will meet to ensure compliance with POC compliance to the POC will be a during monthly QA meetings at the Governing Body no less tha annually. The Facility administ representing the GB will be resensuring implementation and o compliance with this POC.	ection section 8.4.1 e l'anitor's imum 1 will be xisting coording to monthly x 3 . Further reviewed and reported to n semi-tator (FA) ponsible for	*12-31-10 for additional physical plant work	
			:						

EPARTMI	ent of Health ar	ND HUMAN SERVICES	:		and the state of t	FORW	: 11/16/2010 APPROVED 09:38-0391
ENTERS LYBROUT OF D PLAN OF O	DEFECTION COME	MEDICALD BERVICES [X1] PROVIDENSIPPLEMOLY IDENTIFICATION NUMBER:	A BUILD	1143	BTRUCTION DI - CHAROLOTTE EAST DIALYGIS	COMPUT	rd R
		342527	D. WANG			1013	18/2010
	ACCES ON BUPPUEN	A Control of the Cont		\$50£561	landes, chy, etaye, zip code Landia allity		
CHARLOTT	PEAST DIALYSIS	· ·		CHARL	OTTE, NC 28205	ernival	(Clo
CXA ID PHEFIX TAB		TATEMENT OF DEFICIENCES OF MUST BE PRECEDED BY YELL R LEG IDENTIFYING DIFFORMATIONS	PREP TAG		PROVIDENTS PLANOF CORR (BACH COURRECTIVE ACTION & CROSS-PRIFEOSIORIO TO THE AF DEFICIENCI)	HONGLIN BY	DATE
(¥C 014)	416.44(b)(1) LIFE 6	BAFETY CODE STANDARD	lk	014)			
	and hard hearing	nto and ceilings of exis, and exit access turnishing are as Class A. B. Of C).			·		
(K 02	Based on observation between 8:30 AM noised. 1) In the server replaced of the server replaced with 1 "Theore with 1 "Theore with 1 or or alsewhere in this Clare C, shall be from NFPA 255, Surface Burning Materials." 418.44(b)(1) Lift Hazardous area the building by 1 fine realstance r with partitions a with an automa steps are provided a particular system. This STANDAL Based on observation, and the sample of the sampl	is not met as evidenced by: ition on Thursday 0/30/10 and 11:00 AM the following was own the wells were covered with be to insure that the walls are in NFPA 101 Chapter "10.2.3.1 elike this to tequired Code to be Class A, Class B, or classified based on test results Standard Method of Test of Characleristics of Building IE SAPETY CODE STANDARD is tepperated from other parts of into barriors have at least one hour alting or such areas are enclosed and doors and the enes is provided file sprintiples ayaren. High hazard ded with both file barriers and mes 38.3.2, 39.3.2 RD is not met as evidenced by: revalion on Thursday \$/30/10 AM and 11:00 AM the following was likes a Bio Hazard Storaga Room		{K (358)			
4K	032) 418.44(b)(1)	are not self closing of fire rated. LIFE SAFETY CODE STANDARD		ik osz			7001 120

Any denoting sistemant energy with an asserted (*) denotes a deficiency which the instantion may be consisted from consisting providing it is determined that other assertances of the provide the factors are disclosed to the samples of the provide this projection in the passers. (See including the passers of the factors are disclosed to the samples of the provide this samples and place of comparison are disclosed in the factors of the factors of the passers of the pas

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		\$42827	H. VVIO			10/2	8/2010
•	VIDER OR SUPPLIER	geldt.		2204 23	xorese, city, state. 24 code Haromaraty .otte, NO 28206	When	
(XOTO PREFIX TAO	INFACTAL PARTITIONS	A TRE IDENTIFATION PROGRAMMY CAN WRITE BE BESCHING BY LITT LYLENGIAL DE DESCRING BY LITT	PREF TAC		PROVIDERS PLAN OF CORRECT (EACH CORRECTIVE ACTION BHC CROSS-PREFERENCED TO THE APPL DEPOSITION	an dee	DYIN CONSUMUNI CONSUMUNI
(K 033)	other, are provided	gs 1 collect remote from each for each floor or line section of 2.4.1, 21.2.4.1, 7.5.1.4	ſκ	032)			
(१८ ०५६)	Beaed on observation 8:30 AM noted. 1) There is storage tobby that exits to 418.44(b)(1) LIFE Enveroency illumit	is not met as evidenced by: Ison on Thursday \$13010 and 11:00 AM the following was In the front confdor next to the the cide exit door. SAFETY CODE STANDARD nation to provided in ancordance 20.2.9.1, 21.2.9.1		K 046}			
ţK DS	Based on observed the between 8:30 AM noted. 1) The battery of by the re-use root 415.44(b)(1) LIF Plus drills are the verying condition.	b is not met as avidenced by: atton on Thursday \$130/10 it and \$11:00 AM the following was consider amongoncy lights located on did not operate when tested. E SAFETY CODE STANDARD Id at unexpected times under the, at least qualitative on each shift. If with procedures and is aware at of established routing.		{K 050}			
	based on obse between 8:30 /	ID is not mat as evidenced by: nvation on Thursday 8/30/10 IM and 11:00 AM the fellowing was n-services the staff on the drills			3	North Control of the	sation sheet Fegu

ENTERS	FOR MEDICARE & DEFICIENCIES ORKECTION	ID HUMAN SERVICES MEDICAID SERVICES AN PROVIEW BY THE ROLL IDENTIFICATION HUMBERS	A HUILDING	DISTRIBUTION US - CHARLOTTE EAST DIALYSIS	COMPLET	r R
	•	342827	R, WING	to part the second seco	184	10x3010
	MIDER OF SUPPLIER THE EAST DIALYSIS	And the second s	3204	ACCHESO, CHY, STATE, 219 CODE MILOTTE, NG 28206		
(X4) ID PREFIX TAIS	STANAAT S	TATEMENT OF DEPICENCES OF MUST BY PRÉCEDED BY FULL RESC EMITTY VIOLENCES	PREFIX TAB	PROPORTE STANCE TO THE ASSESSMENT OF THE ASSESSM	SHOUND BE	DELLA COMMUNICATION
N/ OFM	Continued From ba	ks b	(K 050)			
(K 115)	and quanto in place u semil bakacpanu	or inciding fire dills at Inder verying conditions, SAFETY CODE STANDARD	[K 115]		. •	
	at least two emoke barriers having at t rating. Doers in an positive latcher. Di than 1% inch thick aquivalent. Vision fored wire class in	care facilities are divided into compartments with emoke set 1 hour line reclatance with emoke set 1 hour line reclatance with parties are constructed of not less and bonded core wood or panels are provided and are of niled to 1,295 eq. inch per 1,20,3,7.2, 20,3,7.3, 21,3,7.1,				
	Bared on observe between 8:20 All noted. 1) The facility is and the facility of the facility	i is not mat as evidenced by: alten on Thursday 9/30/10 I and 11:00 AM the following Wea approximately 7600 ag. il. is size opes not have a smoke bander of this two smoke				

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EPARTMENT OF HEALTH AN	D HUMAI	REMEDICALD CERTIFICATI	ON AND TRA	NSMITTAL		Facility ID: 001554
EPARINENTO	MEDICAL	REMEDICALD CERTIFICATION OF THE COMPLETED BY THE	STATE SURV	EY AGENCY		
\$\frac{1}{2}\text{\$\ext{\$\exitt{\$\ext{\$\exitt{\$\ext{\$\exitt{\$\exitt{\$\exit\\$}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}	PARTI-I	O BE COMPLETED 27	ΓY		4. TYPE OF ACTI	
ICARE-MEDICAID PROVIDER NO		3. NAME AND ADDRESS OF FACILITIES (LS) CHARLOTTE EAST DIALYS	SIS	•	1. Initial	2. Recertification 4. CHOW
- In COS		(L4) 3204 SHARON AMITY		***************************************	3. Termination 5. Validation	6. Complaint
(L1) 342627 2.STATE VENDOR OR MEDICAID NO.		(L5) CHARLOTTE, NC		(L6) 28205	7. On-Site Visit	9. Other
(L2)			v 09	(L7)	8. Full Survey A	fier Complaint
5. EFFECTIVE DATE CHANGE OF OWN	ERSHIP	7. PROVIDER/SUPPLIER CATEGOR	09 ESRD 13	PTIP	2. 740	
		01 Hospital 05 HHA	0, 202	CORF	FISCAL YEAR E	IDING DATE (L35)
(L9') 10/01/201	0 (L34)	'02 SNE/NF/Dual 06 LAB		ASC	12/31	
6. DATE OF SURVEY 10/01/2018 8. ACCREDITATION STATUS:	(L10)	03 SREINFIDERIAL	12 RHC 1	6 Bospice	12/21	
8. ACCREDITATION Date of TIC 1 TIC 2 Court		04 SNF				· .
2 AOA 3 Other		10.THE FACILITY IS CERTIFIED.	\S		ena - Tallening Reg	nirements.
11. LTC PERIOD OF CERTIFICATION		10.THE FACILITY IS CERTIFIED	And	Or Approved Waivers C	1 6 Scope	of Services Limit
		A. In Compliance With Program Requirements		2. Technical Personne	7 Medic	al Director
From (a):		Compliance Based On:		3 24 Hour RN 4, 7-Day RN (Rural S	ENF1 8. Parien	r Koom Size
To (b):	(L18)	1. Acceptable POC	-	5. Life Safety Code	9. Beds/	Room
12. Total Facility Beds 4 Stank	2 (21)		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		(L12)	
	(L17	X B. Nor in Compliance with Property Requirements and/or Appli	ed Waivers: * (Code: B*	(1)	
13. Total Certified Beds Althors	フ			ACILITY MEETS		
, DEEAKDO	X/N		1	36) (e) (1) or 1861 (j) (1)	_ (L1:	3)
14. LTC CERTIFIED BED BREAKDOV	 19 S	NE ICF IMR	1 38	(9) (a) (1) or 160x (1) (1)	•	
18 SNF 18/19 SNF	19 3.	141	}	•		
·	(L3	(L43) (L43)	. \			
(L37) (L38)	11	es)	ON DATE:			
STATE SURVEY AGENCY REN	arks (if ai	PLICABLE SHOW LTC CANCELLATI	On Division			
				R. STATE SURVEY AG	ENCY APPROVAL	Date.
~e Attached Remarks		Date:	1 18	R. STATE SURVEY	· .	1.1
17. SURVEYOR SIGNATURE			Ì	(1)~- (:	while 1	1/2/2010
1/0/mi	a an	10/26/2010	(L191 -		<u> </u>	NCV
- Wagn III		THE NY HOEA	REGIONAL	OFFICE OR SING	LE STATE AGE	SNCI
PA	RT II - TO	BE COMPLETED BY HCFA	2022	21. 1. Statement	of Financial Solvency	(HCFA-2572)
		20. COMPLIANCE V RIGHTS ACT:	MITH CIAM	2 Ownership 3. Both of th	ACCOUNTED THE FOR DIRE	losure Stmt(HCFA-1513)
19. DETERMINATION OF ELIGI	DILLIA A	RIGHTS ACT	•	3. Both of th		·
X 1. Facility is Eligible	to Participate					
2. Facility is not Elig	ible	(L21)	<u>'</u>			(L30)
		A CHEENPAI 24, L'IC AC	REEMENI	26. TERMINATION	ACHON:	INVOLUNTARY
22. ORIGINAL DATE		. WAKETADMA	G DATE	VOLUNTARY	_00_	05-Fail to Meet Health'Safety
OF PARTICIPATION	BE	GINNING DATE ENDIN		01-Merger, Closure		06-Fail to Meet Agreement
01/30/2003				02-Dissatisfaction W/I	Reimbursement	
		41) (1.25)		03-Risk of Involuntary	Termination	OTHER 07-Provider Status Change
(L24) .	27, Al	TERNATIVE SANCTIONS		04-Other Reason for W	lithdrawal	00-Active
25. LTC EXTENSION DATE	A.	Suspension of Admissions	4)			QQ-AGUVG
		(1.74-				
(1.2)	7) B	Rescind Suspension Date:	151	,		
		(1.4		30. REMARKS		
		29. INTERMEDIARY/CARRI	ER NO.	50, 10,000		
28. TERMINATION DATE:		00101		.		
		•	(L31)		•	
	(I	28)				
		32 DETERMINATION OF A	PPROVAL DATE	•		
31. RO RECEIPT OF CMS-15	39	32. DETERMINATION OF A	PPROVAL DATE. (L33	DETERMINAT	TION APPROVA	L

DEPARTMENT OF HEALTH AND HUMAN TOVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE ...EDICATO CERTIFICATION AND TRANSMIT: ...L PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY ID: WB51

racing 1D, 661554

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 enuncation survey was conducted onsite deptember 22-october 1, 2010. As a result of the survey in conjunction what a life dately code survey an immediately 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 II at 1250 based on compliance with a fire alarm system An onside tonow up was conducted at the facility October 20, 2010. The State Agency recommended removal of the 2 at 250 based on compnance with a fire at an 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 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 an place. The Civis Danas regional office was normed of the recommendation Trie continuous in 494.30 infection Contout 494.50 Pily Governance were not recommended to be in compliance based on 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 HUM. (X3) DATE SURVEY CENTERS FOR MEDICARE & MEDICAID SERVICES (X2) MULTIPLE CONSTRUCTION COMPLETED (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES IDENTIFICATION NUMBER: A BUILDING 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 DATE CROSS-REFERENCED TO THE APPROPRIATE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (X4) ID **DEFICIENCY**) REGULATORY OR LSC IDENTIFYING INFORMATION) TAG PREFIX TAG {\O00} : {V 000} INITIAL COMMENTS 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 (X6) DATE (including vials containing diluents), prepare 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.

		CENTERS FO	EDICARE & MEDI	CAID SERVICES
ARTMENT OF HEALTH AND HUMA	INS ICES	TRANSMITTA	بد	ID: WB31 Facility ID: 001554
ARTMENT OF HEALTH MEDICA	RE/MEDICAID CERTIFICATION AND TO BE COMPLETED BY THE STATE	SURVEY AGEN	CY	
PARTI-	TO BE CUMPLETED 2		4. TYPE OF ACT	
3 110	3. NAME AND ADDRESS OF FACILITY (L3) CHARLOTTE EAST DIALYSIS		1. Initial	2. Recertification 4. CHOW
EDICAREMEDICAID PROVIDER NO.	(L4) 3204 SHARON AMITY	20205	3. Termination 5. Validation	6. Complaint
342627 ALL VENDOR OR MEDICAID NO.	(L5) CHARLOTTE, NC	(L6) 28205	7. On-Site Visit	9. Other
•	(L5) CHARLOT ZZ,	<u>09</u> (L7)	8, Kuli Survey	After Complaint
2) FFECTIVE DATE CHANGE OF OWNERSHIP	7. PROVIDER/SUPPLIER CATEGORY	13 PTIP		
	01 Hospital US HEIA	14 CORF	FISCAL YEAR E	NDING DATE: (L35)
(L34)	92 SNE/NE/DUM	15 ASC	12/31	•
DATE OF SURVEY 10/01/2010 (L10) ACCREDITATION STATUS: (L10)	03 SNF/NF/Dictinct 07 X-Ray 08 OPT/SP 12 RHC	16 HOSPICE		
a vr dited	D4 214x			•
2 AOA	10.THE FACILITY IS CERTIFIED AS:	T home to a second W	Vaivers Of The Following Req	uirements:
LTC PERIOD OF CERTIFICATION	A. In Compliance With	2. Technical		
From (a):	December Removements	n of Wome R	N	cal Director at Room Size
	Compliance Based On:	4. 7-Day RN	(Rural SNP) a, rand	Room
	8) Acceptable POC	5. Life Safet	ty Code	
2. Total Facility Beas Stations 16 (LI	X B. Not in Compliance with Program	. + Code: B*	· (L12)	
3. Total Cortified Books Stations 16 (L)	7) X B. Not in Compliance with Fuguara Requirements and/or Applied Waivers:			i
3. Total Commences 712 ((0.5		15. FACILITY MEE	TS -	
14, LTC CERTIFIED BED BREAKDOWN		1861 (c) (1) or 186	er (1) (1): (T)	15)
	SNF ICF IMP.	1		
18 SNF · 18/19 SNF 19	•		•	
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SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

blk ting 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 intraining 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 gestions 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 of picture (1838-0583), Washington, D.C. 20503.

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SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

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Total SA Supervisory Review Hours.....

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Total SA Clerical/Data Entry Hours....

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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: WB3111

Facility ID: 001554

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SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

blic reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and 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, searching existing existing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, searching existing existing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, searching existing existing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, searching existing exi

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SURVEY TEAM AND WORKLOAD DATA

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Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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1			1	plan is place to install sep	aration barriers 12" I	^a
1	I a t. with a box current P	NO TRANSPORT PROTECTION OF THE PROPERTY OF THE	1	height around the medical	10H bich men 10	
1	දෙන්තු) කුසේවියේ	to days a patients.	1	further designate this space Plexiglas barriers will be	nisced to provent	
1			1	material cross contamina	tion.	1
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1			1	0 satsment art harman i	n policy #1-03-11	10-15-1
1	A. The facility	falled to ensure that a clean area	1	144 hanging Transducers	rotectors" on	10-12-1
1	AST GORBINGS	to prevent potential	1	10/07/2010 with emphas	is on the need to	
1	CLOBB-COUPELIN	ration of madicadams/supplies and page, height and store medications		change and inspect wet a	movor blood handliners Facility	1
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ļ		o 494,300,300 (NY) Infaction Control -	1		be included in	.]
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1	to the section	start talked to change and inspect	1	LOALOR "I Hillying Vass	ular Access Clamps	1
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1	nari kumehna	sprior brojugates	1	and distinfacting of vac	miar clamps, Facility	' 1
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1	-Cross refer	to 494.30(a)(1)(1)Infaction Control -	1	minumed by for 3 days W	eckly on each shift x.	3
- {	Teg V0120		1	handen and then this w	ill be included in	1
1			{	monthly infection con	rol audit going forwa	erd.
Į	O. The feel	by falled to ansage that staff d standard infection control	1	cont pg 3		
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FORM APPROVED TREE-SCAN ON BAYO DEPARTMENT OF HEALTH AND HUMAN SERVICES DESIGNATE STIPLEY CENTERS FOR METACARE & MEDICAID SERVICES DESTRUCTIVES OCKRETICAL COMPLETED DENTIFICATION AND SERVICE OF THE PROPERTY OF T STATEMENT OF DETICIENCES AND PLAY OF CONSECTION DELLES A 40/01/2010 e vans 343937 STREET ADDRESS. CATY, STATE 215 COOK MEN HORAHB POR PRINCIPAL RESOLUTION TO THE CHARLOTTE NC 28206 pop pop PADADERS MAN OF CONSECTAN GACH CORRECTIVE ACTION SHOULD BE CHOSE REFERENCES TO THE APPROPRIATE CHARLOYTE FAST DIALYSS PATE ESTREMENT STATEBURY OF DATACHOUSE BY FULL EACH DEFICIENCY NATE OF PARCECES BY FULL STREAMS STATEBURY OF DATACHOUSE DEPORT V110 cont. The CSS in-serviced the team on V.1101 the importance of maintaining a clean environment and ensuring trush is picked up Continued From page 2 precentions by cleaning equipment authors with from the floor. Facility Administrator or temoval of treat from floors in the patient designee will monitor team everyday for 3 प्रस्थानामा शहर स्कृतिमानां देशकांतेषु वार्ष days, weekly on each shift x3 weeks, and then desiried by vertical dempt used in palent this will be included in monthly infection hew near tracts bearing priorite trans work control audit going forward. surfaces during patient harmodalysis hardments. Upon inspection, it was determined that this refrigerator was unable to maintain -Cross refer to 494.30(a)(4)(f) Infection Control • temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as pf Tet V0122 09/29/10. The CSS in-serviced the team on D. The facility falled to excuse that patient used policy 6-01-08 "Reuse Policy" and reviewed districts were adequately refrigerated to which refrigerator log with temp ranges. Paper towel bactarial growth before reprocessing dispenser at patient prop area is a battery 10-18-10 powered hands free style dispenser. The -Cross refer to 454.EX/bX1/Reuse of dispenser was found to be inoperative. Hamodistyzers and Bloodines - Tag V0331 Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will E The facility failed to monitor and maintain monitor team everyday for 3 days, weekly on religerator immematures to inhabit potential each shift x 3weeks and then this will be pacients diamin in stoled tebloccared (ususe) included in monthly infection control audit going forward. Results of audits will be diplyzens. reviewed in Quality Improvement -Cross raise to 484,50(b) Physical Environment-Management Meetings (QIFMM) and addressed as necessary. FA is responsible for Teg V0403 ongoing compliance with POC. F. The facility falled to ensure that patients had a The Governing Body will meet monthly x 3 supply of paper towers available at handwashing to ensure compliance with POC. Further compliance to the POC will be reviewed sinks in the patient treatment area. during monthly QA meetings and reported to -Cross refer to 494.30(a)(1)(i) infection Control the Governing Body no less than semiannually. The Facility administrator (FA) representing the GB will be responsible for ABA. SON NY IO IC-SINKE AVAILABLE Teg V0114. cusuring implementation and ongoing compliance with this POC. A sufficient number of sinks with warm water and som should be available to facilities hand weephing. This STANDARD is not met as evidenced by: 45 Po E agus Hears nothuranco H FACILITIES TO 1884 Kenerili, P. Paris

PARTMENT OF HEALTH AND ENTERS FOR MEDICARE & M PRIME OF DEPOISONS PRIME CONSISTENCY	HUMAN SERVICES EDICAN SERVICES XII PROVANIASUPHURNIA USEMU CATKON MARRET: 347877	e men Peret Oxivey)\$13 3	BTRUCTON	CASH NO. OF COMPLETED	
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PRINTED: 10/09/2010 FORM AFPROVED CMB NO. 0668-0801 DEPARTMENT OF HEALTH AND HIBANA SERVICES CENTERS FOR MEDICARE & MEDICARD SERVICES CONSTELLED ba) with the constantion (A1) LUCAIDEASE AITERCITA ELVIDERAL OF DELICION NO LINE OF CONTROL enaltyang w 40/01/20/10 r was STIGGET ADDRESS, CITY, STATE ZIP CODE 348627 NAME AND PARTY OF PARTY HALE OF PROVIDING CO. BUPPLES CHAPLOTTE, NC 38201 PROMORREM AND CORRECTION (EACH COORECTIVE ACTION BROAD BE CROSS-RETENENCED TO THE APPROPRIATE COLUMN TOWN CHARLOTTE BY 24 CHYTARE EURANDY STATEMENT OF DEFICIONES BY FULL REGILATORY OR LEG IDENTIFYING BY CHILATION PREFIX TAG DOLOGOU) COM XTHING V117 Continued From page 4 should be clearly suparated from contaminated stead shield need amblica and advantaged are handled. Do not handle and store medications or that subsides took editionally of plood analyses are clear emblies in the ento or at addressy man in the entone was the manager to the contract of the contrac handled. When multiple close medication viels wie used (kuchkling visits containing dissents), prepare individual patiers dozes in a clean (contracted) area many from thely als stations and deliver separately to each patient. Do not carry multiple goes usedicated right total station to station Do not use common medication carte to deliver manications to pulsade, il have nie used to daliver medications to individual pastents, they what he clasived person balanta Eliminated the use of a medication cart and the medication station has been relocated. A THIS STANDARD Is not med as evidenced by: Resed to facility policy review, characteristics and state interview, the facility failed to ensure that a designated clean area was created for medication prep on one of the island nurse 10-18-10 stations in the treatment area 09/29/10. A clean area was designated to prevent potential plan is in place to also install separation close-conferquegation of tractications/supplies and barriers 12" in height around the medication for staff to propers, hands and store medications prep area to further designate this space as a to be exiministated to patients. FA is responsible for ongoing compliance cican area. with POC. The findings include: 1. A neview of the facility's policy "Infection Control for Dialysis Families" (revision date 03/2010) revealed "Clean areas should be dealgnated for the preparation, handling, and storege of madicalons and unused supplied and equipment. Clean stoss should be clearly separated from contaminated areas where residing and ediferent am hanged Chaevedon on 09/22/2010 et 1025 in tre patient If positive and break page 5 cf 14 Feday Ex COTEM PURE IDIVERNIT

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DEPOSITION PATE MOLECULAR ACALESTAN REGISTAL OF PET INSULATION DESCRIPTION OF STREET BY LITT Grath desertation, what are electrical by Litt entity and subsection of description Ð V 117 Continued From page 6 Obvervation on Objection of 1650 revealed for medication preparation area used by the facility. Life chackaged tensoled gay an hebsingou alon is located on a mussing can (Cashanau forgraph with the medication visits located on top of the cart with a cleared man right, Observation revealed the medication preparation area (carl) was stationary and located directly basicio of the furthly's designated herekeening sink for patients A Mark their access sites Openintegot tenesing that the tacilly had a clan on the sink that was Million St. al. upable unit Ascal Bress Piss. located at the base of the dak. The observation prend used the foliated out rest postorou south Mar busesus to blansus bosougias capes contamination during medication preparation. Ho rabatale close area was cheeved for puteril medication preparation. An interview on 09/22/2010 at 1555 during the opservation may the paylible ledispared in the प्रकाशनेत् क्षमा ग्रम द्वार अवस क्रम साम्ब स्रोक्त है क tacable untajud etaji babbasae balanje medications. The interview revealed that she never trought of the potential splanking of water from handwesting sink on the clean medication properation area. An interview on 09/22/2010 of 1660 with the facility's administrative staff revealed that the potential cross contamination has to be corrected and that lack of space is a problem at the facility. 484.30(aX1Xb)C-TRANSDLICER V 120 V 120 PROTECTORS NOT WETTED CHANGED fire externel venture and shellel bearing transduter filest precedura for each pallent

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FORM APPROVED CAIR NO. DOSE 0351 DEPARTMENT OF HEALTH AND HUMAN SERVICES PCS DATE BURYEY DENTERS FOR WEDICARE A MEDICAID SERVICES DESCRIPTION FOR THE CONTRACTION COMPLETED ki) wonderhad by Statement of Depatement as and flan by Congestion DENTIFICATION PLINSER BRIDE 10/01/2010 g, WNG 347627 STREET ADDRESS, DITY, STATE, DP COXX YTHE KONAMI DOES HOTE OF BECANDED ON ETIBLICA CHARLOTTE, NEED SEEDS PROVIDERS MAN OF CONFECTION (EACH CORRESTING ACTION MICULIDES CHOCKS HITTER PROVIDED TO THE APPROPRIATE DESCRIPTION (CORRESTION MICE) COLETEROS FORTERIOS CHARLOTTE BAST DIALYSIS . RECORDING OUTER DEMINARIE MACHINICAL ESCHOLOMI TRANSPORTED DE L'ARCEDES MACHT. DESTRUMA RIVERNESI CA DENCRICE E PREFIX PLAY V 198 Continued From page 12 This STANDARD is not med us evidenced by: V 198 Breed ou jaryly boyst tooled the jaryly's topy chlorine tevery log raview and staff sharvisw, the facility failed to ensure regularly performed testing to would the total citizine is its make when used in patient hemodialysis and talled to provide V195-The CSS in-serviced the teammates on the color televides realing in 2 of 4 sumpled staff importance of completing the water system URLIDANG LINI BEST (IN LACEDA'S MAIR) और श्रिप्त (A) total chlorine monitoring every 4 hours per the presents of chicaton (stall \$1.5). policy 2-07-04 "Daily Water Total Chlorine Monitoring" and documenting on the 10-18-10 appropriate log. FA/designee will be The findings include: checked daily for 7 days then weekly on going. Color blindness testing was completed A review of the fecialty's policy "Delly Water System Total Chilorine Monticolog (revision data on the 2 RN's cited and it was found that they did have testing and results are in teammates 02/2010) reverted "Total Chimine leating is done files. Color blindness testing will be done on on a daily basis prior to the first patient heatment भार्य every form (4) मत्यान मती हो। स्टोग्डोवन नेपरे all new hires and annually there after. Facility Administrator will spot check 25% toding this of quality ditally notel me of teammates file monthly for 3 months and annually there after. Results of audits will be completed." reviewed in Quality Improvement A review on 09/23/2010 of the facility's "Routine Management Meetings (QIFMM) and Total Chlorina Testing Lng" for 122/15/2010 neversied that the facility staff falled to document addressed as necessary. FA is responsible for ongoing compliance with POC. Chloring being every 4 hours. The review revealed that for 02/19/2010, the locally start documented Chlorina testing at 0300, 0540, 1346 and 1740. The review kuther revealed that the tacility stall wrote a time of 0945 on the log but folled to document any results, hittaks or elignatures for the Chlorine testing. The raview toward that the most feeting for Chlotine was ातां तंत्रस्थात्वांच्यं का एवाएंवांकां An intended with the facility's Blomed technicien On CRIZAZOTO BY 1400 Haveshed Bred the total chlorine checks should be done every 4 hours with a 15 minute extra window of time given. The interview leasured that sector states the futured stall dose boy buil goldhung ou the Aspet lod K nontransion about Page 13 of 54

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1	dishasts port caps, barrier assessment of 30 tubing must be distributed for a policy of 30 minutes but no greater than 24 hours prior to				Physical Environment (V40) Governance (V750 that are i		15	
1	WINTER BALLIN	· Andrew	1					
	usa."	Ann to Hos Farlin's	- 1				at	
.]	Observation C	on 09/22/2010 at 1005 in the facility's	l					
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- \	Based	HER IN DESIGNATION OF HOSTICAL PROPERTY OF THE	ung ta	1	cont pg 19			
1	l Safety	Report of a cult amount in their solution).		1			1	
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PASTEX	RECORDATION C	STR DEMIK HIM.			V400 cont. Upon inspection, it was determined	
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V.400	Continued From P	Instrumental and a good	1		that this refrigerator was unable to make the temperature within acceptable limits. The reuse temperature within acceptable and verified to be	ĺ
1	torsily falled to th	amain a private to trailing	1		refrigerator has been replaced in 19/29/10. The	l
1	THE DECIDERED IN	Bill Male had stall like	1		within acceptable limits as on Policy CSS in-serviced the teammates on Policy	1
1	LANGUAGE CHE LANGUAGE	CONTRACTOR ALL MANAGEMENT NA	1		CSS in-serviced the teammans on 6-01-08 Reuse of Dialyzers with emphasis on 6-01-08 Reuse of Dialyzers with emphasis on 9-30-10	1
1	I BANKHAN YARWA WAN	Washington and the state of the	1		dialyzer storage in reuse telling	1.
	pating brane	ancke delector al the thisms, and president and valler belief in the president allows apparating	1		the temperature required to the sections to	1
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1	AND THE PROPERTY AND A	Mil di tropinia di Jan manthes fieti ali	١.		recorded was also reviewed a review the log	İ
Ì	JEDO Bilitaria is	not in size; isseed to entered mark to trany operated light located mark to the way in operation; failed to hold	1		Administrator or designee with the transfer of the country days, weekly on each shift x3 everyday for 3 days, weekly on each shift x3	1
\	40 10 4150 MO	tiony operation ight stated to hold my was in operation; failed to hold	1		weeks, and then the log with a ming basis.	1
1	gradnita Bill	Man Lanks	- 1		by the charge nurse on an our street in Omality	
1	CONCENSIONS NO	THE PARTY OF THE PARTY OF BUILDING	1		Results of audits will be reviewed in Mental Mental Management Mental Me	1
	Interior of at	MANUSCROP CYSCHALIGAT TO MCKIGG BIT	1		Improvement Management FA is responsible and addressed as necessary. FA is responsible *10-22-	10
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	I WHAMPHORNESS IS	SE COMP IN THE SECOND PARTY OF THE SECOND PART			Since the Facility is approximately 7,600 sq. ft. system	1
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1	Leading again	FEET 1991 (49) [49]			Roof Deck, as indicated in the attached for	
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	in emission	the charges facility.		1.	Smoke/Fire Partition and 20 Minutes Doors will be installed at key locations in order Doors will be installed at key locations in order	1
	er Lave	ngs Includa:		1	to provide the needed pantway will also	1
1	1	File read a series	n of	1	1 * *	- 1
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•		STANDARD Is not med as evidenced i sed on facility policy raview, observation	ȴ:			and the state of t	ndinunden nebesal Pre

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An interview patient etc	ou during the observation of 1105 w elysis care abolf member revealed the	esa ka w		FROM ES CONSEI	Y conf	invalum etrest PABA

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PRINTED: 10/08/2010 FORM APPROVED CHE DE 8880 DIA BIND DEPARTMENT OF HEALTH AND HUMAN SERVICES VALUE STATE OF THE CONTRACTOR CENTERS FOR MEDICARE & MEDICAID SERVICES HONTOLENTERCO ELENTALIONO H IN PROMERRAPHERELLA STATEMENT OF DEFICENCIES AND PLAN OF CORRECTION a kriuning growand of e. www 342627 STREET ADDRESS, CITY, STATE, LIP CODE HAVE OF PROVIDER OR SUPPLEA THE CHERT AND AND THE CHARLOTTE, NO 2010E PRANCES IN AN OF COPPECTION ENCHROPMENTS OFFICE ACTION SHOULD BE COPPECTED TO THE APPROPRIATE OFFICE NO. CHARLOTTE EAST DIALYSIS g XParty Qay REQUISION OF THE DENIELS AND ELCHRONICH INTO THE LEGISLES AND THE THREE STATES AND THE CONTRACT OF DELICIENTS TIAG V 403 Continued From page 21 V 403 the temperature was 58 degrees F and that the temperature should not be that high. The class member revealed that the temperature in the rafrigurator had been elevated for a white and MRE ENG SING TO THE SHOOTING GREET OF FLIER? A teniem ou delection of the teludoring for 09/2010 teacaged that he person, topicoson, temporature Write enould be 38 degrees F to 48 degrees F. The review of the log for comodic MANUAL IN THE STEEL HEG GOLTSLEEURY pemperature chacks as ranges instead of a single duranteering temperature, Review of Dentil2010 reversed documentation by the staff that the retribulator femberatura to per a tendra of 25-38 degrees F. On Davi7/2010 the range of the remperature was documented as 32-42 degroes F. Review of the log for Day22/2010 (43M of chectation) tavasted that the equiperature reading was documented so 30-48 degrees F. An interview on 09/22/2010 at 1390 with the tactily administrator revenied that the purposables of the refrigerators should be monitored every day and that the exect temperature about the documented. The interview also revealed that the sauce storage inhiperator should not be presum them 50 degrees F. The interview bother revealed that he log used pà the stall ARE LIERLY for the for impidesgious containing madications, and that the bills on the log ware set for medication streams, instead of showing the highest degree of 50 F. V 408 494.BO(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis lackly must implement processes and procedures to menego medical and non wedcel emergencies that are thely to brosses 14 jo str agan keafe kalkarahasa U

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DCT-08-2010 15:05 PRINTED: 10/08/2010 FORM APPROVED CANB MO DESE COST DEPARTMENT OF HEALTH AND HUMAN SERVICES DISTRIBUTED CENTERS FOR MEDICARE & MEDICAID SERVICES DCZ) MALTIPLE DOMETRICTION KIN PROVIDERGIERASTICIA L BRIDE WED LIVIN ON CONVECTION HIVERSHILD CONVECTION DENTE KATION HUM 1070112010 B. WWW. CIRCLY ADDRESS. CITY, STATE, SW CODE **343527** VIEWA PROBLEMEN ASSITY NAME OF PROVIDER OR SUPPLIES CHARLOTTE, NO 10309 FROMERS HAN OF CONSCION

ENGLISHED TO THE APPROPRIATE

CROBS REPERSIONS TO THE APPROPRIATE

DEFINATION DYE EXTENSION CHARLOTTE EAST CIALYING SUSMARY STATEMENT OF DEFICENCES EACH DEPERFORM MATE BE PRECEDED BY FIRE REGULATORY OR LCC DESTRYING BY CRANTON Ö KTERY Day KAEPAX DXQ ED V408- *The current Patient Station #7 will be V 408 relocated. A minimum 5'-0" portion of the Continued From page 22 Treatment Chase will be demolished to the health or existy of the pasents, the staff, or the public These emergencies include, but are provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum not brided to, fire, equipment or power februse. 5'-0"ADA Accessible Sidewalk will be care related emergencies, well supply installed to connect this new door to the intermedian, and meaned diseases likely to occur existing parking area. After installed the emergency evacuation plan will be updated to in the facility's geographic area. reflect the exit routes. A copy of Certificate of Occupancy has been This STANDARD is not mot as successful by: requested from the city of Charlotte, original 10-13-10 Based on observations, his safety reports review architect and general contractor, Going But stall busivess, the facility isled to ensure an forward any fire inspections will be kept on effective ausidancy executation routs for the file in the facility. FA is responsible for fecialy's patients, staff and visitors to Include an ongoing compliance with POC. भीवार्गाम् केल क्या प्रापंत क्षेत्र क्षेत्र केल केल क्षेत्र क्षेत्र केल treatment area in the event of the one fire ext becaute was theched or unbassable *The facility has been diligently working on correcting all the issues cited since the survey. This report was received on 10-11-10 stating completion dates could be no later than The findings include: +12-31-10 10-18-10. The fires system was ordered on the Observation on 09/22/2010 at 1016 during tour of for day of the survey. The installation of the fire the facility's patient treatment seem is unused that additional system is subject to the availability of the the facility had a total of sixteen (18) total stations physical vendor who is working with the facility to plant for hemodialysis heatments. The facility expedite the process. An agreement is in work hanndlalysia station locations wore aquint है के place with a local vendor to install a smoke four (4) walls of the patient business area. The detection system and fire alarm system that OPSCHARTON OF THE BECKER IN BENEATH BUCKERS). meets local code on 10-22-10. In addition the eversation route severaled that the lately had care physical plant issues will require more time as amargancy and landing directly into a failway they are also dependent upon permits and from the patient treatment area. The exit route had vendor availability as well the fact that much to a door with a fire end sign leading out to the of the work will have to be completed during non-operational hours. These issues have tectify's lostry area and main eall doors. The been evaluated by an architect and a plan to observation trapper severaged that these page up nove forward is in place. Estimated time other exist location or tenestrated executation totals frame to complete is 9-12 weeks. We request in the ballour peanually may Oppolication your consideration in these particular issues. landing that only one (1) and tomplomere existed in the parism beamen and he petents. visitors and stall. We other doors as soils were phonored in the passent transment area.

OCT-08-2010 15:85 CEPARTMENT OF HEALTH AN	d Huisan Services Educaid Services		e de la companya de l	CHATRISTICH	PRINTEIX 1 FORM AS OMH NO. O 604 DATE SURVI GOLD LETER	138-0381 138-0381	
CENTERS FOR MEDICARE S. STATEMENT OF DEFICIENCES AND PLAN OF CONSECURON	THERE POR BUILDING TO THE PROPERTY OF THE PROP				1991	2910	
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V 750 Continued From page 31 This CONDITION is not met as evidenced by: Based on tackity policy review, observations, estimated transcenses but review and staff interviews, it was determined that the teachty's governing body failed to provide averaging and interviews, it was determined that the teachty implantation in place to ensure the facility implantation in place to ensure the facility implantation in place to ensure the facility implantation and program; and failed to ensure indicate control program; and failed to ensure indicate control program; and failed to ensure indicate of have a fine alarm system or a beatery failed to have a fine alarm system or a beatery present annive relevant in the building to ensure for the fine the failed to ensure the staff of a fine; failed to have a entote the transcense storage for a facility that is approximately 7600 aquare for the first of hour fine raised complication and also had a 1 hour fine raised complication and for desirection of dialyzers; failed to ensure to the review room was in operation; feeled to an emergency bettery operated light located next conduct fine drills at unexpected fines under the conduct fine drills at unexpected fines under leasting from on the fine drill; tailed to ensure the finest a emergency evacuation make for the alternative fine axit route from hadde the present instruction entering tenture to inhish potential materials grown in stand represented (reuse) distructs. The cumpative effect of these anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand represented (reuse) anatorial grown in stand of the one fine one anatorial grown in stand of the one anatorial grown in the dreat of the one anatorial grown in t	V 7:	550 V750 cont. In addition the physic issues will require more time as a dependent upon permits and ven availability as well the fact that work will have to be completed operational hours. These issues evaluated by an architect and a forward is in place. Estimated the complete is 9-12 weeks. We reconsideration in these particular The Server Room's Plywood with currently non-rated Wallsupgraded to Minimum 1 Hour Partitions, in accordance with sketches. This will allow the 1 Rating to run behind the plywing the compartmentalization will be by extending the existing non to the Roof Deck, as indicate Sketches. This will provide the 1,140 S.F. in either compartmentalization will be by extending the existing non a Rated Doors will be installed in order to provide the needle exterior wall to exterior wall also include a passage latch Fire Rated Frame, and Clos The Facility Bio Hazard Sketching non-rated partition a minimum 1 Hour Fire Re The Door between the Bio room and the Corridor will minimum 45 min. rated deling 133	they are also dor much of the during non-have been plean to move time frame to puest your r issues. It be removed. It be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is be removed. It is a complished the attached the minimum neart as well as ments. New I and 20 Minute Fired at key locations and pathway from 1. Each door will system, I Hour or device. It is to the roof deck as sistant assembly. Hazard Storage I be upgraded to a nor with a minimum closer devise.	dditional hysical lant work
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TAS	1	V 780\	
V 780 Combrand From page 32	1	ļ	to any tree it is in Working of the
1 .			during monthly facility audits.
The findings include:	1		Fire drill was conducted on to transported times by
the condition for integral			be conducted quartery at mixty the Facility Administrator or designee. These the Facility Administrator or designee.
A For findings causing the Condition for infection Control to be not med, see V110 and its	- 1		the Facility Administrator of designors, the fire drills will be documented and evaluated in
1 A-Affel ED DU 1809 1100 1 100 1100 110	1		OIFMM.
consideration are well and held of the enternation of the state of the enternation of the	- 1		QIFMM. Storage items have been removed from the corridor and relocated to the records storage corridor and relocated to the records storage.
	1		area as of 09/30/10. Route will be monitored
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ACTORS 1919 to 484.30 Intertion Control		- 1	produced; where hazactured, stored, or explosives are manufactured, stored, or handled under conditions producing flammable
Condition 1881 44.10		- 1	handled under commons partial from the flyings; and other situations of similar
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B. The facility labed to maintain a physical arminent that decreased the potential the service of patients, vicious are	Y (0)	. }	cont pg 34
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IEDICARE & MEDICAID SERVICES CENTERS FC EPARTMENT OF HEALTH AND HUMAN. ID: OB2211 MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL VICES Facility ID: 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. i_ Initial 4, CHOW 3. Termination 342627 (L4) 3204 SHARON AMITY Œ 6. Complaint (L6) 28205 s Validation STATE VENDOR OR MEDICAID NO. 9, Other (L5) CHARLOTTE, NC 7. On-Site Vielt (1.2)09_ (LT) 7. PROVIDER/SUPPLIER CATEGORY 8. Full Survey After Complaint EFFECTIVE DATE CHANGE OF OWNERSHIP 13 PTIP 69 ESED 05 HHA 01 Hospital (L35) FISCAL YEAR ENDING DATE: 14 CORF 10 NF (L9) ne LAB 82 SNF/NF/Dock (1.34)04/15/2009 15 ASC DATE OF SURVEY 11 IMR 07 X-Ray 03 SNF/NF/Distinct 12/31 (L10)16 HOSPICE . ACCREDITATION STATUS: 12 RHC OR OPTISP D4 SNE 1 JCAHO 0 Unaccredited 3 Other 2 AOA 10. THE FACILITY IS CERTIFIED AS: And/Or Approved Waivers Of The Following Requirements: 1. 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) (b): To X 1 Acceptable POC 9. Beds/Room 5. Life Safety Code (L18) 2. Total Facility Beds B. Not in Compliance with Program Requirements and/or Applied Waivers: (L12) 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) (LA2)(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 Strat (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)(L30)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 (L25) 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: (L44) 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 (L33)(1.32)

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rtment of Health and Human sare/Medicaid/CLIA Complain	Form	by Component Fir	st Receiving C	omplaint (S.	A OF RO	eived
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342627	CHARDO	Source of C	Townlaint			6B. Total Number
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19 Life Safety Code 8. Action (if multiple actions						
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2 RO 3 Other (Specif	v)					
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12. Proposed Actions Taken by	SA of RO		9 Pro	visional License	17 TA & Training 18 State Onsite M	for Unsuccessful PT
		Termination (23-day)	10 Spc	cial Monitor	40	port of Medicare Paymonia
1: 0 4	- T)	I GITIMIATION (> 4>)	. 11 TV-	ented POC	on a minor of	All Medicare Payments
2:	3 Recommend 4 POC (No S	Intermediate Sanction	12 . Lin	nitation of Certifi spension of Certi	71 hlome	
3: 1				vocation of Certi	ficate 22 Other (Specificate 23 Enforcement A	action
	6 Denial of P	ayment for New Admissic	15 To	metion	alter	
	7 License Re	vocation	16 Ci	vil Monetary Pen	11C Date	Forwarded to CMS RO or
		Parties Notified and D	ates Pa	10	Date Medic	atd SA (MSA)
13. Date of	14.	Parties Notified and 2	1. 1.		4 1 0 0 2 4 2 1 0 9 (Attac	h HCFA-2567)
Proposed Action	\	2 Complainant	2.	및 ド		
	1	3 Representative	3.	그 - 느	M D D Y Y M D	MD DY Y
041509	1	A Other (Specify	· ——		I WI D D	
M MD DY Y			· m-la Trine	i Close-Out	Action (RO/MSA)	
Dort	III - To Be Comp	oleted By Compone	nt Laking Pills	C 7 1-4	atirm of Certificate	18. Date of Final Action Si
	17	. CMS RO/MSA Action	o .	D 1.1001	ension of Certification	
16. Date of CMS/MSA	\^'			7 Susp 8 Revo	cation of Certificate	
Receipt	*			น ไกร์เช	ection	MMDDYY
	1	-		or a	Monetary Penalty	
	· ·	1 None		11 TA	& Training For Unsuccessful PT	
MMDDYY	ı	2 Termination (23-day) 3 Termination (90-day)		12 Can	cellation of Medicare Approval	
	1	Sanctim	1	13 O f l	er (Specify)	
	1	5 Move Routine Surve	y Date Forward		orcement Action	
	1	3 2024 - 11				Page 1

APR-24-2009 FRI 02:43 PM DAV . CHAR EAST

FAX: NO. 70453181.

HLK-54-5009 LVI OF	,			ያብብር በ ሰ	PRINTED: 0 FORM AF	PROVED
EPARTMENT OF HEALTH	AND HUMAN SERVICES	RE	CEIVED APR		OMB NO. D	938-0391
ENTERS FOR MEDICARE	A WEDICALD OLL STORY	(X2) MULTIPLE	CONSTRUCTION		(X3) DATE SUR COMPLETI	ED ED
TEMENT OF DEFICIENCIES OPLAN OF CORRECTION	IDENTIFICATION NUMBER:	A, BUILDING			C	1
	A LACAT	B. WING	The second secon		04/15	2009
	342627	STREE	T ADDRESS, CITY, STAT	re, zip gode		1
AME OF PROVIDER OR SUPPLIER		3204	SHARON AMITY			1
CHARLOTTE EAST DIALYSIS		CH.	PROVIDER'S PL	HI AC MODEL	HOIT	COMPLETION
(X4) ID SUMMARY ST PREFIX (EACH DEFICIENT TAG REGULATORY OR	ATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREFIX TAG	(EACH CORRECTI			DATE
V 147 494.30(a)(2) CDC REFERENCE	RR-10 AS ADOPTED BY	V 147	5ee	Alteded		Spla
	ns for Placement of Intravascula its and Children	r	,			
I. Health care wo A. Educate h appropriate in prevent intravas B. Assess k	orker education and training ealth-care workers regarding the effection control measures to scular catheter-related infections to make the effections of and adherence to edically for all persons who escular catheters.					
II. Surveillance A. Monitor to individual patie the insertion si other manifest [blood stream removed to all site.	he catheter sites visually of onts. If patients have tenderness te, fever without obvious source cations suggesting local or BSI infection], the dressing should blow thorough examination of the	' 				-
l Hamodialysis	us Catheters, Including PICCs, , and Pulmonary Artery Catheter diatrio Patients.	rs in				
B, Antibio	and catheter-site care lic lock solutions: Do not routine c lock solutions to prevent CRBS ated blood stream infections].	ly I				
Based on t clinical rec facility's sta	DARD is not met as evidenced in the facility's policies and procedured review, and staff interview, it failed to change or clean an e	xit site		TILE .	FA	(X8) D.

Any deficiency statement ending with an esterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days the safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the above findings and plans of correction are disclosable 14 following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 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 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) PROVIDER/SUPPLIER/CLIA 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 IEACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE CHARLOTTE EAST DIALYSIS COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC (DENTIFYING INFORMATION) ID PREFIX TAG DEFICIENCY TAG V 147 Continued From page 1 V 147 of a patient's central venous catheter dressing 7 of 16 hemodialysis treatments (Patient #1). 1. An in-service on Central Venous Catheter changes and initiation of treatment was The findings include: Completed on 4-15-09 by the vascular Review of the facility's policy "Central Venous Access Manager with attendance all Catheter (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 fernoral 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 MD verbalized to pt, the importance was made aware of the patient not having his 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.

PRINTED: 04/15/2009 FORM APPROVED

EDA PT i	FNT OF HEALTH	AND HUMAN SERVICES				OMB NO	0.0938-0391
ENTERS	CUD MILITIARE	& MEDICAID SERVICES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) ML A. BUIL		CONSTRUCTION		C
7 1 W 1(1 - 1 - 1		342627	B. WIN		r address, city, state, zip c		/15/2009
	OVIDER OR SUPPLIER			3204	SHARON AMITY ARLOTTE, NC 28205		
HARLOT	TE EAST DIALYSIS		10	1	PROVIDER'S PLAN OF C	ORRECTION ON SHOULD BE	COMPLETION DATE
(X4) ID PREFIX TAG	SUMMARY ST (EACH DEFICIENC REGULATORY OR	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREI		CROSS-REFERENCED TO TI DEFICIENCY	131m har a second tree or	unic
V 147		o revealed that the stall should stration aware if the patient was leation and cleaning of the CVC		147			
	Reference intak	e #NC00054102.					
		·					
	1				Excelled the 001554	If car	ntinuation sheet Page

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

blic reporting burden for this collection of information is estimated to average 10 minutes per response, incining data needed, and completing and reviewing the collection of information. Send comments regarintationing data needed, and completing and reviewing the collection of information. Send comments regarintations for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimor gestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimor	cluding time for reviewing instructiving this burden estimate or any of a MD 21207; or to the Office of	ons, scarching existing data s her aspect of this collection of Management and Budget, Pa	ources, gathering and of information, including perwork Reduction
Les solvers the difficult woulder			
gestions to Technolog and Technolog D.C. 20503.	•		

rovider/Supplier Number	Provider/Supplier N CHARLOTTE EA	Name AST DIALYSIS		
Fype 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 Rontine/Standard Survey (all I B Extended Survey (HHA or Lor C Partial Extended Survey (HHA D Other Survey	ng term care racing)	·	

SURVEY TEAM AND WORKLOAD DATA

		Please			On-Site	On-Site	On-Site	114901	Off-Site Report Preparation
urveyor ID	Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	Hours 12am-8am (E)	Hours 8am-6pm (F)	Hours 6pm-12sm (G)	Hours (H)	Hours (I)
	15546	04/15/2009	04/15/2009	.1.00	0.00	4,00	0.00	11.00	2.50
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4.					<u> </u>				
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11.									
12.									
13.									
14.		l				Total RO	Supervisory Rev	iew Hours	0.00

Total SA Supervisory Review Hours....

1.00

Total SA Clerical/Data Entry Hours....

0,50

EventID: OB2211

Total RO Clerical/Data Entry Hours

0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

SEMANTANO HUMBOR SERVICES
PART I - APPLICATION - TO B. County Part I - Application - To B. County Part I - Application - To B. County Part I - Application - Part I - Application - Part I - Application - Part I - Public Public - Part I - Public Public - Part I - Public Public - Part I - Public Public - Part I - Public Public - Part I - Public Public - Part I - Public Public - Part I - Public
3. Street Address 4. City 6. State 7. ZIP Code 7. ZIP Code 8. Telephone No. (10 Fiscal Year Ending Date 7. ZIP Code 8. Telephone No. (10 Fiscal Year Ending Date 7. ZIP Code 8. Telephone No. 11. Name/Address/Telephone Number of Authorized Official 12. Type of Application/Notification: (N) 12. Type of Application/Notification: (N) 13. Change of location 14. Change of location 7. Check all that apply and specify in Remarks section [see item 27]) 13. Ownership (N2) 14. Is this Facility Hospital-Based (check one) 15. Is this Facility SNF-Based (check one) 16. Is this facility owned and/or managed by a multi-facility organization? (N) (N) (N) (N) (N) (N) (N) (N) (N) (N)
3. Street Address 4. City
5. County Neck S. Neuro
4. City 6. State 7. ZIP Code 7. ZIP Code 7. ZIP Code 7. ZIP Code 8. Telephone No. (2 31 10 11. Name/Address/Telephone Number of Authorized Official Name: (Action No. State No. S
8. Telephone No. (2 31 10 10. Fiscal Year Ending Date (2 31 10 11. Name/Address/Telephone Number of Authorized Official Name: (A RELES SHERE O 3204 N. Shaven Mark 14 Charlest NC-2625 (204) 53 [-157] 12. Type of Application/Notification: (vi) (check all that apply and specify in Remarks section [see item 27]) 12. Type of Application/Notification: (vi) (check all that apply and specify in Remarks section [see item 27]) 13. Ownership (v2) 14. Is this Facility Hospital-Based (check one) 15. Is this Facility SNF-Based (check one) 16. Is this facility owned and/or managed by a multi-facility organization? (vi) Yes No If Yes, name and address of parent organization Address: (N8) DAVITA CHASE 1428 Facore Facore Wast-incton See item 27] 17. Services Provided: (vs) (check all that apply and specify in Remarks section [see item 27]) 18. Themedialysis Hemodialysis Hemodialysis Hemodialysis 19. Facsimile No. (2 31 10 (3 31 10 (4 Address: Namarks section [see item 27]) (4 Charles Income
8. Telephone No. 11. Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name: Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Name/Address/Telephone Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Authorized Official Number of Official Nu
8. Telephone No. \[\cap \cap \cap \cap \cap \cap \cap \cap
11. Name/Address/Telephone Number of Authorized Official Name: Address
Name: Carries Stephan Stephan Stephan Stephan Carries
3204 N. Scaved funt by Pett New Part
12. Type of Application/Notification: (v1) (check all that apply and specify in I and speci
1. Initial 2. Expansion to new bottom 6. Change of services/operations 4. Change of location 5. Expansion in current location 4. Change of location 5. Expansion in current location 4. Change of location 5. Expansion in current location 7. Other (specify) Public 13. Ownership (v2) For Profit Not for Profit Public 14. Is this Facility Hospital-Based (check one) (v3) Yes No If Yes, hospital provider number (v4)
3. Ownership (v2) For Profit Not for Profit Public 13. Ownership (v2) For Profit Not for Profit Public 14. Is this Facility Hospital-Based (check one) (v3) Yes No If Yes, hospital provider number 15. Is this Facility SNF-Based (check one) (v5) Yes No If Yes, SNF provider number 15. Is this facility owned and/or managed by a multi-facility organization? (v7) Yes No If Yes, name and address of parent organization 16. Is this facility owned and/or managed by a multi-facility organization? (v7) Yes No If Yes, name and address of parent organization 16. Is this facility owned and/or managed by a multi-facility organization? (v7) Yes No If Yes, name and address of parent organization Address: 16. Is this facility owned and/or managed by a multi-facility organization? No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, No If Yes, no If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name and address of parent organization No If Yes, name
13. Ownership (vz) 14. Is this Facility Hospital-Based (check one) (v3) Yes No If Yes, hospital provider number (v4)
14. Is this Facility Hospital-Based (check one) (vs) Yes No If Yes, SNF provider number (vs) Yes No If Yes, SNF provider number (vs) No If Yes, name and address of parent organization (vs) No If Yes, name and address of parent organization Name: (va) DAVITA DIALYSIS 1423 Accepted Ave Taconnal Machinette New Office Ave Taconnal Machinette New Office Ave Taconnal Machinette New Office New
15. Is this Facility SNF-Based (check one) (V5) Yes No If Yes, SNF provider number (V6)
15. Is this Facility SNF-Based (check one) (vo) (vo) (vo) (vo) (vo) (vo) (vo) (vo)
Name: No. Is this facility owned and/or managed by a multi-facility organization? (V) Yes No. If Yes, name and address of parent organization Address: Name: (Va) DAVITA DIALYSTS 1473 Pacific Ave Tacoma Washington (V) 9840(17. Services Provided: (Vs) (Check all that apply and specify in Remarks section [see item 27]) 17. Services Provided: (Vs) (Check all that apply and specify in Remarks section [see item 27]) 18. Home Training: S. Home Support: Hemodialysis Hemodialysis Hemodialysis
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Hemodialysis — 12. Peritoneal Dialysis — 3. Transplantation — Hemodialysis — 13. Transplantation
Peritoneal Dialysis Pentoneal Dialysis
(V10) Ves No
18. Is Reuse Practiced?
19 Reuse System (V11) (check all that apply)
20. Germicide (vsz) (check all that apply) 1. Formalin 2. Heat 3. Gibleratuenyou 5. Other (specify) 5. Other (specify)
21. Number of Dialysis Patients Lamortialysis t (V15) Peritoneal Dialysis
TO Hemodialysis + (VIS) - Charles
(the literal apply and include isolation stations under Total Stations)
(Vis) Ves VNo
23. Does the facility have isolation stations?
24. Total Number of Patients (enter number of dialysis facility patients treated on each control of D. WEDNESDAY 25. Total Number of Patients (enter number of dialysis facility patients treated on each control of the patients of the pati
A. SUNDAY 1 2 3 4 1 2 1 1 (a) 1 (a) 1 (b) 1 4
The Market Control of Satispay
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E. THURSDAY 4 1 2 3 4 1 2 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1
E. THURSDAY

Anonymous I Resident/Patient Family Onbadsman Facility Employee/Ex-Employ O1 Substantiated O2 Umsubstantiated O2 Umsubstantiated O3 10 6 10 9 M M D D Y Y OR Total Number of Complainants O1 I 7.C. Number of Complainants per Allegation 1 0 1 1 2 3 4 5 5 1 O2 Umsubstantiated O3 Umsubstantiated O4 Umsubstantiated O5 Umsubstantiated O6 Umsubstantiated O7 Umsubstantiated O8 Umsubstantiated O9 Umsubstantiated
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O2 Unsubstantiated/ Unable to Verify 3 4 5
Unable to Verify 4 5
cify)
city)
the state of the s
execting ting Complaint (SA or RO)
nvestigating Complaint (SA or RO) 11. Findings (Under 7B Above)
Tampaperful PT
9 Provisional License 17 TA & Training for Unsuccessful PT 18 State Onsite Monitoring
10 Special Monitor 10 and of Part of Medicare Payments
11 Directed POC 12 Limitation of Cartificate 13 Suspension of All Medicare Payments 21 None
13 Suspension of Certificate 22 Other (Specify)
15 Teimerina
16 Civil Monetary Penalty 15 Date Forwarded to CMS RO or
Party GALLIC IO O Medicaid SA (MSA)
1. 1 (Attach HCFA-2567) 2. 2 (Attach HCFA-2567)
M M D D Y Y M MD D Y Y
Divisi Class-Out Action (RO/MSA)
ting Final Close-Out Action (RO/MSA) 6 Limitation of Certificate 18. Date of Final Action Sign
of Certification
8 Revocation of Certificate
o Injunction
TA & Training For Unsuccessitur
11 12 Cancellation of Medicare Approval
13 Other (Specify)
onward 14 Enforcement Action
Page 1 of
-

END STAGE RENAL DISEASE APPLICATION/N	OTIFICATION AN	ID SURVEY AND C	ERTIFICATION REPORT
PART I - APPLICATION	I-TO BE COMPLE	TFD BY FACIL!! Y	2. Provider Number
Name of Facility		. '.	342627
Davita East Charlotte			
3. Street Address 8. Sharon Anity Rd.			
4. City	5. County		
4. Char Lotte	MECKIENE	surg	
6, State	7. ZIP Code 7.8205	. J	
NC			10. Fiscal Year Ending Date
8, Telephane No.	9. Facsimile No.	8122	12/31
(104)531-1990	104)531	Charlotte	1-15 161
11. Name/Address/Telephone Number of Authorized Official	Address:		Telephone No.
Name: CHARLES DUENDARD 3204 N	Grava fruity	a. NC.	(704)531-1990
12. Type of Application/Notification: V1) (check all that a	pply and specify in R	emarks section [see item 3. Change of ownersh	12/ <i>)</i> in
1. Initial 2. Expansion to new i		3. Change of owners6. Change of services	/operations
4. Change of location 5. Expansion in curre 7. Other (specify) Cown a UT	in location.		
	☑ For P	rofit	t 🔲 Public
13. Ownership (V2)	√a∏ Yes	No If Yes, hospital p	rovider number
14. Is this Facility Hospital-Based (check one)	(10)	,	(V4)
	□ Voc	No If Yes, SNF prov	ider number
15. Is this Facility SNF-Based (check one)	(V5) L.1 165	TAO II 100, OK Pro-	(V5)
16. Is this facility owned and/or managed by a multi-facility organ	Yes Sporterie	No. If Yes, name and ad	dress of parent organization
16. Is this facility owned and/or managed by a muni-racinity organ	Address:		
Name:			
(V5) 17. Services Provided: (V5) (check all that apply and specify	in Remarks section	see item 27])	
	nsplantation	4. Home training.	5. Home Support
. 1. Hemodialysis 2. Peritoneal Dialysis 3. Tra	,	Hemodialysis Peritoneal Dia	Hemodialysis lysis Peritoneal Dialysis
			lysis
18. Is Reuse Practiced?	. (V1	Yes No	
19. Reuse System (v11) (check all that apply)] 1. Manual	2. Semi-Automated	
20. Germicide (viz) (check all that apply)	in 2. Heat	3. Gluteraldehyde	4. Peracetic Acid Mixture
20. Germicide (VI2) (Check all that apply)			
21. Number of Dialysis Patients	45 1 . 4-	(V15)Peritoneal Dia	alveis
(V18) 12 Total Patients = (V14) 2 Herr			
22. Number of Stations (check all that apply and include i	solation stations unde	er Total Stations)	
1 (a Transistations - way) (a Hen	nodialysis +	(V18)Hemodialysis	Training
(VIS) TOTAL OTHER		(V19) Yes	No
23. Does the facility have isolation stations?		• .	submission of this form)
24. Total Number of Patients (enter number of dialysis facilities) B. MONDA	ty patients treated on ea	C. TUESDAY	D. WEDNESDAY
A, SUNDAY B, MONUF	3 4 1	2 3 4	
le le c	3 14	1/3	16 16 7
E. THURSDAY F. FRIDA		G, SATURDAY	
1 2 3 4 1 2	5 10	1 13	
14 13 16 141	<u> </u>	<u> </u>	
25. Total Number of patients followed at home (v20)			

	(V21) Pegistered Nurs	ie	(vzz) Licensed Practic	al Nurse
Tist full-time equivalents)	(V23) Social Worker	.25	(V24) 🖸 Dietitian	<u></u>
	. (vzs) 'Technicians	7.00	(vze) Others	
7. Remarks: (Use this space	e for explanatory statement	ts for Items 1–26)		
	•		•	
•				
	•			
•				
	6			
gneture of Authorized Official		Title		
distributed official				Date
harhDey	and :	PN.	Administrator	4-15-09
harhibrer	and :	BE COMPLETED B	Administrator Y STATE AGENCY	4-15-09
harh Dup	PART II TO	BE COMPLETED B	Administrator Y STATE AGENCY	4-15-09
harhlung 9. ESRD Provider Number	PART II TO	BE COMPLETED B	Administrator Y STATE AGENCY	4-15-09
D. Network Number (vzr)	PART II TO	BE COMPLETED B	Administrator Y STATE AGENCY	4-15-09 342626
9. ESRD Provider Number 0. Network Number (vzz) 1. State Region (vzs)	PART II TO (if the facility has a provide) NCC	BE COMPLETED B'	Administrator Y STATE AGENCY	4-15-09 3 9 2 6 2 6 0 6 590
9. ESRD Provider Number 0. Network Number (vzz) 1. State Region (vzs)	PART II TO (if the facility has a provide I/CC eck all that apply)	BE COMPLETED B'	State County Code (vzs)	4-15-09 3 4 2 6 2 6 0 6 590 on Other
9. ESRD Provider Number 0. Network Number (vzz) 1. State Region (vzs) 3. Type of Survey (vso) (characteristics)	PART II TO (if the facility has a provide // eck all that apply) (print)	PN BE COMPLETED BY Tr number) Initial Basic Initial	STATE AGENCY 32. State County Code (vzs) mplaint	4-15-09 3 4 2 6 2 6 590 on Other al Combination
D. Network Number (vzr) 1. State Region (vzs) 3. Type of Survey (vso) (che 4. Survey Protocol (vs1) (che	PART II TO (if the facility has a provide // eck all that apply) (print)	BE COMPLETED BY	Administrator Y STATE AGENCY 32. State County Code (vze) mplaint	4-15-09 3 4 2 6 2 6 5 90 on Other al Combination
9. ESRD Provider Number 0. Network Number (vzr) 1. State Region (vzs) 3. Type of Survey (vso) (cha	PART II TO (if the facility has a provide // eck all that apply) (print)	PN BE COMPLETED BY Tr number) Initial Basic Initial	STATE AGENCY 32. State County Code (vzs) mplaint	4-15-09 3 4 2 6 2 6 590 on Other al Combination
9. ESRD Provider Number 0. Network Number (vzr) 1. State Region (vzs) 3. Type of Survey (vso) (che 1. Survey Protocol (vs1) (che	PART II TO (if the facility has a provide // eck all that apply) (print)	PN BE COMPLETED BY Tr number) Initial Basic Initial	STATE AGENCY 32. State County Code (vzs) mplaint	4-15-09 3 4 2 6 2 6 590 on Other al Combination
9. ESRD Provider Number 0. Network Number (vzz) 1. State Region (vzs) 3. Type of Survey (vso) (cho 4. Survey Protocol (vs1) (che 5. Surveyor Name/Number	PART II TO (if the facility has a provide // eck all that apply) (print)	PN BE COMPLETED BY Tr number) Initial Basic Initial	STATE AGENCY 32. State County Code (vzs) mplaint	4-15-09 3 4 2 6 2 6 590 on Other al Combination
9. ESRD Provider Number 0. Network Number (vzz) 1. State Region (vzs) 3. Type of Survey (vsb) (che 4. Survey Protocol (vs1) (che	PART II TO (if the facility has a provide // eck all that apply) (print)	PN BE COMPLETED BY Tr number) Initial Basic Initial	STATE AGENCY 32. State County Code (vzs) mplaint	4-15-09 3 4 2 6 2 6 590 on Other al Combination
9. ESRD Provider Number 0. Network Number (vzz) 1. State Region (vza) 3. Type of Survey (vsa) (che 4. Survey Protocol (vs1) (che 5. Surveyor Name/Number i. Date of Survey	PART II TO (if the facility has a provide ACC eck all that apply) c(print) Mills, AN B eduction of 1995, no persons a	BE COMPLETED BY In number) Initial Basic Initial Are required to respond to	32. State County Code (vz) mplaint	4-15-09 3 4 2 6 2 6 590 on Other al Combination not) Nuse