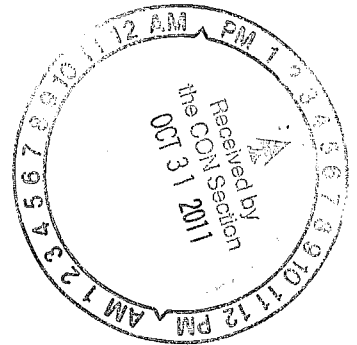


**COMMENTS BY RENAL ADVANTAGE, INC.  
REGARDING PROJECT I.D. NO. F-8746-11  
FILED BY DVA HEALTHCARE RENAL CARE, INC.  
D/B/A CHARLOTTE DIALYSIS CENTER  
ADD TWO STATIONS**



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.

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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.

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Jeff Horton  
Chief Operating Officer





ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 25, 2011  
FINDINGS DATE: March 4, 2011

PROJECT ANALYST: Tanya S. Rupp  
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8577-10 / Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center / Add five dialysis stations to an existing facility for a facility total of 20 stations / Cabarrus County

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

F-8584-10 / Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center / Add six dialysis stations to an existing facility for a facility total of 27 stations / Cabarrus County

F-8590-10 RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers - Concord / Develop a 23-station dialysis facility in Concord / Cabarrus County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC  
All Applications

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

EXHIBIT

B

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.
- **F-8581-10 Total Renal Care of North Carolina, LLC d/b/a Cabarrus County Dialysis** proposes to develop a new 12-station dialysis facility in Concord in Cabarrus County. In Section L8, page 3, the applicant states the facility will offer in-center 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 Guidelines<sup>1</sup>, 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 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

<sup>1</sup> 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,<sup>2</sup> 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,

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<sup>2</sup> 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 with 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 utilize [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 x 4) = 0.875].

Population to be Served

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

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS PERCENT OF TOTAL	
	2011	2012	2012	2013	YEAR 1	YEAR 2
	IN-CTR. PTS.	HOME PTS.	IN-CTR. PTS.	HOME PTS.		
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 in-center 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:

$$\begin{aligned} \diamond 118.2 \times 0.085 &= 10.047 + 118.2 = 128.247 \\ \diamond 128.2 \times 0.425 &= 5.4485 + 128.2 = 133.6485 \end{aligned}$$

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.*

$$July\ 1,\ 2010\text{-}June\ 30,\ 2011\ \text{---}\ 49\ \text{in-center}\ \text{patients}\ \times\ 1.085 = 53.165$$

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

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

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

In addition, the applicant states on page 28,

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

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

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

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

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

$$16 \times .085 = 1.36 + 16 = 17.36$$

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

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

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



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

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

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

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

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

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

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

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

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

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

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

Population to be Served

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

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

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

Demonstration of Need

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

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

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

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

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

$$\diamond 218.085 \times 1.085 = 236.622$$

$$\diamond 236.622 \times 1.0425 = 246.677$$

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

$$\diamond 246.7 \times 0.139 = 34.288$$

$$\diamond 246.7 - 34.3 = 212.4, \text{ or } 212$$

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:

$$\diamond 118.265 \times 1.085 = 128.318$$

$$\diamond 128.318 \times 1.0425 = 133.77$$

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.*

$$36 \times 0.085 = 3.06 + 36 = 39.06$$

*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 X .085 [=] 3.315 + 39.0 = 42.315."*

Thus, the applicant projects to serve, in the proposed new 12-station dialysis facility, 39 in-center patients in Operating Year 1 and 42 in-center patients in Operating Year 2. 39 in-center 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.  $91 \text{ patients} / (27 \times 4) = 0.8425$ ].

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:

COUNTY	OPERATING YEAR 1 2011-2012		OPERATING YEAR 2 2012-2013		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR. PTS.	HOME PTS.	IN-CTR. PTS.	HOME PTS.	YEAR 1	YEAR 2
Cabarrus	91	0	98	0	100%	100%
Total	91	0	98	0	100%	100%

\*Source: Application page 25

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

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

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

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

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

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

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

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

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

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

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

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

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

$$246.5 \times 0.139 = 34.2635.$$

$$246.5 - 34.2635 = 212.2365$$

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

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

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



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

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

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

The applicant projects that figure forward 1.5 additional years, to arrive at the projected Harrisburg and Copperfield in-center dialysis population as of June 30, 2012 [ $118.2 \times 0.085 = 10.047 + 118.2 = 128.247$ .  $128.2 \times 0.425 = 5.4485 + 128.2 = 133.6485$ ]. 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.*

$$\text{July 1, 2010-June 30, 2011} \text{ — } 60 \text{ in-center patients } \times 1.085 = 65.10$$

$$\text{July 1, 2011-June 30, 2012} \text{ — } 65.10 \text{ in-center patients } \times 1.085 = 70.634$$

$$\text{July 1, 2012-June 30, 2013} \text{ — } 70.634 \text{ in-center patients } \times 1.085 = 76.637."$$

In addition, the applicant states on page 28,

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

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

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

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

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

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

$$19 \times .085 = 1.615 + 16 = 20.615$$

*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):*

$$\text{July 1, 2011-June 30, 2012—}84 \text{ in-center patients } \times 1.085 = 91.14$$

$$\text{July 1, 2012-June 30, 2013—}91.14 \text{ in-center patients } \times 1.085 = 98.8869$$

*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 in-center 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:

	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients
Cabarrus	65	7	67	7	86.7%	100.0%
Mecklenburg	10	0	11	0	13.3%	0
<b>Total</b>	<b>75</b>	<b>7</b>	<b>78</b>	<b>7</b>	<b>100.0%</b>	<b>100.0%</b>

\*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 of 60 with a majority of these patients being over 40 years of age."*

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

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

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

On page 38, the applicant states,

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

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

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

**Cabarrus County Total Dialysis Patients Historical and Projected**

	12/05	12/06	12/07	12/08	12/09	12/10
<b>No. Patients</b>	146	150	170	174	201	218.1
<b>% Change*</b>	-	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

	HISTORICAL				
	12/05	12/06	12/07	12/08	12/09
No. Patients	45	47	53	55	109
% Change	-	4.4%	12.3%	3.8%	98.2%

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

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

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

Facility	HISTORICAL NUMBER OF CABARRUS COUNTY DIALYSIS PATIENTS			
	12/06	12/07	12/08	12/09
Harrisburg DC**	-	-	-	49
Copperfield DC	47	53	55	60
Branchview*	44	51	50	-
Total	91	104	105	109

\*Closed in 2009

\*\*Opened 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 in-center 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

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:

$$92 \times 1.085 = 99.8 \text{ (December 2010)}$$

$$99.8 \times 1.085 = 108.3 \text{ (December 2011)}$$

$$108.3 \times 1.085 = 117.5 \text{ (December 2012)}$$

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:

	YEAR 1-2011	YEAR 2-2012
Population 65+	20,752	21,608
Home Dialysis Patients	7	7
In-Center Dialysis Patients	75	78

\* Applicant states this includes a "Year 1 ramp-up period"



COUNTY	PATIENTS			
	YEAR 1		YEAR 2	
	IN-CENTER	HOME DIALYSIS	IN-CENTER	HOME 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 serving as medical director of a new dialysis center to be located in \_\_\_\_\_, which will be owned by RAI 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:

CITY	COUNTY	LETTERS
Concord	Cabarrus	1
Harrisburg	Cabarrus	2
Charlotte	Mecklenburg	1
Huntersville	Mecklenburg	3
Total Cabarrus County		3
Total Mecklenburg County		4

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:

PROJECTED EXPENSES AND NET REVENUE	OP. YEAR 1	OP. YEAR 2
Projected Operating Costs	\$2,990,071	\$3,189,462
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:

PROJECTED EXPENSES AND NET REVENUE	OF YEAR 1	OF YEAR 2
Projected Operating Costs	\$1,894,521	\$2,072,639
Net Patient Revenue	\$1,995,824	\$2,248,536

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

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

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

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

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

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

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

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

PROJECTED EXPENSES AND NET REVENUE	ON YEAR 1	ON YEAR 2
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

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:

PROJECTED EXPENSES AND NET REVENUE	OP YEAR 1	OP YEAR 2
Projected Operating Costs	\$2,078,878	\$3,049,459
Net Patient Revenue	\$1,982,269	\$3,602,277

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

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



C

Harrisburg Dialysis Center  
Cabarrus County Dialysis Center  
Copperfield Dialysis Center

NC

RAI Care Center-Concord

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

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

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

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

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

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

**C**  
**All Applicants**

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

POSITION	TOTAL FTE'S
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
<b>TOTAL</b>	<b>15.5</b>

\*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:

WEEKLY HOURS OF OPERATION			
DAY	MORNING	AFTERNOON	TOTAL
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
<b>Total</b>	<b>30</b>	<b>30</b>	<b>60</b>
<b>Total Hours Operation per Year (weekly hours x 52)</b>			<b>3,120</b>

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:

	# FTEs	Hrs/Yr/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION ANNUAL	FTE HRS/HRS OF OPERATION
RNs	3	2,080	6,240	3,120	2.0
Techs	8.5	2,080	17,680	3,120	5.7
<b>Total</b>	<b>11.5</b>	<b>2,080</b>	<b>23,920</b>	<b>3,120</b>	<b>7.7</b>

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:

TIME/SHIFT	M/W/F PATIENTS	T/SA PATIENTS
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.

POSITION	TOTAL FTEs 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
Bio-Med Tech	0.3
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0.3
Social Worker	0.3
Unit Secretary	1.0
Other - Rense	0.5
<b>TOTAL</b>	<b>11.7</b>

\*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:

DAY	WEEKLY HOURS OF OPERATION			TOTAL
	MORNING	AFTERNOON	EVENING	
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
<b>Total</b>	<b>18</b>	<b>18</b>	<b>6</b>	<b>42</b>
<b>Total Hours Operation per Year (weekly hours x 52)</b>				<b>2,148</b>

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:

	FTEs	HRS/YR/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS. OF OPERATION (ANNUAL)	FTE HRS./HRS OF OPERATION
RNs	2.55	2,080	5,304	2,148	2.5
Techs	5.75	2,080	11,960	2,148	5.6
Total	8.3	2,080	17,264	2,148	8.0

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

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

TIME/SHIFT	MAX. PATIENTS	PAT./STATION
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.

POSITION	TOTAL FTE YEAR 1
RN (dc)	4.0
Pt. Care Technician (dc)	11.0
Bio-Med Tech	0.7
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0.7
Social Worker	0.7
Unit Secretary	1.0
Other - Reuse	1.5
<b>TOTAL</b>	<b>20.6</b>

\*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:

DAY	WEEKLY HOURS OF OPERATION		TOTAL
	MORNING	AFTERNOON	
Monday	7	7	14
Tuesday	7	7	14
Wednesday	7	7	14
Thursday	7	7	14
Friday	7	7	14
Saturday	7	7	14
Sunday	0	0	0
<b>Total</b>	<b>42</b>	<b>42</b>	<b>72</b>
<b>Total Hours Operation per Year (weekly hours x 52)</b>			<b>4,368</b>

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:

	# FTEs	HRS/YR/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RNs	4	2,080	8,320	4,368	1.9
Techs	11.7	2,080	24,336	4,368	5.6
<b>Total</b>	<b>15.7</b>	<b>2,080</b>	<b>32,656</b>	<b>4,368</b>	<b>7.5</b>

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:

TIME/SHIFT	M/W/F PATIENTS	T/TH/SA PATIENTS
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 in-center 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.

POSITION	TOTAL FTE 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
<b>TOTAL</b>	<b>15.5</b>

\*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:

WEEKLY HOURS OF OPERATION				
DAY	MORNING	AFTERNOON	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:

TITLES	HRS/YR/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/HRS OF OPERATION
RNs	4.5	2,080	9,360	3.7
Techs	7.0	2,080	2,496	5.8
Total	11.5	2,080	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/SHIFT	M/W/F 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 in-center 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.

NA

- (11) Repealed effective July 1, 1987.

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

NA

Harrisburg Dialysis Center  
Copperfield Dialysis Center

C

Cabarrus County Dialysis  
RAI Care Center-Concord

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

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

Harrisburg Dialysis Center  
Cabarrus County Dialysis  
Copperfield Dialysis Center

NA

RAI Care Center-Concord

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

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

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

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

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Harrisburg Dialysis Center  
Copperfield Dialysis Center

NA

Cabarrus County Dialysis  
RAI Care Center Cabarrus County

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

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

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

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

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

C  
All Applicants

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

PAYOR MIX	
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:

PAYOR MIX	
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:

Medicare	15.1%
Medicaid	7.5%
Medicare/Medicaid	34.0%
Medicare/Commercial	28.3%
VA	1.9%
Commercial Insurance	13.2%
<b>Total</b>	<b>100.0%</b>

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

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

Medicare	77.5%
Medicaid	3.0%
Self Pay	3.3%
Commercial Insurance	16.1%
<b>Total</b>	<b>100.0%</b>

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 VL5(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 VL5(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 VL5(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 nursing 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.

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

NC  
All Applicants

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

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NC

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

NA

F-8590-10, RAI Care Center-Concord

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

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic

medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

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

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

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

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

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

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

**.2202 INFORMATION REQUIRED OF APPLICANT**

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
- (1) *Utilization rates;*
  - (2) *Mortality rates;*
  - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
  - (4) *The number of transplants performed or referred;*
  - (5) *The number of patients currently on the transplant waiting list;*
  - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
  - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

- C- **Harrisburg Dialysis Center** – The applicant provides the requested information in Section IV, questions 1 – 7, on pages 32 – 33 of the application.
- C- **Cabarrus County Dialysis** – The applicant provides the requested information in Section IV, questions 1 – 7, on page 9 of the application.
- C- **Copperfield Dialysis Center** – The applicant provides the requested information in Section IV, questions 1 – 7, on page 8 of the application.
- C- **RAI Care Center-Concord** - The applicant provides the requested information in Section IV, questions 1 – 7, on page 15 of the application.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

**-NA- Harrisburg Dialysis Center –**

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

**-NA- Copperfield Dialysis Center –**

**-C- RAI Care Center-Concord** – In Exhibit 9 the applicant provides a September 10, 2010 letter signed by the Vice President of Clinical Services at Carolinas Medical Center-NorthEast that outlines the services to be provided to RAI patients. In addition, the applicant provides similar letters from other Carolinas Medical Center facilities as well as from Presbyterian Healthcare. The applicant also provides copies of laboratory services agreements between RAI and Renalab, Inc. The application is conforming to this rule.

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*

(E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- NA- **Harrisburg Dialysis Center** – Harrisburg Dialysis Facility is not a new facility, but the applicant provides a copy of a transfer agreement Harrisburg Dialysis facility has with the Charlotte-Mecklenburg Hospital Authority in Exhibit 8.
- C- **Cabarrus County Dialysis** – In Exhibit 7, the applicant provides an September 8, 2010 letter signed by the Assistant Vice President of Transplant Services at Carolinas Medical Center which states the hospital will enter into a transplant agreement with Cabarrus County Dialysis in the event a certificate of need is issued. Further, the agreement commits that the hospital will provide the information required by this rule. Therefore, the application is conforming to this rule.
- NA- **Copperfield Dialysis Center** – Copperfield Dialysis Center is not a new facility but the applicant provides a copy of a transfer agreement Copperfield Dialysis facility has with Carolinas Medical Center in Exhibit 8..
- C- **RAI Care Center-Concord** – in Exhibit 10 the applicant provides a September 13, 2010 letter from Carolinas Medical Center which outlines the terms of the transplant agreement to be entered into between RAI Concord and CMC. Therefore, the application is conforming to this rule.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

- NA- **Harrisburg Dialysis Center** – Harrisburg Dialysis Center is not a new facility.
- C- **Cabarrus County Dialysis Center** – In Section XL5(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 XL6(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.

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

2203 **PERFORMANCE STANDARDS**

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- **Harrisburg Dialysis Center** – Harrisburg Dialysis Facility is not a new facility.
- C- **Cabarrus County Dialysis Center** – The applicant proposes to develop a twelve-station dialysis facility and to serve 3.2 patients per station at the end of the first year of operation, based on projections of serving 39 patients in the first operating year. Thus, the requirement of 3.2 patients per station is satisfied. Consequently, the applicant is conforming to this rule. See Criterion (3) for discussion.
- NA- **Copperfield Dialysis Center** - Copperfield Dialysis Center is not a new facility.
- NC- **RAI Care Center-Concord** – The applicant proposes to develop a new 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- **Cabarrus County Dialysis Center** See Application Section V.1.
  - C- **Copperfield Dialysis Center** – See Application Section V.1.
  - C- **RAI Care Center-Concord** – See Application Section V.1, page 46.
- (3) *accessible self-care training;*
- C- **Harrisburg Dialysis Center** – In Application Section II, page 20, the applicant refers to Application Section V.1, page 34 for the information regarding accessible self-care training. However, the information is contained in Section V.2, pages 35 – 36.
  - C- **Cabarrus County Dialysis Center** - The applicant states that self-care training will be provided by the applicant. See Application Sections II.2 and V.1.
  - C- **Copperfield Dialysis Center** – See Application Section V.1.
  - C- **RAI Care Center-Concord** – See Application Section V.1, page 46.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- **Harrisburg Dialysis Center** - See Section V.1, page 34 of the application and Exhibit 11.
  - C- **Cabarrus County Dialysis Center** See Section V.1 of the application.
  - C- **Copperfield Dialysis Center** – See Application Section V.1.
  - C- **RAI Care Center-Concord** – See Application Section V.1, page 46.
- (5) *x-ray services;*
- C- **Harrisburg Dialysis Center** – See Section V.1, page 34 of the application. The applicant refers to Exhibit 7 for information regarding the provision of x-ray services; however, Exhibit 7 does not contain the stated information.
  - C- **Cabarrus County Dialysis Center** – See Section V.1 of the application
  - C- **Copperfield Dialysis Center** – See Application Section V.1.
  - C- **RAI Care Center-Concord** – See Application Section V.1, page 46.
- (6) *laboratory services;*
- C- **Harrisburg Dialysis Center** – See Section V.1, page 34 and Exhibit 12 of the application.
  - C- **Cabarrus County Dialysis Center** See Section V.1 of the application.
  - C- **Copperfield Dialysis Center** – See Application Section V.1.
  - C- **RAI Care Center-Concord** – See Application Section V.1, page 46.
- (7) *blood bank services;*
- NC- **Harrisburg Dialysis Center** – See Section V.1, page 34 of the application. The applicant refers to Exhibit 7 for information regarding blood bank services; however, Exhibit 7 contains procedures for back-up dialysis services, and information regarding blood bank services is not contained within the remaining exhibits. Therefore, the application is not conforming to this rule.

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

(8) *emergency care;*

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

(9) *acute dialysis in an acute care setting;*

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

(10) *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 VII.5, page 46 of the application.
- C- **RAI Care Center-Concord** - See Section VII.5, page 58 of the application.

## COMPARATIVE ANALYSIS OF THE COMPETING APPLICATIONS

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

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

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

### SMFP Principles

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

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

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

a) Home Training

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

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

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

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

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

b) Hours of Availability

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

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

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

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

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

c) Services in rural, remote areas

Cabarrus County is not a rural, remote area.

### Facility Location

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

### Access by Underserved Groups

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

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

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

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

### Service to Cabarrus County Residents

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

### Access to Alternative Providers

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

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

**Operating Costs and Revenues**

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

**Operating Costs**

HARRISBURG DIALYSIS CENTER		
	FY1	FY2
Projected Expenses	\$2,990,071	\$3,189,462
# Dialysis Treatments	10,530	11,388
Average Cost per Treatment	\$283.96	\$280.10

CABARRUS COUNTY DIALYSIS CENTER		
	FY1	FY2
Projected Expenses	\$1,894,521	\$2,072,639
# Dialysis Treatments	5,850	6,318
Average Cost per Treatment	\$323.85	\$328.05

COPPERFIELD DIALYSIS CENTER		
	FY1	FY2
Projected Expenses	\$3,873,451	\$4,141,685
# Dialysis Treatments	13,650	14,742
Average Cost per Treatment	\$284.14	\$280.95

RAI CARE CENTER-CONCORD		
	FY1	FY2
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**

HARRISBURG DIALYSIS CENTER	FY1	FY2
Projected Net Revenue	\$3,393,664	\$3,625,976
# Dialysis Treatments	10,530	11,388
Revenue per Treatment	\$322.85	\$318.40

CABARRUS COUNTY DIALYSIS CENTER	FY1	FY2
Projected Net Revenue	\$1,995,824	\$2,248,536
# Dialysis Treatments	5,850	6,318
Revenue per Treatment	\$341.17	\$355.89

COPPERFIELD DIALYSIS CENTER	FY1	FY2
Projected Net Revenue	\$4,495,936	\$4,855,496
# Dialysis Treatments	13,650	14,742
Revenue per Treatment	\$329.37	\$329.36

RAI CARE CENTER-CONCORD	FY1	FY2
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.

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

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

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

#### **Availability of Staff**

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

#### **Provision of Quality of Care**

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

#### **CONCLUSION**

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

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

Exhibit C

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

DATE: February 10, 2009

PROJECT ANALYST: Angie Matthes  
TEAM LEADER: 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

2008 Davie County Competitive Dialysis Review

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

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

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

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

*"A CON application to meet the need for new healthcare facilities, services or equipment shall be consistent with the three Basic Principles governing the State Medical Facilities Plan (SMFP); promote cost-effective approaches, expand health care services to the medically underserved, and encourage quality health care services. The Applicant shall document plans for providing access to services for patients with limited financial resources, commensurate with community standards, as well as the availability of capacity to provide those services. The Applicant shall also document how its projected volumes incorporate the three Basic Principles in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area."*

The applicants respond to Policy GEN-3 as follows:

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

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

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

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

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

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

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*"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 cost-effectiveness 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.*

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*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 in-center 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 Operating Year 2
	In-center patients	Home patients	
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

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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 in-center 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 is less congested than the commute to Salisbury. Three of the four patients living in the 28054 zip code receive their dialysis treatments at the Dialysis Care of Rowan County. One of the home-trained patients living in Mocksville receives their services from the Dialysis Care of Rowan County facility.*

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

The table below illustrates TRC's methodology and assumptions used to project in-center 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)	$27 + (50\% \text{ of } 1.13) = 28.755$ (applicant rounds down to 28)
Projected # of Davie County In-Center Patients as of 6/30/09 (a 12-month time period)	$28 \times 1.13 = 31.64$ (applicant rounds down to 31)
Projected # of Davie County In-Center Patients as of 6/30/10 (a 12-month time period)	$31 \times 1.13 = 35.03$
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	$35 \times 1.13 = 39.55$ [applicant rounds down to 39 and then projects to serve 90% ( $39 \times .9 = 35.1$ )] $35 + 1 = 36$
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	$39 \times 1.13 = 44.07$ [applicant rounds down to 44 and then projects to serve 90% ( $44 \times .9 = 39.6$ )] $39 + 1 = 40$

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:

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*"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."*

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- *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

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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.

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NC – TRC  
CA – WFU

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

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

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

C – Both Applications

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

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

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,



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

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

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

	Year 1	Year 2
Projected Operating Expenses	\$1,289,095	\$1,484,411
Projected # of Dialysis Treatments	4,718	6,002
Average Cost per Treatment	\$273.23	\$247.32
Net Patient Revenue	\$1,189,958	\$1,513,972
Projected # of Dialysis Treatments	4,718	6,002
Net Revenue per Treatment	\$252.22	\$252.24
Net Profit/Loss	(\$99,137)	\$29,561

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

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

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

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

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.

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	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
<b>Total</b>	<b>9.2</b>

\* 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.

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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
<b>Total</b>	<b>11.6</b>

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;

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.



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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.

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- (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;*

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- (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%

2008 Davie County Competitive Dialysis Review

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 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

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

Revenues

TRC	Year 1	Year 2
Patient Revenue	\$1,189,958	\$1,513,972
# of Dialysis Treatments	4,718	6,002
Net Revenue per Treatment	\$252.22	\$252.24

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

2008 Davie County Competitive Dialysis Review

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.

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.





**ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

**FINDINGS**

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 8, 2009  
PROJECT ANALYST: Paula Quirin  
TEAM LEADER: Martha J. Frisone

PROJECT I.D. NUMBER: O-8252-08 / Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center/ Relocate 28 existing dialysis stations from Southeastern Dialysis Center-Wilmington to Cape Fear Dialysis Center, a new facility to be located in Wilmington / New Hanover County

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

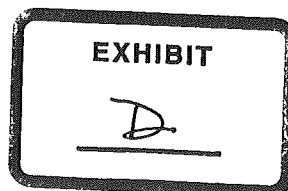
G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

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

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:



000038

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 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 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		Operating Year 2		County Patients as a Percent of percent of TOTAL	
	In-center patients	Home dialysis patients	In-center patients	Home dialysis patients	Year 1	Year 2
New Hanover	95	0	97	0	100%	100%
<b>TOTAL</b>	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 Need 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 Tech	0.75
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.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section 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;

C

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 ethnic 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.

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 back-up capabilities.*

-C- See Section XI.6(f), page 52, and Exhibit 11.

.2202(b)(4) *For new facilities, the location of the site on which the services are to be operated. if such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-C- The applicant identifies a primary site and a secondary site in Section XI. On page 48, the applicant states it will lease the space for the proposed facility. Exhibit 27 contains a document signed by the applicant and the lessor indicating that 2 sites are available and an intent for the lessor to lease 11,000 square feet of space to the applicant for the proposed facility.

.2202(b)(5) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*

-C- See Section II, pages 9-15, Section VII.1, pages 34-37, and Section XI.5, page 51.

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

### .2203 PERFORMANCE STANDARDS

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

of the proposed facility.

**.2204 SCOPE OF SERVICES**

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

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

**.2205 STAFFING AND STAFF TRAINING**

.2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

-C- See Sections VII., pages 34-37.

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

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



CC Exhibit E

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.ncdhhs.gov/dhsr/>

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

Drexdal Pratt, Director

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

January 10, 2011

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

Re: Follow-up Survey  
ESRD CMS Certification Number (CCN):34-2627

Dear Mr. Sheppard

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

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

Sincerely,

*Ralph Mills*

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

RECEIVED NOV 20 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 Amity  
Charlotte, NC 28205

Dear Administrator:

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

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

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

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.

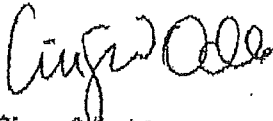


2. The procedure for implementing the acceptable plan of correction for the specific deficiency cited.
3. The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements.
4. The title of the person responsible for 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 Charlotte Observer in Charlotte, North Carolina advising the public of your termination from the Medicare program. Please be advised that, under Medicare, a provider is not entitled to a formal hearing before termination, but only after adverse action actually takes place.

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

Sincerely,



Ginger Odle, Manager  
Non-Long Term Care Certification & Enforcement Branch

cc:  
North Carolina Department of Health and Human Services



**COPY**  
PDF'd 10/4/10

**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>  
Drex dall Pratt, Division Director

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

**\*\* VIA FACSIMILE \*\***

**October 4, 2010**

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

RE: Recertification Survey Immediate Jeopardy]

Dear Mr. Sheppard,

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



Location: 1205 Umstead Drive (Lineberger Building) ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603  
An Equal Opportunity / Affirmative Action Employer



COPY

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

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Drex dall Pratt, Division Director

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October 4, 2010

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3204 Sharon Amity  
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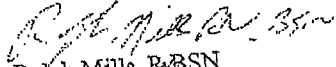
Ms. Glenda Payne  
Division of Survey and Certification  
CMS Dallas Regional Office  
1301 Young Street, Room 827  
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214-767-6301



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, RBSN  
Facility Survey Consultant  
Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief

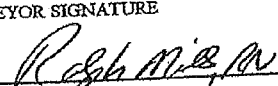
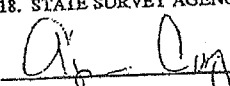
\*\* VIA FACSIMILE \*\*

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL  
PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

ID: WB31

Facility ID: 001554

1. MEDICARE/MEDICAID PROVIDER NO. (L1) 342627		3. NAME AND ADDRESS OF FACILITY (L3) CHARLOTTE EAST DIALYSIS (L4) 3204 SHARON AMITY (L5) CHARLOTTE, NC (L6) 28205			4. TYPE OF ACTION: <u>2</u> (L8) 1. Initial 2. Recertification 3. Termination 4. CHOW 5. Validation 6. Complaint 7. On-Site Visit 9. Other 8. Full Survey After Complaint	
2. EFFECTIVE DATE CHANGE OF OWNERSHIP (L9)		7. PROVIDER/SUPPLIER CATEGORY <u>09</u> (L7) 01 Hospital      05 HHA      09 ESRD      13 PTIP 02 SNF/NF/Dual      06 LAB      10 NF      14 CORF 03 SNF/NF/Distinct      07 X-Ray      11 IMR      15 ASC 04 SNF      08 OPT/SP      12 RHC      16 HOSPICE			FISCAL YEAR ENDING DATE: (L35) 12/31	
5. DATE OF SURVEY 10/01/2010 (L34)		10. THE FACILITY IS CERTIFIED AS: A. In Compliance With Program Requirements Compliance Based On: ___ 1. Acceptable POC ___ 2. Technical Personnel ___ 3. 24 Hour RN ___ 4. 7-Day RN (Rural SNF) ___ 5. Life Safety Code ___ 6. Scope of Services Limit ___ 7. Medical Director ___ 8. Patient Room Size ___ 9. Beds/Room			And/Or Approved Waivers Of The Following Requirements: * Code: B* (L12)	
6. ACCREDITATION STATUS: ___ (L10) 0 Unaccredited      1 TIC 2 AOA      3 Other		11. LTC PERIOD OF CERTIFICATION From (a): To (b): 12. Total Facility Beds (L18) 13. Total Certified Beds (L17)			15. FACILITY MEETS 1861 (e) (1) or 1861 (f) (1): (L15)	
14. LTC CERTIFIED BED BREAKDOWN 18 SNF (L37)      18/19 SNF (L38)      19 SNF (L39)      ICF (L42)      IMR (L43)		16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE): See Attached Remarks				

17. SURVEYOR SIGNATURE  Date: 01/11/2011 (L19)		18. STATE SURVEY AGENCY APPROVAL  Date: 1/16/11 (L20)	
---	--	---	--

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY <input checked="" type="checkbox"/> 1. Facility is Eligible to Participate <input type="checkbox"/> 2. Facility is not Eligible (L21)		20. COMPLIANCE WITH CIVIL RIGHTS ACT:		21. 1. Statement of Financial Solvency (HCFA-2572) 2. Ownership/Control Interest Disclosure Stmt (HCFA-1513) 3. Both of the Above:	
22. ORIGINAL DATE OF PARTICIPATION 01/30/2003 (L24)		23. LTC AGREEMENT BEGINNING DATE (L41)		24. LTC AGREEMENT ENDING DATE (L25)	
25. LTC EXTENSION DATE: (L27)		27. ALTERNATIVE SANCTIONS A. Suspension of Admissions: (L44) B. Rescind Suspension Date: (L45)		26. TERMINATION ACTION: (L30) VOLUNTARY <u>00</u> 01-Merger, Closure 02-Dissatisfaction W/ Reimbursement 03-Risk of Involuntary Termination 04-Other Reason for Withdrawal INVOLUNTARY 05-Fail to Meet Health/Safety 06-Fail to Meet Agreement OTHER 07-Provider Status Change 00-Active	
28. TERMINATION DATE: (L28)		29. INTERMEDIARY/CARRIER NO. 00101 (L31)		30. REMARKS	
31. RO RECEIPT OF CMS-1539 (L32)		32. DETERMINATION OF APPROVAL DATE (L33)		DETERMINATION APPROVAL	

STATE SURVEY REMARKS - CMS 1539 FORM

A recertification 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 (IJ) was identified on October 1, 2010 at 1130. The IJ was not 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 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. (RM)

Another follow up survey was conducted December 21, 2010. The State Agency recommends that the condition level deficiencies in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance are back in compliance. No other deficiencies were found during the follow up survey.

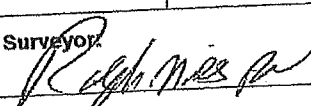
Post-Certification Revisit Report

This 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 reviewing the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(1) Provider / Supplier / CLIA / Identification Number 342627	(Y2) Multiple Construction A. Building B. Wing	(Y3) Date of Revisit 12/21/2010
Name of Facility CHARLOTTE EAST DIALYSIS	Street Address, City, State, Zip Code 3204 SHARON AMITY CHARLOTTE, NC 28205	

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix V0110 Reg. # 494.30 LSC	Correction Completed 12/21/2010	ID Prefix V0114 Reg. # 494.30(a)(1)(ii) LSC	Correction Completed 12/21/2010	ID Prefix V0117 Reg. # 494.30(a)(1)(ii) LSC	Correction Completed 12/21/2010
ID Prefix V0120 Reg. # 494.30(a)(1)(ii) LSC	Correction Completed 12/21/2010	ID Prefix V0122 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 V0331 Reg. # 494.50(b)(1) LSC	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) LSC	Correction Completed 12/21/2010	ID Prefix V0408 Reg. # 494.60(d) LSC	Correction Completed 12/21/2010	ID Prefix V0417 Reg. # 494.60(e)(1) LSC	Correction Completed 12/21/2010
ID Prefix V0463 Reg. # 494.70(a)(12) LSC	Correction Completed 12/21/2010	ID Prefix V0502 Reg. # 494.80(a)(1) LSC	Correction Completed 12/21/2010	ID Prefix V0686 Reg. # 494.140(b)(3)(ii)-(iii) LSC	Correction Completed 12/21/2010

Reviewed By _____	Reviewed By _____	Date: _____	Signature of Surveyor: 	Date: 12/21/2010
State Agency _____	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____
Reviewed By _____	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____



Post-Certification Revisit Report

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 reviewing data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number 342627	(Y2) Multiple Construction A. Building B. Wing	(Y3) Date of Revisit 12/21/2010
Name of Facility CHARLOTTE EAST DIALYSIS	Street Address, City, State, Zip Code 3204 SHARON AMITY CHARLOTTE, NC 28205	

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix <u>V0750</u>	Correction Completed 12/21/2010				
Reg. # <u>494.190</u>					
LSC _____					

Reviewed By _____	Reviewed By _____	Date: _____	Signature of Surveyor: <i>Ralph Niles</i>	Date: 12/22/12
State Agency _____	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____
CMS RO _____	Followup to Survey Completed on: _____			
Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility?			YES	NO

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

The reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project(0838-0583), Washington, D.C. 20503.

Provider/Supplier Number 342627	Provider/Supplier Name CHARLOTTE EAST DIALYSIS
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Type of Survey (select all that apply)

<input type="checkbox"/> I	<input type="checkbox"/> D	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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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)

<input type="checkbox"/> A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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A Routine/Standard Survey (all providers/suppliers)  
 B Extended Survey (HHA or Long Term Care Facility)  
 C Partial Extended Survey (HHA)  
 D Other Survey

SURVEY TEAM AND WORKLOAD DATA

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

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID								
1. 15546	12/21/2010	12/21/2010	1.00	0.00	3.00	0.00	5.00	2.00
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00      Total RO Supervisory Review Hours..... 0.00

Total SA Clerical/Data Entry Hours..... 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

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project (0838-0583), Washington, D.C. 20503.

Provider/Supplier Number 342627	Provider/Supplier Name CHARLOTTE EAST DIALYSIS
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Type of Survey (select all that apply)

<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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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)

<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------	--------------------------	--------------------------	--------------------------

A Routine/Standard Survey (all providers/suppliers)  
 B Extended Survey (HHA or Long Term Care Facility)  
 C Partial Extended Survey (HHA)  
 D Other Survey

SURVEY TEAM AND WORKLOAD DATA

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

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	12/21/2010	12/21/2010	1.00	0.00	3.00	0.00	5.00	2.00
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00      Total RO Supervisory Review Hours..... 0.00

Total SA Clerical/Data Entry Hours..... 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/29/2010
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 324 SHARON AVENUE CHARLOTTE, NC 28205
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) CORRECTION DATE
(V 000)	<b>INITIAL COMMENTS</b>  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 000)	V000- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm was installed as required. The physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.	
(V 110)	494.30 CFC-INFECTION CONTROL  This CONDITION is not met as evidenced by: Not reviewed onsite on 10/28/2010.  Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility failed to implement and maintain an effective infection control program. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit	(V 110)	The Governing Body will meet monthly x 3 or more often as required to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi- annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing errors, the findings stated above are dischargeable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are dischargeable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3294 SHARON AVENUE CHARLOTTE, NC 28206		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
(V 110)	<p>Continued From page 1</p> <p>bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality infection control practices for dialysis patients.</p> <p>The findings include:</p> <p>A. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients.</p> <p>-Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0117</p> <p>B. The facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors.</p> <p>-Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0120</p> <p>C. The facility failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments.</p> <p>-Cross refer to 494.30(a)(4)(ii) Infection Control - Tag V0122</p>	(V 110)	<p>V110- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is place to install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. Plexiglas barriers will be placed to prevent potential cross contamination. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with 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.</p> <p>cont pg 3</p>	10-15-10	

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CMS NO. 0938-0301

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE HASY DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 3204 RHARON AVENUE CHARLOTTE, NC 28205
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COLLECTION DATE
(V 110)	Continued From page 2 D. The facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing. -Cross refer to 494.50(b)(1) Reuse of Hemodialyzers and Bloodlines - Tag V0331 E. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. -Cross refer to 494.50(b) Physical Environment- Tag V0403 F. This facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. -Cross refer to 494.50(a)(1)(i) Infection Control- Tag V0114	(V 110)	V110 cont. The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. 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. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	10-18-10
(V 114)	494.50(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: No reviewed on-site on 10/26/2010.  Based on facility policy review, observations and staff interview, the facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area.  The findings include:  A review of the facility's policy "Infection Control	(V 114)		

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

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OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. MAINLINE _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/20/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 7204 SHARON AVENUE CHARLOTTE, NC 28285		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE	
(V 114)	Continued From page 3 for Dialysis Facilities" (revision date 03/2010) revealed "The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination must be available at each sink."  Observation on 08/23/2010 at 1300 in the patient treatment area revealed that a paper towel dispenser located for the patients to wash their access sites at the exit area had no available paper towels for use after handwashing. The observation revealed that the paper towels were located in a machine with a sensor to dispense the towels. After washing hands was observed by a patient and surveyor, it was noted that the sensor was not working and no paper towels were available.  An interview with the facility's registered nurse during the observation on 08/23/2010 at 1300 revealed that the paper towel dispenser was not working. The interview revealed that paper towels would have to be obtained in a different fashion until the sensor was fixed.	(V 114)	V114 Paper towels in the dispenser were replaced and threaded properly. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10/18/10.	
(V 117)	484.30(a)(1)(i) IC-CLEAN/DIRTY/MED PREP 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	(V 117)			

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OMB NO. 0938-0301

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  3428ZT	DOES MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3804 SHARON AMITY CHARLOTTE, NC 28208		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
[V 117]	<p>Continued From page 4</p> <p>(including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010.</p> <p>Based on facility policy review, observations and staff interview, the facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients.</p> <p>The findings include:</p> <p>1. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled."</p> <p>Observation on 08/22/2010 at 1025 in the patient treatment area revealed that a medication cart filled with medications and other unused supplies along with syringes was located directly beside the handwashing sink used by patients to wash their access sites. The sink was designated for patient hand washing and had a sign that was</p>	[V 117]	<p>V117 Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. FA is responsible for ongoing compliance with POC.</p>	10-18-10	



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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	ID COMPLETION DATE
(V 117)	<p>Continued From page 5</p> <p>written as "Patients must wash access sites" and located at the base of the sink. The observation further revealed that no splash guard or barrier was noted to prevent water splashes on the medications and supplies.</p> <p>An interview on 09/22/2010 at 1000 with the facility's nursing staff revealed that the patient medications and unused supplies are stored on the cart was kept beside the handwashing sink. The interview revealed that the staff has always kept the medications and supplies in this location due to lack of space. The interview also confirmed that the supplies and medications can get wet from patients and staff washing hands. The interview revealed that the staff had not considered the potential contamination of the medications or supplies.</p> <p>An interview with the facility administrator on 09/22/2010 at 1240 revealed that the supplies and medications should be prevented from being wet or contaminated from people washing their hands at the nearby sink.</p> <p>2. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled."</p> <p>Observation on 09/22/2010 at 1550 revealed the medication preparation area used by the facility. The observation revealed that the preparation area is located on a wheeled cart (Craftman Brand) with the medication vials located on top of</p>	(V 117)		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(K1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(K2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(K3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3801 SHARDN ARMY CHARLOTTE, NC 28205		
(K4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(K5) COMPLETION DATE	
(V 117)	Continued From page 6 the cart with a cleared area noted. Observation revealed the medication preparation area (cart) was stationary and located directly beside of the facility's designated handwashing sink for patients to wash their access sites. Observation revealed that the facility had a sign on the sink that was written as "Patients must wash access sites" located at the base of the sink. The observation further revealed that no barrier and splash guard was present to prevent potential cross contamination during medication preparation. No separate clean area was observed for patient medication preparation.  An interview on 08/22/2010 at 1555 during the observation with the facility's registered nurse revealed that the cart was the area where the facility's nursing staff prepares patients medications. The interview revealed that she never thought of the potential splashing of water from handwashing sink on the clean medication preparation area.  An interview on 08/22/2010 at 1650 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.	(V 117)			
(V 120)	404.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED  Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.  If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified	(V 120)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/PLAN/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 3304 BRARON AVENUE CHARLOTTE, NC 28205
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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(V 120)	<p>Continued From page 7</p> <p>personnel 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 deinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.</p> <p>Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.</p> <p>This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010.</p> <p>Based on facility policy review, observations and staff interview, the facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients whose dialysis machines were observed to have wet or blood tinged external transducer protectors (Patient stations #1,11).</p> <p>The findings include:</p> <p>A review of the facility's policy "Changing Transducer Protectors" (revision date of 12/2009) revealed "External transducer protectors will be inspected for the presence of blood or saline every 30 minutes during patient treatment and included in the monitoring process. The external transducer protector will be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector."</p>	(V 120)	<p>V120</p> <p>The Clinical Services Specialist (CSS) inspected the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect the external transducers for the presence of blood or saline every 30 minutes during patient treatment. The external transducer protector is to be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10-7-10
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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(K1) PROVIDER/CLIA IDENTIFICATION NUMBER:  342527	(K2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(K3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE BABY DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2304 BHARON AVENUE CHARLOTTE, NC 28205	
(M) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(N) COMPLETION DATE
(V 120)	Continued From page 8  1. Observation on 09/22/2010 at 1608 for the patient in station #1 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector.  2. Observation on 09/22/2010 at 1610 for the patient in station #11 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector.  3. An interview on 09/22/2010 at 1650 with the facility's registered nurse in the patient treatment area revealed that the staff should change the bloody transducers and check the back of the transducer to make sure that the machine is not contaminated.  4. An interview with the facility's administrative staff on 09/22/2010 at 1655 revealed that the transducer protectors should be immediately changed and checked by staff when they become bloody.	(V 120)		
(V 122)	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRTTEN PROTOCOL  [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the- (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.	(V 122)		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2304 SHARON AVENUE CHARLOTTE, NC 28206	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X6) COMPLETION DATE
(V 122)	<p>Continued From page 9</p> <p>This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010.</p> <p>Based on facility policy review, observations and staff interview, the facility failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments.</p> <p>The findings include:</p> <p>A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Equipment if accessible to patients and teammates including outside of sharps containers and all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of procedures, after spills of blood, throughout the day, and after each treatment. Any areas contaminated with visible blood or body fluids are cleaned promptly with a wet wring out wipe using 1:10 bleach solution."</p> <p>1. a. Observation on 08/22/2010 at 1013 in the patient treatment area revealed that a rolling wheeled cart with a total of six (6) acid bath jugs on the cart had noted dialysate powder (white in color and chalky) and dust noted on the cart.</p> <p>1. b. Observation on 08/22/2010 at 1605 revealed trash (paper wrappers) scattered on the patient treatment area floor near patient stations #4 and #11. Observation further revealed three trash cans in the patient treatment area that were full</p>	(V 122)	<p>V122-</p> <p>The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor and blood stains and blood stains are cleaned when they occur. Carts will be replaced by 10/15/2010; removed the existing soap dispensers and mounting brackets and replaced with disposable bottle-type dispensers. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with 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. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10-15-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(01) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(02) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(03) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3201 SHARON AVENUE CHARLOTTE, NC 28205		
(04) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(05) COMPLETION DATE	
(V 122)	<p>Continued From page 10            and overflowing with trash.</p> <p>1. c. Observation on 09/22/2010 at 1518 revealed that two automated (GOJO Brand) soap dispensers in the facility's service area at handwashing sinks designated as clean had raked rated buildup observed directly under the dispensers. No observed evidences of cleaning the dispenser was observed.</p> <p>An interview with the facility administrator on 09/22/2010 revealed that the area should remain free from clutter and dirty buildup around supplies. The interview also revealed that the trash should be cleaned up by the staff. No reason was given as to why the areas were not cleaned by the staff.</p> <p>2. Observation on 09/22/2010 at 1020 in the patient treatment area revealed that vascular clamps used for patient vascular access sites were located in a container of 1:100 bleach disinfectant and had visible clotted blood on the clamp heads. The observation further revealed that the clamps were not fully submerged in the disinfectant bleach.</p> <p>An interview with the facility administrator on 09/22/2010 at 1215 revealed that the clamps should be below the level of bleach solution according to the facility policy.</p> <p>3. Observation on 09/22/2010 at 1015 in the patient treatment area revealed blood stains on top of the needle sharps container located directly beside the patient dialyzing in station #16. The blood stains were located on top of the sharps container from 1045 through 1155 without staff observed to clean the stains.</p>	(V 122)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(K1) PROVIDER/CLIA IDENTIFICATION NUMBER:  342837	(M) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(C3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28209		
(H4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(H3) COMPLETION DATE	
(V 122)	Continued From page 11	(V 122)			
(V 189)	<p>An interview with the facility administrator on 09/22/2010 at 12:10 revealed that the blood stains should be cleaned when they occur or soon as possible.</p> <p>494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY</p> <p>6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.</p> <p>Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-dichloro-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAM] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].</p> <p>Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.</p> <p>This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010.</p>	(V 189)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATA SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3804 SHARON AVENUE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DOB COMPLETION DATE
(V 188)	Continued From page 12  Based on facility policy review, the facility's total chlorine testing log review and staff interview, the facility failed to ensure regularly performed testing to monitor the total chlorine in its water system used in patient hemodialysis and failed to provide color blindness testing in 2 of 4 sampled staff members that test the facility's water system for the presence of chlorine (Staff #1,3).  The findings include:  A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 05/2010) revealed "Total Chlorine testing is done on a daily basis prior to the first patient treatment and every four (4) hours until all activities that require use of dialysis quality water are completed."  A review on 09/23/2010 of the facility's "Routine Total Chlorine Testing Log" for 02/15/2010 revealed that the facility staff failed to document Chlorine testing every 4 hours. The review revealed that for 02/15/2010, the facility staff documented Chlorine 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 signatures for the Chlorine testing. The review revealed that the 0945 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 minute extra window of time given. The interview revealed that some times the nursing staff does not fully document on the water log	(V 188)	V196- The CSS in-serviced the teammates on the importance of completing the water system total chlorine monitoring every 4 hours per policy 2-07-04 "Daily Water Total Chlorine Monitoring" and documenting on the appropriate log. FA/designee will be checked daily for 7 days then weekly on going. Color blindness testing was completed on the 2 RN's cited and it was found that they did have testing and results are in teammates files. Color blindness testing will be done on all new hires and annually thereafter. Facility Administrator will spot check 25% of teammates file monthly for 3 months and annually thereafter. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-18-10



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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  S42827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/29/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON ANNY CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) CORRECTION DATE	
[V 105]	Continued From page 13 record.  A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 09/20/10) revealed that the facility uses the "Lamotte SL-MW Test Kit Colorimeter" for the chlorine testing in its water system. The policy also revealed that the staff instructions include "Holding the Octa-Slide Viewer so that non-direct light enters the back of the comparator. Match the test tube color standard on the Octa-Slide and read the ppm value on the Octa-Slide standard that matches color of the test tube sample."  1. A review of the facility's personnel file for staff nurse #1 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed.  2. A review of the facility's personnel file for staff nurse #3 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed.  3. An interview on 09/23/2010 at 1400 with the facility administrator revealed that three staff nurses did not have any documented color blindness testing in her personnel file. The interview revealed no reason as to why these staff nurses did not have any testing done. The interview also revealed that these nurses do check the water system for chlorine and should have color blind testing to ensure that each nurse	[V 105]			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(01) PROVIDER/CLIA IDENTIFICATION NUMBER  342627	(02) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(03) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE HART DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3201 SHARON AVENUE CHARLOTTE, NC 28226		
(X) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X) ID PREFIX TAG	COMPLETION DATE
(V 198)  (V 331)	Continued From page 14 can read the color matches. 494.60(b)(1) REPROCESSING-TRANSPORTATION & HANDLING  11 Reprocessing 11.1 Transportation and handling Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party.  This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010.  Based on facility policy review, observation, refrigerator temperature log review and staff interview, the facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing.  The findings include:  A review of the facility policy "Reuse of Dialyzers" (revision date 02/2009) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial 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 storage is maintained between 36-50 degrees	(V 198)  (V 331)	V331  Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the 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.		9-30-10

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 11/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3284 SHARON AVENUE CHARLOTTE, NC 28208		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	RE3 COMPLETION DATE	
(V 331)	Continued From page 16 Fahrenheit.  Observation on 08/22/2010 at 1100 in the patient treatment area revealed a total of seven (7) patient used dialyzers inside of the storage refrigerator used for reusa storage. Inspection of the thermometer revealed that the temperature was 55 degrees Fahrenheit at 1105. The observation of the outside of the refrigerator revealed that a handwritten notation was placed on the front of the refrigerator that was written as "Temperature should be 35 degrees F (Fahrenheit) - 50 degrees F." An interview during the observation at 1105 with a patient dialysis care staff member confirmed that the temperature was 55 degrees F and it should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times.  A review on 08/22/2010 of the refrigerator log for 08/2010 revealed that the facility's refrigerator temperature limits should be "35 degrees F to 45 degrees F." The review of the 08/2010 log revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review for 08/01/2010 revealed documentation by staff of the refrigerator temperature to be a range of 32-38 degrees F. On 08/07/2010 the range of the temperature was documented as 32-42 degrees F. Review of the log for 08/22/2010 (date of observation) revealed that the temperature reading was documented as 30-45 degrees F.  An interview with the registered nurse in the patient treatment area on 08/22/2010 at 1105 revealed that the refrigerator has constantly been	(V 331)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(C1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  442827	(C2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(C3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3101 SHARON AVENUE CHARLOTTE, NC 28206		
(L4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(L5) COMPLETION DATE	
(V 331)	Continued From page 16 a concern with the temperature readings. The interview revealed "Everytime we put hot dialyzers in that refrigerator, the temperature goes in the 50s."	(V 331)			
(V 340)	An interview with the facility administrator on 09/22/2010 at 1210 revealed that he was not aware of the elevated temperature readings of the reprocessing storage refrigerator. The interview revealed that the staff had not informed him of the elevated temperature changes. <b>494.50(b)(1) DIALYZER GERM=90% CONC/CAPS DISINFECT</b>  11.4.1.4 Chemical germicidal procedure: = 90% copolyp cap disinfectant If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90% of the prescribed concentration.  The parts of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer.  This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010.  Based on facility policy review, observations and staff interview, the facility's reuse staff failed to ensure that reuse dialyzer caps were cleaned and disinfected by appropriate immersion in a germicide before reassembling of the reprocessed dialyzers.	(V 340)	V340- The CSS in-serviced reuse teamates on policy 6-04-03 Cleaning and Disinfection of Reuse Supplies with emphasis on the need to fully immerse the caps below the germicide surface level. Facility Administrator will monitor submersion of caps per policy for 7 days then once a week for 2 weeks, then monthly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 334 BARNHARTY CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
(V 340)	Continued From page 17  The findings include:  A review of the facility's policy "Cleaning and Disinfection of Reuse Supplies Policy" (originated date 08/26/08) revealed "Reuse supplies will be cleaned and disinfected with a 1% peracetic acid solution for a minimum of 30 minutes. Blood and dialysate port caps, barrier adapters, extension tubing must be disinfected for a period of 30 minutes but no greater than 24 hours prior to use."  Observation on 09/22/2010 at 1006 in the facility's reprocessing room revealed that reprocessing caps and port caps used for patient reprocessed dialyzers were placed in two 1% peracetic acid (germicide) solution plastic containers located in the designated dirty section for disinfection. The observation revealed that the caps in both containers of the disinfectant were not fully immersed below the disinfectant germicide surface level. The observation was during a time when no staff was present in the reprocessing area.  An interview on 09/22/2010 at 1620 with the facility's reuse technician revealed that the containers with the caps should have the caps fully below the level of the disinfection surface. The interview revealed no reason as to why the caps in both containers were not below the disinfectant surface level.	(V 340)	V400-Physical Environment Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm has been installed as required. *In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. cont pg 19	10-22-10 for Fire system  12-31-10 for additional physical plant work	
(V 400)	494.60 CFC-PHYSICAL ENVIRONMENT  This CONDITION is not met as evidenced by: Not reviewed onsite on 10/28/2010.	(V 400)			

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(K1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(C2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(C3) DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28205		
(H4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	POC COMPLETION DATE	
(V 400)	Continued From page 18  Based on observations as referenced in the Life Safety Report of a complaint investigation completed 09/30/2010, facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility failed to maintain a physical environment that decreased the potential risks to the health and safety of patients, visitors and staff. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7800 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only interviewing staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the health and safety of patients, staff and visitors at the dialysis facility.  The findings include:  A. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7800 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying	(V 400)	V400 cont. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the 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. * Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device.  This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. cont. pg 20	9-30-10	*12-31-10 for additional physical plant work  10/07/10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342537	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3804 SHARON AVENUE CHARLOTTE, NC 28206		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE	
(V 400)	Continued From page 19 conditions each quarter in place of only interviewing staff on the fire drills, and failed to remove storage in the front corridor of the facility next to the lobby at the slide exit door.  -Cross refer to 494.60(a)(1) Physical Environment Fire Safety and Life Safety Code-Tag V0417  B. The facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or impassable.  -Cross refer to 494.60(d) Physical Environment - Tag V0408  C. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers.  -Cross refer to 494.60(b) Physical Environment - Tag V0403.	(V 400)	V400 cont. *The current Patient Station #7 will be relocated. A minimum 3'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0" ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes.  Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work  10-1-10  09/30/10.	
(V 403)	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU  The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.  This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010.	(V 403)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  542827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 8204 SHARON AVENUE CHARLOTTE, NC 28205		
D-0 ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	CIR COMPLETION DATE	
(V 403)	<p>Continued From page 20</p> <p>Based on facility policy review, observations, refrigerator temperature log review and staff interview, the facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reuse dialyzers. This deficient practice placed all patients participating in the reprocessing program at risk for exposure to contamination from bacterial growth in the dialyzers.</p> <p>The findings include:</p> <p>A review of the facility policy "Reuse of Dialyzers" (revision date 08/2008) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial growth until reprocessing is begun. Reprocessed dialyzers may be stored for up to 36 hours prior to being reprocessed.</p> <p>The refrigerator used for contaminated dialyzer storage is maintained between 39-50 degrees Fahrenheit."</p> <p>Observation on 08/22/2010 at 1100 in the patient treatment area revealed that the facility had a refrigerator in the patient treatment area that was used to store reuse dialyzers at a temperature to inhibit potential bacterial growth. The observation revealed a total of seven (7) patient used dialyzers inside of the refrigerator used for the reuse storage. The observation at 1105 of the thermometer revealed that the temperature was 56 degrees Fahrenheit. The observation of the outside of the refrigerator revealed that a handwritten note was placed on the front of the refrigerator indicating "Temperature should be 36 degrees F."</p>	(V 403)	<p>V403</p> <p>Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the 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 PCC.</p>	9-30-10	



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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/CLINIC/ENROLLMENT IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/20/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3704 HARRON AVE CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
(V 403)	Continued From page 21 An interview during the observation at 1105 with patient dialysis care staff member revealed that the temperature was 68 degrees F and that the temperature should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times.  A review on 09/22/2010 of the refrigerator log for 08/2010 revealed that the facility's refrigerator temperature limits should be "35 degrees F to 45 degrees F." The review of the log for 08/2010 revealed that the staff had documented temperature checks at ranges instead of a single documented temperature. Review of 09/01/2010 revealed documentation 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 (date of observation) revealed that the temperature reading was documented as 30-48 degrees F.  An interview on 09/22/2010 at 1330 with the facility administrator revealed that the temperatures of the refrigerators should be monitored every day and that the exact temperature should be documented. The interview also revealed that the reuse storage refrigerator should not be greater than 50 degrees F. The interview further revealed that the log used by the staff was meant for use for refrigerators containing medications, and that the limits on the log were set for medication storage, instead of showing the highest degree of 50 F.	(V 403)			
(V 403)	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES  The dialysis facility must implement processes	(V 403)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	CMI PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	DCI) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		CMI) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS		STREET ADDRESS, CITY, STATE, ZIP CODE 3304 BISHOP ANNITY CHARLOTTE, NC 28208		
CMI) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	CMI) COMPLETION DATE
V40B)	<p>Continued From page 22 and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p> <p>This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010.</p> <p>Based on observations, fire safety reports review and staff interview, the facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or unpassable.</p> <p>The findings include:</p> <p>Observation on 09/22/2010 at 10:15 during tour of the facility's patient treatment area revealed that the facility had a total of sixteen (16) total stations for hemodialysis treatments. The facility hemodialysis station locations were against the four (4) walls of the patient treatment area. The observation of the facility's fire safety emergency evacuation route revealed that the facility had one emergency exit leading directly into a hallway from the patient treatment area. The exit route led to a door with a fire exit sign leading out to the facility's lobby area and main exit doors. The observation further revealed that there was no other exit location or emergency evacuation route in the patient treatment area. Observation revealed that only one (1) exit route/egress</p>	V40B)	<p>V40B- *The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0" ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes. *</p> <p>A copy of Certificate of Occupancy has been requested from the city of Charlotte, original architect and general contractor. Going forward any fire inspections will be kept on file in the facility. FA is responsible for ongoing compliance with POC.</p> <p>*The facility has been diligently working on correcting all the issues cited since the survey. The fire system has been installed as required. The physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.*</p>	<p>10-13-10</p> <p>*12-31-10 for additional physical plant work</p>

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342877	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/28/2010
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 2204 SHARON AVENUE CHARLOTTE, NC 28208
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE
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(V 408)	<p>Continued From page 23</p> <p>located in the patient treatment area for patients, visitors and staff. No other doors or exits were observed in the patient treatment area.</p> <p>An interview on 09/22/2010 at 1110 with the facility's registered nurse in the patient treatment area revealed that there was only one way out of the patient treatment area at the facility. The interview revealed, "I have never thought about it, but if there was a fire, the only way out would be through the that area (staff indicating by pointing to the one exit) there." The interview revealed that the staff were trained in fire drills to use the one exit in the treatment area to evacuate the patients. The interview also revealed that the facility administration did not instruct the staff what to do if that one fire exit route was blocked with fire or other objects.</p> <p>A review of the local fire marshal reports on 09/28/2010 revealed that no report could be found at the facility where any fire marshal or local fire inspection was done at the facility to determine fire safety compliance. No documentation could be produced by the facility that revealed any fire safety inspections were conducted at the facility.</p> <p>An interview on 09/23/2010 at 1000 with the facility administrator and regulatory staff revealed that the facility could not find or produce a fire marshal or local county/city report for any past inspection of the facility's fire safety. The interview revealed that the facility should have one on file, but the administrative staff were unable to produce this document during the survey.</p>	(V 408)	<p>V417-</p> <ol style="list-style-type: none"> <li>The fire system has been installed as required.</li> <li>The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled.</li> <li>Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device.</li> <li>The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer device.</li> </ol> <p>cont pg 25</p>	*10-22-10 for Fire system
(V 417)	434.60(e)(1) PE-FIRE SAFETY-LIFE SAFETY CODE 2000	(V 417)		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342027	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3304 SHARON AVE CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
(V 417)	Continued From page 24  (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009, The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744 (a)(1)(i) of this chapter).  This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010.  Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following were noted:  1) The Server Room is lined with a plywood interior finish on the walls which does not comply with the required fire resistance rating for the area. 2) Facility is approximately 7800 sq. ft. in size and does not have a smoke barrier separating the building into two separate smoke compartments. 3) The facility has Bio Hazard Storage room is not self closing nor fire-rated. 4) The emergency battery operated light located next to the re-use room was not operational when tested. 5) The facility instructs the staff on Fire Drills each quarter in place of holding Fire drills being held at unexpected times under varying conditions. 6) There is storage in the front corridor next to the lobby to the side exit door, partially blocking the exit.  (V 463) 484.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC	(V 417)	V417 cont. 5. This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. 6. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. 7. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. *The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm has been installed as required. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.*		*12-31-10 for additional physical plant work

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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE HART DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVE CHARLOTTE, NC 28209		
(X3) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	OSR COMPLETION DATE	
(V 463)	<p>Continued From page 26</p> <p>The patient has the right to-</p> <p>(12) Receive the necessary services outlined in the patient plan of care described in §494.50;</p> <p>This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010.</p> <p>Based on facility policy review, clinical record review, patient interview and staff interview, the facility failed to include the patient in the facility's interdisciplinary team annual meeting involving the patient's plan of care for 2 of 7 sampled patient records (Patient #1,B).</p> <p>The findings include:</p> <p>A review of the facility policy "Patient Assessments and Plan of Care" (revision date 03/2010) revealed "The patient plan of care will be completed by the facility's interdisciplinary team, including patient or personal representative and be signed by team members including the patient or the patient's personal representative."</p> <p>A review on 09/22/2010 of the open clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2009. The review of the clinical record revealed that an "Annual Care Plan" meeting was scheduled for Wednesday 03/03/2010 for the patient. A review of the form inviting the patient was found in the clinical record of the patient. The review of the form revealed that the facility's clinician signed the staff signature portion and dated it 03/03/2010 but failed to obtain a patient signature that she would either attend or not attend the meeting. The</p>	(V 463)	<p>V463- Policy #1-01-07 Patient Assessment and Plan of Care" was reviewed with the interdisciplinary team (IT) with emphasis on the need to include the patient/patient designee in the development of the plan of care unless the patient declines. Each patient will be given a written and verbal invitation to the care plan meeting as care plans become due. Patients will be asked to sign invitation and note if they will attend. If patient declines the invitation the plan of care a member of the IDT will review with them and ask for their signature on the plan. If the patient refuses to sign, this will be noted in the record as well. FA/designee will audit all plans of care completed x 3months and then 10% of those completed quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10-18-10	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(C1) PROVIDER/PLU/CLIA IDENTIFICATION NUMBER:  342627	(C2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(C3) DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2206 SHARON AVE CHARLOTTE, NC 28205	
(M4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	IS PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(M5) COMPLETION DATE
(V 463)	Continued From page 20 space was not completed and left blank but the staff member (diplomat) had signed the staff signature witness section. No documentation was found where the patient received individualized care and a chance to participate in her plan of care meeting.  An interview with patient #8 on 09/22/2010 at 1040 during the facility tour and observation revealed that the patient had not been invited by the facility staff to her plan of care meetings. The interview revealed "I am usually told they happened, but the staff does not really invite me to attend. I would try to make it if possible. I usually sign the paper after the meeting happens."	(V 463)		
(V 502)	484.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS  The patient's comprehensive assessment must include, but is not limited to, the following:  (1) Evaluation of current health status and medical condition, including co-morbid conditions.  This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010.  Based on facility policy review, clinical record	(V 502)	V502- The Required documentation for the administration of PRN medication to include the reason given and effectiveness of the medication was reviewed with RN's. Facility Administrator will monitor documentation of PRN meds once a week for 3 weeks then complete random audits quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28205
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
(V 502)	<p>Continued From page 27</p> <p>review and staff interview, the facility failed to ensure that registered nurses met the clinical needs of patients by failing to document and reassess as needed (PRN) medication administration in 5 of 5 sampled patients receiving PRN medication (Patients #1,2,3,4,6).</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. A review on 09/22/2010 of the clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2008 for chronic hemodialysis. A review of the patient treatment sheets for 08/18/2010 and 08/27/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/16/2010 at 1705 and on 08/27/2010 at 1430 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.</li> <li>2. A review on 09/23/2010 of the clinical record for patient #2 revealed that the patient was admitted to the facility on 10/20/2008 for chronic hemodialysis. A review of the patient treatment sheets for 08/24/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment</li> </ol>	(V 502)		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2205 SHARON AVENUE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	CRN COMPLETION DATE
(V 502)	<p>Continued From page 28</p> <p>of the medication effectiveness. The review revealed that on 08/24/2010 at 1149 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.</p> <p>3. A review on 08/23/2010 of the clinical record for patient #3 revealed that the patient was admitted to the facility on 12/29/2009 for chronic hemodialysis. A review of the patient treatment sheets for 08/18/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1422 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.</p> <p>4. A review on 09/23/2010 of the clinical record for patient #4 revealed that the patient was admitted to the facility on 03/11/2010 for chronic hemodialysis. A review of the patient treatment sheets for 08/20/2010 revealed that the facility</p>	(V 502)	<p>V686</p> <p>The facility will ensure qualified charge nurse is designated for each shift during hemodialysis treatments. The opening nurse is designated as the charge nurse for the day and this will be identified on the daily schedule on an ongoing basis. FA is responsible for ongoing compliance with POC.</p>	10-15-10



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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	DCI MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		PCN DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3214 SHANDH AVENUE CHARLOTTE, NC 28205		
OSD ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROCEDURE PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	PER COMPLETION DATE	
(V 502)	<p>Continued From page 29</p> <p>Nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 09/20/2010 at 1807 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.</p> <p>8. A review on 09/23/2010 of the clinical record for patient 68 revealed that the patient was admitted to the facility on 07/21/2009 for chronic hemodialysis. A review of the patient treatment sheets for 08/18/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1443 the patient was administered the medication "Loperamide (and at times medication) 2 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.</p>	(V 502)	<p>V750</p> <p>Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height will also be installed around the medication prep area to further designate this space as a clean area. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift. 3 weeks, and then this will be included in monthly infection control audit going forward.</p> <p>The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need appropriate cleaning and disinfecting of vascular clamps. cont. pg 31</p>	10-18-10	
(V 688)	<p>994.140(b)(3)(i)-(ii) PG-CHARGE NURSE-12 MO NURSING+3 MO DIALYSIS</p>	(V 688)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  347827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3201 SHARON AVENUE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLIANCE DATE
V 685	<p>Continued From page 30</p> <p>The charge nurse responsible for each shift must:</p> <p>(1) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;</p> <p>(2) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis.</p> <p>This STANDARD is not met as evidenced by:                  Not reviewed onsite on 10/26/2010.</p> <p>Based on facility policy review and staff interview, the facility failed to designate a charge nurse for each shift during hemodialysis treatments.</p> <p>The findings include:</p> <p>A review of the facility policy "Teammate Qualifications, Licensure and Adequate Teammate Staffing" (revision date of 12/2008) revealed "Charge Nurse Standards: The charge nurse responsible for each shift will be a registered nurse, licensed practical nurse/vocational nurse who meets the practice requirements in each State in which he or she is employed."</p> <p>An interview on 09/22/2010 at 0900 with the facility administrator revealed that the facility does not currently have a designated charge nurse during the hemodialysis treatments. The interview revealed "We do not have enough patients to have an established charge nurse. All of the staff knows we have a nurse that can handle things and who to report problems to."</p>	V 686	<p>V750 cont. 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.</p> <p>The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. 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.</p> <p>Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward.</p> <p>*The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm has been installed as required. cont pg 32</p>	10-18-10
				*10-22-10 for Fire system

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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28209		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	CORRECTION DATE	
(V 088)	Continued From page 31	(V 088)	V750 cont. *The physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.		
(V 760)	494.180 CFC-GOVERNANCE  This CONDITION is not met as evidenced by: Not reviewed onsite on 10/28/2010.  Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility's governing body failed to provide oversight and have systems in place to ensure the facility implemented and maintained an effective infection control program; and failed to ensure that the facility maintained a physical environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Renalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to conduct fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit	(V 760)	*The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer device. cont pg 33	*12-31-10 for additional physical plant work	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 324 SHARON ARMY CHARLOTTE, NC 28201	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
(V 750)	Continued From page 82 blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure safe and effective care for all dialysis patients, and the safety of staff and visitors.  The findings include:  A. For findings causing the Condition for Infection Control to be not met, see V110 and its associated tags. reprocessing; and failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area; appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area.  -Cross refer to 484.30 Infection Control Condition- Tag VQ110  B. The facility failed to maintain a physical	(V 750)	V750 cont. This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee.  Please review the attached MSDS Sheet for Renalin, Section 16 for Other Information. The NFPA Flammability Classification for this chemical is 0, thereby qualifying as a low hazard in accordance with NFPA 101 Section 6.2.2.2.  NFPA 101 Section A6.2.2.4 for High Hazardous contents are described as the following "contents include occupancies where flammable liquids are handled or used or are stored under conditions involving possible release of flammable vapors; where grain dust, wood flour, or plastic dust, aluminum or magnesium dust, or other explosives are produced; where hazardous chemicals or explosives are manufactured, stored, or handled under conditions producing flammable flyings; and other situations of similar hazards." cont pg 34	10/07/10          09/30/10    12-31-10 for additional physical plant work

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  R 10/30/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28208		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
(V 750)	Continued From page 33 environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7800 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Remalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to retrieve storage in the front corridor of the facility next to the lobby at the side exit door; failed to announce an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers.  *Cross refer to 494.80 Physical Environment Condition- Tag V0400	(V 750)	V750 cont *The Storage Room is classified as a Low Hazard area in accordance with Section 6.2.2.2. Due to this, NFPA 101 Section 8.4.1 will require this area as well as the Janitor's Closet to be upgraded to the Minimum 1 Hour Fire Resistant Rating. This will be accomplished by upgrading the existing Non-Rated Partition and Doors according to the attached Sketches.  The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342527	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - CHARLOTTE EAST DIALYSIS B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/28/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2204 SHAWEN ARMY CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
(K 014)	416.44(b)(1) LIFE SAFETY CODE STANDARD  Interior finish on walls and ceilings of exits, enclosed corridors, and exit access furnishings are Class A or B (offices Class A, B, or C). 39.3.3.2, 39.3.3.2  This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) In the server room the walls were covered with plywood. Facility is to insure that the walls are in compliance with NFPA 101 Chapter "10.2.3.1 Interior wall or ceiling finish that is required elsewhere in this Code to be Class A, Class B, or Class C, shall be classified based on test results from NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials."	(K 014)		
(K 028)	416.44(b)(1) LIFE SAFETY CODE STANDARD  Hazardous areas separated from other parts of the building by fire barriers have at least one hour fire resistance rating or such areas are enclosed with partitions and doors and the area is provided with an automatic sprinkler system. High hazard areas are provided with both fire barriers and sprinkler systems 39.3.2, 39.3.2  This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The facility has a Bio Hazard Storage Room and the doors are not self closing or fire rated.	(K 028)		
(K 032)	416.44(b)(1) LIFE SAFETY CODE STANDARD	(K 032)		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement showing an asterisk (\*) denotes a deficiency which the institution may be excused from correcting provided it is determined that other appropriate protective action is taken. (See instructions.) Except for nursing homes, the findings stated above are due within 90 days following the date of survey unless or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are due within 14 days following the date these documents are made available to the facility. If the statement is cited, an approved plan of correction is required to confirm program participation.

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(K1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(K2) MULTIPLE CONTRIBUTION A. BUILDING 01-CHARLOTTE EAST DIALYSIS B. WING _____		(K3) DATE SURVEY COMPLETED  R 10/20/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 5204 SHARON AVENUE CHARLOTTE, NC 28206		
(K4) ID PREFIX TAG	BRIEF STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COR COMPLETION DATE	
(K 032)	Continued From page 1 At least two exits, located remote from each other, are provided for each floor or fire section of the building. 20.2.4.1, 21.2.4.1, 7.5.1.4	(K 032)			
(K 045)	This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) There is storage in the front corridor next to the lobby that exits to the side exit door. 416.44(b)(1) LIFE SAFETY CODE STANDARD  Emergency illumination is provided in accordance with section 7.9. 20.2.9.1, 21.2.9.1	(K 045)			
(K 050)	This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The battery operated emergency lights located by the re-use room did not operate when tested. 416.44(b)(1) LIFE SAFETY CODE STANDARD  Fire drills are held at unexpected times under varying conditions, at least quarterly on each shift. The staff is familiar with procedures and is aware that drills are part of established routine. 20.7.1.2, 21.7.1.2	(K 050)			
	This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The facility in-services the staff on fire drills				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - CHARLOTTE EAST DIALYSIS B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE SHERBORN AVENUE CHARLOTTE, NC 28208	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
(K 050)	Continued From page 2	(K 050)		
(K 115)	each quarter in place of holding fire drills at unexpected times under varying conditions, 418.44(b)(1) LIFE SAFETY CODE STANDARD  Ambulatory health care facilities are divided into at least two smoke compartments with smoke barriers having at least 1 hour fire resistance rating. Doors in smoke barriers are equipped with positive latches. Doors are constructed of not less than 1 1/2 inch thick solid bonded core wood or equivalent. Vision panels are provided and are of fixed wire glass limited to 1,295 sq. inch per panel. 20.3.7.1, 20.3.7.2, 20.3.7.3, 21.3.7.1, 21.3.7.2, 21.3.7.3  This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The facility is approximately 7500 sq. ft. in size and the facility does not have a smoke barrier separating the building into two smoke compartments.	(K 115)		



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CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL  
PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

ID W631

Facility ID: 001554

1. HCARE/MEDICAID PROVIDER NO. (L1) 342627	2. STATE VENDOR OR MEDICAID NO. (L2)	3. NAME AND ADDRESS OF FACILITY (L3) CHARLOTTE EAST DIALYSIS (L4) 3204 SHARON AMITY (L5) CHARLOTTE, NC (L6) 28205	4. TYPE OF ACTION: <u>2</u> (L8) 1. Initial 2. Recertification 3. Termination 4. CHOW 5. Validation 6. Complaint 7. On-Site Visit 8. Full Survey After Complaint 9. Other
5. EFFECTIVE DATE CHANGE OF OWNERSHIP (L9)	6. DATE OF SURVEY 10/01/2010 (L34)	7. PROVIDER/SUPPLIER CATEGORY 09 (L7) 01 Hospital 02 SNF/NF/Dual 03 SNF/NF/Distinct 04 SNF 05 HHA 06 LAB 07 X-Ray 08 OPT/SP 09 ESRD 10 NF 11 ENR 12 RHIC 13 PTP 14 CORF 15 ASC 16 HOSPICE	FISCAL YEAR ENDING DATE (L35) 12/31
8. ACCREDITATION STATUS: 0 Unaccredited 2 AOA 1 TJC 3 Other	11. LTC PERIOD OF CERTIFICATION From (a): To (b):	10. THE FACILITY IS CERTIFIED AS A. In Compliance With Program Requirements Compliance Based On: ___ 1. Acceptable POC B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: B* (L12)	And/Or Approved Waivers Of The Following Requirements ___ 2. Technical Personnel ___ 3. 24 Hour RN ___ 4. 7-Day RN (Rural SNF) ___ 5. Life Safety Code ___ 6. Scope of Services Limit ___ 7. Medical Director ___ 8. Patient Room Size ___ 9. Beds/Room
12. Total Facility Beds <u>Station 16</u> (L18)	13. Total Certified Beds <u>Station 16</u> (L17)	14. LTC CERTIFIED BED BREAKDOWN 18 SNF (L37) 18/19 SNF (L38) 19 SNF (L39) ICF (L42) IMR (L43)	15. FACILITY MEETS 1861 (e) (1) or 1861 (j) (1): (L15)

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE)  
None Attached Remarks

17. SURVEYOR SIGNATURE: Ralph M. [Signature] Date: 10/26/2010 (L19)

18. STATE SURVEY AGENCY APPROVAL: [Signature] Date: 11/2/2010 (L1)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY <input checked="" type="checkbox"/> 1. Facility is Eligible to Participate <input type="checkbox"/> 2. Facility is not Eligible (L21)	20. COMPLIANCE WITH CIVIL RIGHTS ACT: 21. 1. Statement of Financial Solvency (HCFA-2572) 2. Ownership/Control Interest Disclosure Stmt (HCFA-1513) 3. Both of the Above.		
22. ORIGINAL DATE OF PARTICIPATION 01/30/2003 (L24)	23. LTC AGREEMENT BEGINNING DATE (L41)	24. LTC AGREEMENT ENDING DATE (L25)	26. TERMINATION ACTION: <u>VOLUNTARY</u> <u>00</u> (L30) 01-Merger, Closure 02-Dissatisfaction W/ Reimbursement 03-Risk of Involuntary Termination 04-Other Reason for Withdrawal <u>INVOLUNTARY</u> 05-Fail to Meet Health/Safety 06-Fail to Meet Agreement <u>OTHER</u> 07-Provider Status Change 00-Active
25. LTC EXTENSION DATE (L27)	27. ALTERNATIVE SANCTIONS A. Suspension of Admissions (L44) B. Rescind Suspension Date: (L45)	28. TERMINATION DATE (L28)	30. REMARKS
31. RO RECEIPT OF CMS-1539 (L32)	32. DETERMINATION OF APPROVAL DATE (L33)	29. INTERMEDIARY/CARRIER NO. 00101 (L31)	DETERMINATION APPROVAL

C&T REMARKS - CMS 1539 FORM

Recertification 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 (IJ) was identified on October 1, 2010 at 1130. The IJ was not 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 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 (RM).

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 11/02/2010  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  R 10/26/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS		STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AMITY CHARLOTTE, NC 28205	

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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{V 000} INITIAL COMMENTS {V 000}

An onsite follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the IJ at 1250 based on compliance with a fire alarm system in place. The CMS Dallas regional office was notified of the recommendation. The conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended to be in compliance based on the plan of correction not completed during follow up survey.

{V 110} 494.30 CFC-INFECTION CONTROL {V 110}

This CONDITION is not met as evidenced by:

{V 114} 494.30(a)(1)(i) IC-SINKS AVAILABLE {V 114}

A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.

{V 117} 494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS {V 117}

This STANDARD is not met as evidenced by:

Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.

When multiple dose medication vials are used (including vials containing diluents), prepare

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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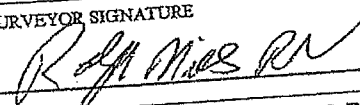
Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continue program participation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**CENTERS FOR MEDICARE & MEDICAID SERVICES**  
**MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL**  
**PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY**

ID: WB31  
 Facility ID: 001554

MEDICARE/MEDICAID PROVIDER NO. (L1) 342627 STATE VENDOR OR MEDICAID NO. (L2)	3. NAME AND ADDRESS OF FACILITY (L3) CHARLOTTE EAST DIALYSIS (L4) 3204 SHARON AMITY (L5) CHARLOTTE, NC (L6) 28205	4. TYPE OF ACTION: <u>2</u> (L8) 1. Initial 2. Recertification 3. Termination 4. CHOW 5. Validation 6. Complaint 7. On-Site Visit 8. Full Survey After Complaint 9. Other FISCAL YEAR ENDING DATE: (L35) 12/31
EFFECTIVE DATE CHANGE OF OWNERSHIP (L9) DATE OF SURVEY 10/01/2010 (L34) ACCREDITATION STATUS: (L10) 0 Unaccredited 1 TIC 2 AOA 3 Other	7. PROVIDER/SUPPLIER CATEGORY <u>09</u> (L7) 01 Hospital 05 HEA 09 ESRD 13 FTIP 02 SNF/NF/Dual 06 LAB 10 NF 14 CORF 03 SNF/NF/Distinct 07 X-Ray 11 IMR 15 ASC 04 SNF 08 OPT/SP 12 RHC 16 HOSPICE	
1. LTC PERIOD OF CERTIFICATION From (a): To (b): 12. Total Facility Beds <u>Stations 16</u> (L18) 13. Total Certified Beds <u>Stations 16</u> (L17)	10. THE FACILITY IS CERTIFIED AS: A. In Compliance With Program Requirements Compliance Based On: I. Acceptable POC X B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: B* (L12) And/Or Approved Waivers Of The Following Requirements: 2. Technical Personnel 3. 24 Hour RN 4. 7-Day RN (Rural SNF) 5. Life Safety Code 6. Scope of Services Limit 7. Medical Director 8. Patient Room Size 9. Beds/Room	
14. LTC CERTIFIED BED BREAKDOWN 18 SNF (L37) 18/19 SNF (L38) 19 SNF (L39) ICF (L42) IMR (L43)	15. FACILITY MEETS 1861 (e) (1) or 1861 (f) (1): (L15)	

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):  
 A recertification 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 (I) was identified on October 1, 2010 at 1130. The IJ 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 494.140 Personnel Qualifications. A plan of correction was requested.

17. SURVEYOR SIGNATURE  Date: 10/11/2010 (L19)	18. STATE SURVEY AGENCY APPROVAL Date: <u>1</u> (L20)
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**PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY**

19. DETERMINATION OF ELIGIBILITY <input checked="" type="checkbox"/> 1. Facility is Eligible to Participate <input type="checkbox"/> 2. Facility is not Eligible (L21)	20. COMPLIANCE WITH CIVIL RIGHTS ACT: 21. 1. Statement of Financial Solvency (HCFA-2572) 2. Ownership/Control Interest Disclosure Stmt (HCFA-1513) 3. Both of the Above:	
22. ORIGINAL DATE OF PARTICIPATION 01/30/2003 (L24)	23. LTC AGREEMENT BEGINNING DATE (L41) 24. LTC AGREEMENT ENDING DATE (L25)	26. TERMINATION ACTION: <input checked="" type="checkbox"/> VOLUNTARY <u>00</u> (L30) 01-Merger, Closure 02-Dissatisfaction W/ Reimbursement 03-Risk of Involuntary Termination 04-Other Reason for Withdrawal INVOLUNTARY 05-Fail to Meet Health/Safety 06-Fail to Meet Agreement OTHER 07-Provider Status Change 00-Active
25. LTC EXTENSION DATE: (L27)	27. ALTERNATIVE SANCTIONS A. Suspension of Admissions: (L44) B. Rescind Suspension Date: (L45)	
28. TERMINATION DATE: (L28)	29. INTERMEDIARY/CARRIER NO. 00101 (L31)	30. REMARKS
31. PRO RECEIPT OF CMS-1539 (L32)	32. DETERMINATION OF APPROVAL DATE (L33)	DETERMINATION APPROVAL

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

The reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project (0838-0583), Washington, D.C. 20503.

Provider/Supplier Number 342627	Provider/Supplier Name CHARLOTTE EAST DIALYSIS
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Type of Survey (select all that apply)

I				
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- 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				
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- A Routine/Standard Survey (all providers/suppliers)
- B Extended Survey (HHA or Long Term Care Facility)
- C Partial Extended Survey (HHA)
- D Other Survey

SURVEY TEAM AND WORKLOAD DATA

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

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-3am (E)	On-Site Hours 3am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. 14819	09/22/2010	10/01/2010	0.50	0.00	1.00	0.00	4.00	0.50
2. 15546	09/22/2010	10/01/2010	1.00	0.00	19.00	0.00	13.00	10.50
3. 26594	09/22/2010	10/01/2010	0.50	0.00	4.00	0.00	1.50	0.50
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Supervisory Review Hours.... 0.00

Total RO Clerical/Data Entry Hours..... 0.00

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

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project(0838-0583), Washington, D.C. 20503.

Provider/Supplier Number 142627	Provider/Supplier Name CHARLOTTE EAST DIALYSIS
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Type of Survey (select all that apply)

<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Extent of Survey (select all that apply)

<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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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

A Routine/Standard Survey (all providers/suppliers)  
 B Extended Survey (HHA or Long Term Care Facility)  
 C Partial Extended Survey (HHA)  
 D Other Survey

SURVEY TEAM AND WORKLOAD DATA

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

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID								
1. 15546	10/26/2010	10/26/2010	1.00	0.00	3.00	0.00	5.00	2.00
2. 13743	10/26/2010	10/26/2010	0.50	0.00	1.00	0.00	0.00	0.00
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Supervisory Review Hours.... 0.00

Total RO Clerical/Data Entry Hours.... 0.00

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

PRINTED: 10/28/2010  
FORM APPROVED  
OMB NO. 0938-0081

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  343227	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2804 SHARON AVENUE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROMISER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 000	INITIAL COMMENTS  An on-site recertification survey was conducted on September 22 through October 1, 2010. During the survey, concerns were found in the Life Safety Code and a complaint issue was generated for a Life Safety Code survey. The survey on September 30, 2010 from the Life Safety Code survey team resulted in an Immediate Jeopardy (IJ) identification on October 1, 2010 at 1130. The IJ was identified when the facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire. The lack of the fire alarm system or a battery powered smoke detector in the building created a physical environment that increased the risk for harm during fire in the health and safety of patients, visitors and staff while at the facility resulting in immediate jeopardy. The IJ was not removed onsite during the recertification survey. The Conditions for Coverage 494.180 Governance, 494.30 Infection Control and 494.60 Physical Environment were not met.	V 000	V000- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. 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 10-18-10. The fire system was ordered the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.	
V 110	494.30 CFC-INFECTION CONTROL  This CONDITION is not met as evidenced by: Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility failed to implement and maintain an effective infection control program. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with water	V 110	The Governing Body will meet monthly x 3 or more often as required to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	

LABORATORY DIRECTOR OR PROVIDER/CLIA IDENTIFICATION NUMBER SIGNATURE  
*Charles Beyonder*

TITLE  
*Administrator* 10-15-10

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from complying provided it is established that other safeguards provide sufficient protection to the patients. (See instructions.) Except for writing hours, the findings listed above are considered as days following the date of survey whether or not a plan of correction is provided. For marking hours, the above findings and lists of corrections are displayed 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is required to continue program participation.

PRINTED: 10/18/2010  
FORM APPROVED  
OMB NO. 0938-0091

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342527	DOE MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  10/17/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3304 SHARON AVENUE CHARLOTTE, NC 28206		
(X4) ID PREFIX TAG	PRIMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 110	Continued From page 1 bloodinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. The cumulative affect of these systemic problems resulted in the facility's inability to ensure the provision of quality infection control practices for dialysis patients.  The findings include:  A. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients.  ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0117  B. The facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or bloodinged external transducer protectors.  ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0120  C. The facility failed to ensure that staff implemented standard infection control	V 110	V110- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is place to install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. Plexiglas barriers will be placed to prevent potential cross contamination.  The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift 3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with 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. cont pg 3	10-15-10	



PRINTED: 10/08/2010  
FORM APPROVED  
OMB NO. 0938-0301

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		PROVIDER/CLIA IDENTIFICATION NUMBER 343837	MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	DATE SURVEY COMPLETED 10/01/2010
NAME OF PROVIDER OR SUPPLIER CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1804 SHARON AVE CHARLOTTE, NC 28205	
CLIA ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE
V 110	Continued From page 2 precautions by cleaning equipment surfaces with removal of trash from floor in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments.  -Cross refer to 494.50(a)(4)(ii) Infection Control - Tag V0122  D. The facility failed to ensure that patient used dialyzers were adequately reprocessed to inhibit bacterial growth before reprocessing.  -Cross refer to 494.50(b)(1) Reuse of Hemodialyzers and Bloodlines - Tag V0331  E. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers.  -Cross refer to 494.50(b) Physical Environment - Tag V0409  F. The facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area.  -Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0114.	V 110	V110 cont. The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. 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. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	10-18-10
V 114	494.30(a)(1)(D) 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 114		

PRINTED: 10/08/2010  
FORM APPROVED  
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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(N1) PROVIDER/CLIA IDENTIFICATION NUMBER:  342227	(K2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(K3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1364 SHARON AVENUE CHARLOTTE, NC 28205		
(K4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	(L) PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE REFERENCED TO THE APPROPRIATE DEFICIENCY)	(M) COMPLETION DATE	
V 114	<p>Continued From page 3</p> <p>Based on facility policy review, observations and staff interview, the facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area.</p> <p>The findings include:</p> <p>A review of the facility's policy "Infection Control for Dialysis Facilities" (revised date 03/2010) revealed "The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination must be available at each sink."</p> <p>Observation on 08/23/2010 at 1300 in the patient treatment area revealed that a paper towel dispenser located for the patients to wash their access sites at the exit area had no available paper towels for use after handwashing. The observation revealed that the paper towels were located in a machine with a sensor to dispense the towels. After washing hands was observed by a patient and surveyor, it was noted that the sensor was not working and no paper towels were available.</p> <p>An interview with the facility's registered nurse during the observation on 08/23/2010 at 1300 revealed that the paper towel dispenser was not working. The interview revealed that paper towels would have to be obtained in a different fashion until the sensor was fixed.</p>	V 114	<p>V114</p> <p>Paper towels in the dispenser were replaced and threaded properly. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10/18/10.	
V 117	<p>494.95(a)(1)(D) IC-CLEAN/DIRTY; MED PREP AREA; NO COMMON CARTS</p> <p>Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas</p>	V 117			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/CLINICAL IDENTIFICATION NUMBER  148527	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2284 WYNDHAM BLVD CHARLOTTE, NC 28209	
DOID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COMPLETION DATE
V 117	<p>Continued From page 4</p> <p>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.</p> <p>When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (contaminated) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.</p> <p>Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.</p> <p>The STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients.</p> <p>The findings include:</p> <p>1. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled."</p> <p>Observation on 09/22/2010 at 1028 in the patient</p>	V 117	<p>V117</p> <p>Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height around the medication prep area to further designate this space as a clean area.</p> <p>FA is responsible for ongoing compliance with POC.</p>	10-18-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342337	PCN MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 6304 BRANSON AVE CHARLOTTE, NC 28208	
OCAS ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	PCN COMPLETION DATE
V 117	<p>Continued From page 6</p> <p>Inspection area revealed that a medication cart filled with medications and other unused supplies along with syringes was located directly beside the handwashing sink used by patients to wash their access sites. The sink was designated for patient hand washing and had a sign that was written as "patients must wash access sites" and located at the base of the sink. The observation further revealed that no splash guard or barrier was noted to prevent water splashes on the medications and supplies.</p> <p>An interview on 09/22/2010 at 1000 with the facility's nursing staff revealed that the patient medications and unused supplies are stored on the cart was kept beside the handwashing sink. The interview revealed that the staff has always kept the medications and supplies in this location due to lack of space. The interview also confirmed that the supplies and medications can get wet from patients and staff washing hands. The interview revealed that the staff had not considered the potential contamination of the medications or supplies.</p> <p>An interview with the facility administrator on 09/22/2010 at 1240 revealed that the supplies and medications should be prevented from being wet or contaminated from people washing their hands at the nearby sink.</p> <p>2. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled."</p>	V 117		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	C30 DATE SURVEY COMPLETED  10/08/2010	
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 9204 BURNING ARMY CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COR COMPLETION DATE	
V 117	Continued From page 6  Observation on 09/22/2010 at 1650 revealed the medication preparation area used by the facility. The observation revealed that the preparation area is located on a wheeled cart (Craftman brand) with the medication vials located on top of the cart with a cleared area noted. Observation revealed the medication preparation area (cart) was stationary and located directly beside of the facility's designated handwashing sink for patients to wash their access sites. Observation revealed that the facility had a sign on the sink that was written as "Patients must wash access sites" located at the base of the sink. The observation further revealed that no barrier and splash guard was present to prevent potential cross contamination during medication preparation. No separate clean area was observed for patient medication preparation.  An interview on 09/22/2010 at 1655 during the observation with the facility's registered nurse revealed that the cart was the area where the facility's nursing staff prepares patients medications. The interview revealed that she never thought of the potential splashing of water from handwashing sink on the clean medication preparation area.  An interview on 09/22/2010 at 1650 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.	V 117			
V 120	404.50(a)(1)(b) IC-TRANSDUCER PROTECTORS NOT WETTED/CHANGED  Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the	V 120			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	OSR DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 324 MARION AVE CHARLOTTE, NC 28205	
OSR ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	IR PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	IR COMPLETION DATE
V 120	<p>Continued From page 7</p> <p>dialysis machines' pressure monitors.</p> <p>If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel 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 bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.</p> <p>Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.</p> <p>The STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients whose dialysis machines were observed to have wet or blood tinged external transducer protectors (Patient stations #1,11).</p> <p>The findings include:</p> <p>A review of the facility's policy "Changing Transducer Protectors" (revision date of 12/2008) revealed "External transducer protectors will be inspected for the presence of blood or saliva every 30 minutes during patient treatment and</p>	V 120	<p>V120</p> <p>The Clinical Services Specialist (CSS) inspected the teamates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect the external transducers for the presence of blood or saline every 30 minutes during patient treatment. The external transducer protector is to be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10-7-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/09/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 534 SHARON AVE CHARLOTTE, NC 28208	
(C4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(C6) COMPLETION DATE
V 120	Continued From page 6 included in the monitoring process. The external transducer protector will be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector.  1. Observation on 09/22/2010 at 1608 for the patient in station #1 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector.  2. Observation on 09/22/2010 at 1610 for the patient in station #11 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector.  3. An interview on 09/22/2010 at 1650 with the facility's registered nurse in the patient treatment area revealed that the staff should change the bloody transducers and check the back of the transducer to make sure that the machine is not contaminated.  4. An interview with the facility's administrative staff on 09/22/2010 at 1655 revealed that the transducer protectors should be immediately changed and checked by staff when they become bloody.	V 120		
V 122	494.30(a)(4)(i) IC-DISINFECT SURFACES/EQUIP/WITTEN PROTOCOL  [The facility must demonstrate that it follows standard infection control precautions by implementing: (A) And maintaining procedures, in accordance with applicable state and local laws and accepted	V 122		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		PROVIDER/UPPLIER/CLIA IDENTIFICATION NUMBER:  343837		DATE SURVEY COMPLETED  10/01/2010	
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS		STREET ADDRESS, CITY, STATE, ZIP CODE 334 EPHRAIM AVENUE CHARLOTTE, NC 28204			
(X) IS PRECIP TAG	PRIMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PREVICOR PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS REFERENCED TO THE APPROPRIATE DEFICIENCY)	# OF DEFICIENCY DATE	
V 122	<p>Continued From page 9</p> <p>public health procedures, for the: (H) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.</p> <p>This STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments.</p> <p>The findings include:</p> <p>A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Equipment if accessible to patients and trainees including outside of sharps containers and all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of procedure, after spills of blood, throughout the day, and after each treatment. Any areas contaminated with visible blood or body fluids are cleaned promptly with a wet wrung out wipe using 1:10 bleach solution."</p> <p>1. a. Observation on 09/22/2010 at 10:13 in the patient treatment area revealed that a rolling wheeled cart with a total of six (6) acid bath jugs on the cart had noted drystate powder (white in color and chalky) and dust noted on the cart.</p> <p>1. b. Observation on 09/22/2010 at 18:06 revealed trash (paper wrappers) scattered on the patient treatment area floor near patient stations #4 and</p>	V 122	<p>VI22-</p> <p>The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor and blood stains and blood stains are cleaned when they occur. Carts will be replaced by 10/15/2010; removed the existing soap dispensers and mounting brackets and replaced with disposable bottle-type dispensers.</p> <p>The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with 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 Results of audits will be reviewed in Quality Improvement Management Meetings (QIPMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10-15-10	



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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(K1) PROVIDER/PLAN/CLIA IDENTIFICATION NUMBER  342877	(K2) MULTIPLE CORRECTION A. BUILDING _____ B. WING _____	(K3) DATE SURVEY COMPLETED  10/09/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 324 MARION AVENUE CHARLOTTE, NC 28205	
(K4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL NESTED OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE
V 122	<p>Continued From page 10</p> <p>#11. Observation further revealed three trash cans in the patient treatment area that were full and overflowing with trash.</p> <p>1. a. Observation on 09/22/2010 at 1615 revealed that two automated (GOJO Brand) soap dispensers in the facility's service area at handwashing sinks designated as clean had caked rusted buildup observed directly under the dispensers. No observed evidence of cleaning the dispensers was observed.</p> <p>An interview with the facility administrator on 09/22/2010 revealed that the area should remain free from clutter and dirty buildup around supplies. The interview also revealed that the trash should be cleaned up by the staff. No reason was given as to why the areas were not cleaned by the staff.</p> <p>2. Observation on 09/22/2010 at 1020 in the patient treatment area revealed that vascular clamps used for patient vascular access sites were located in a container of 1:100 bleach disinfectant and had visible clotted blood on the clamp heads. The observation further revealed that the clamps were not fully submerged in the disinfectant bleach.</p> <p>An interview with the facility administrator on 09/22/2010 at 1215 revealed that the clamps should be below the level of bleach solution according to the facility policy.</p> <p>3. Observation on 09/22/2010 at 1015 in the patient treatment area revealed blood stains on top of the needle change container located directly beside the patient dialyzing in station #16. The blood stains were located on top of the stamps</p>	V 122		

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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AVENUE CHARLOTTE, NC 28205		
DIG ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	OS COMPLETION DATE	
V 122	Continued From page 11 containers from 1018 through 1155 without staff observed to clean the stains.	V 122			
V 188	An interview with the facility administrator on 09/22/2010 at 1210 revealed that the blood stains should be cleaned when they occur or soon as possible. 484.4(X) CARBON ADSORP-MONITOR, TEST FREQUENCY  6.2.5 Carbon adsorption monitoring, testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no test patient shifts, testing should be performed approximately every 4 hours.  Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.  Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-dimethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to measure the maximum levels described in [44M] 4.1.1 (Table 1) (which is a maximum level of 0.1 mg/L).  Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.	V 188			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		DATE SURVEY COMPLETED  10/04/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3304 INARON AVENUE CHARLOTTE, NC 28208		
ORA ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	IC PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	IC PREFIX TAG	DATE COMPLETION DATE
V 198	<p>Continued From page 12</p> <p>This STANDARD is not met as evidenced by:                      Based on facility policy review, the facility's total chlorine testing log review and staff interview, the facility failed to ensure regularly performed testing to monitor the total chlorine in its water system used in patient hemodialysis and failed to provide color blindness testing in 2 of 4 sampled staff members that test the facility's water system for the presence of chlorine (Staff #1,3).</p> <p>The findings include:</p> <p>A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 03/2010) revealed "Total Chlorine testing is done on a daily basis prior to the first patient treatment and every four (4) hours until all activities that require use of dialysis quality water are completed."</p> <p>A review on 09/23/2010 of the facility's "Routine Total Chlorine Testing Log" for 02/15/2010 revealed that the facility staff failed to document Chlorine testing every 4 hours. The review revealed that for 02/15/2010, the facility staff documented Chlorine 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 signatures for the Chlorine testing. The review revealed that the 0945 testing for Chlorine was not documented as completed.</p> <p>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 minute extra window of time given. The interview revealed that some times the nursing staff does not fully document on the water log</p>	V 198	<p>V196-                      The CSS in-serviced the teammates on the importance of completing the water system total chlorine monitoring every 4 hours per policy 2-07-04 "Daily Water Total Chlorine Monitoring" and documenting on the appropriate log. FA/designee will be checked daily for 7 days then weekly on going. Color blindness testing was completed on the 2 RN's cited and it was found that they did have testing and results are in teammates files. Color blindness testing will be done on all new hires and annually thereafter. Facility Administrator will spot check 25% of teammates file monthly for 3 months and annually thereafter. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>		10-18-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(41) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  367837	(42) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(43) DATE SURVEY COMPLETED  10/07/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3304 MARION AVENUE CHARLOTTE, NC 28208	
(44) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	(45) PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(46) DATE OF COMPLETION DATE
V 186	<p>Continued From page 19 record.</p> <p>A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 03/2010) revealed that the facility uses the "Lamotte SL-MW Test Kit Colorimeter" for the chlorine testing in its water system. The policy also revealed that the staff instructions include "Holding the Octa-Slide Viewer so that non-direct light enters the back of the comparator. Match the test tube color standard on the Octa-Slide and read the ppm value on the Octa-Slide standard that matches color of the test tube sample."</p> <p>1. A review of the facility's personnel file for staff nurse #1 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed.</p> <p>2. A review of the facility's personnel file for staff nurse #3 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed.</p> <p>3. An interview on 09/23/2010 at 1400 with the facility administrator revealed that these staff nurses did not have any documented color blindness testing in her personnel file. The interview revealed no reason as to why these staff nurses did not have any testing done. The interview also revealed that these nurses do check the water system for chlorine and should have color blind testing to ensure that each nurse</p>	V 186		

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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1804 SHARON AVE. CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 186	Continued From page 14 can read the color matches.	V 186		
V 331	494.50(b)(1) REPROCESSING-TRANSPORTATION & HANDLING  11 Reprocessing 11.1 Transportation and handling Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party.  This STANDARD is not met as evidenced by: Based on facility policy review, observation, refrigerator temperature log review and staff interview, the facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing.  The findings include:  A review of the facility policy "Reuse of Dialyzers" (revision date 03/2007) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial 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 storage is maintained between 36-50 degrees Fahrenheit."	V 331	V331  Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the 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.	9-30-10

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/IDENTIFICATION NUMBER  342227	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/09/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3284 SHARON ASBY CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	BRIEF STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 331	<p>Continued From page 16</p> <p>Observation on 09/22/2010 at 1100 in the patient treatment area revealed a total of seven (7) patient used dialyzers inside of the storage refrigerator used for reuse storage. Inspection of the thermometer revealed that the temperature was 56 degrees Fahrenheit at 1100. The observation of the outside of the refrigerator revealed that a handwritten notation was placed on the front of the refrigerator that was written as "Temperature should be 36 degrees F (Fahrenheit) - 50 degrees F." An interview during the observation at 1105 with a patient dialysis care staff member confirmed that the temperature was 56 degrees F and it should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times.</p> <p>A review on 09/22/2010 of the refrigerator log for 09/2010 revealed that the facility's refrigerator temperature limits should be "36 degrees F to 46 degrees F." The review of the 09/2010 log revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review for 08/17/2010 revealed documentation by staff of 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 (date of observation) revealed that the temperature reading was documented as 30-48 degrees F.</p> <p>An interview with the registered nurse in the patient treatment area on 09/22/2010 at 1155 revealed that the refrigerator has constantly been a concern with the temperature readings. The interview revealed "Everytime we put hot dialyzers</p>	V 331		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342837	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2304 SHARON AVENUE CHARLOTTE, NC 28204	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROPOSED PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE
V 331	Continued From page 18 In that refrigerator, the temperature goes in the 50s."	V 331		
V 340	An interview with the facility administrator on 09/22/2010 at 1210 revealed that he was not aware of the elevated temperature readings of the reprocessing storage refrigerator. The interview revealed that the staff had not informed him of the elevated temperature changes. 494.50(X1) DIALYZER GERM=90% CONGCAPS DISINFECT  11.4.1.4 Chemical germicidal procedure: = 90% concen caps disinfect If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 80% of the prescribed concentration.  The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer.  This STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility's reuse staff failed to ensure that reuse dialyzer caps were cleaned and disinfected by appropriate immersion in a germicide before reassembling of the reprocessed dialyzers.  The findings include:  A review of the facility's policy "Cleaning and	V 340	V340- The CSS in-serviced reuse teamatics on policy 6-04-03 Cleaning and Disinfection of Reuse Supplies with emphasis on the need to fully immerse the caps below the germicide surface level. Facility Administrator will monitor submersion of caps per policy for 7 days then once a week for 2 weeks, then monthly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/CLIA IDENTIFICATION NUMBER 302827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/21/2010
NAME OF PROVIDER OR SUPPLIER CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3003 SHARON AVE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	IS PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 340	Continued From page 17 Disinfection of Reuse Supplies Policy (origination date 08/2008) revealed "Reuse supplies will be cleaned and disinfected with a 1% peracetic acid solution for a minimum of 30 minutes. Blood and dialyzer port caps, banner adapters, extension tubing must be disinfected for a period of 30 minutes but no greater than 24 hours prior to use."  Observation on 09/22/2010 at 1005 in the facility's reprocessing room revealed that reprocessing caps and port caps used for patient reprocessed dialyzers were placed in two 1% peracetic acid (germicide) solution plastic containers located in the designated dirty section for disinfection. The observation revealed that the caps in both containers of the disinfectant were not fully immersed below the disinfectant germicide surface level. The observation was during a time when no staff was present in the reprocessing area.	V 340	V400-Physical Environment Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. * 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 10-18-10. The fire system was ordered on the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. *In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. cont pg 19	*10-22-10 for Fire system
V 400	494.60 CFC-PHYSICAL ENVIRONMENT  This CONDITION is not met as evidenced by: Based on observations as referenced in the Life Safety Report of a complaint investigation completed 09/30/2010, facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the	V 400		*12-31-10 for additional physical plant work



STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED
DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		342277		10/01/2010
NAME OF PROVIDER OR SUPPLIER CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 284 MARION AVENUE CHARLOTTE, NC 28265	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 400	<p>Continued From page 78</p> <p>facility failed to maintain a physical environment that decreased the potential risks to the health and safety of patients, visitors and staff. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only inspecting staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerant temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the health and safety of patients, staff and visitors at the dialysis facility.</p> <p>The findings include:</p> <p>A. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying</p>	V 400	<p>V400 cont. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degrees Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the 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.</p> <p>Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device</p> <p>This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. cont. pg 19</p>	9-30-10
			*10-22-10 for Fire system	
			*12-31-10 for additional physical plant work	
				10/07/10

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DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342637	A. BUILDING  B. WING	10/21/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 824 SHERRON ASHBY CHARLOTTE, NC 28204	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 400	Continued From page 10 conditions each quarter in place of only inspecting staff on the fire drills and failed to remove storage in the front corridor of the facility next to the lobby at the side exit door. ~Cross refer to 494.60(X1) Physical Environment Fire-Safety and Life Safety Code-Tag V0417 B. The facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or impassible. ~Cross refer to 494.60(d) Physical Environment - Tag V0408 C. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers. ~Cross refer to 494.60(b) Physical Environment - Tag V0403. 494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on facility policy review, observations,	V 400	V400 cont. The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0" ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work  10-1-10  09/30/10.
V 403	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based on facility policy review, observations,	V 403		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  345827	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  10/07/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 324 CHARLENN ANITY CHARLOTTE, NC 28265		
(X4) ID PREFIX TAG  V 403	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG  V 403	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE  9-30-10	
	<p>Continued From page 20</p> <p>refrigerator temperature log review and staff interview, the facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers. This deficient practice placed all patients participating in the reprocessing program at risk for exposure to contamination from bacterial growth in the dialyzers.</p> <p>The findings include:</p> <p>A review of the facility policy "Reuse of Dialyzers" (revision date 08/2009) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial growth until reprocessing is begun. Refrigerated dialyzers may be stored for up to 36 hours prior to being reprocessed. The refrigerator used for contaminated dialyzer storage is maintained between 38-50 degrees Fahrenheit."</p> <p>Observation on 08/22/2010 at 1100 in the patient treatment area revealed that the facility had a refrigerator in the patient treatment area that was used to store reused dialyzers at a temperature to inhibit potential bacterial growth. The observation revealed a total of seven (7) patient used dialyzers inside of the refrigerator used for the reuse storage. The observation at 1105 of the thermometer revealed that the temperature was 56 degrees Fahrenheit. The observation of the outside of the refrigerator revealed that a handwritten note was placed on the front of the refrigerator indicating "Temperature should be 38 degrees F."</p> <p>An interview during the observation at 1105 with patient dialysis care staff member revealed that</p>		<p>V403</p> <p>Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the 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.</p>		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE REVIEW COMPLETED 9/30/10/2010
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  343627	
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS		STREET ADDRESS, CITY, STATE, ZIP CODE 2304 SHILTON AVENUE CHARLOTTE, NC 28205	
DAID IDENT TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)
V 403	Continued From page 21 the temperature was 66 degrees F and that the temperature should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times.  A review on 09/22/2010 of the refrigerator log for 09/20/10 revealed that the facility's refrigerator temperature limits should be "50 degrees F to 45 degrees F." The review of the log for 09/20/10 revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review of 09/01/2010 revealed documentation by the staff that the refrigerator temperature to be a range of 32- 33 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 (date of observation) revealed that the temperature reading was documented as 30-40 degrees F.	V 403	
V 403	404.80(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES  The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten	V 403	

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342527	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 504 SHAWAN AVENUE CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	CORRECTION DATE	
V 408	<p>Continued From page 22</p> <p>the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p> <p>The STANDARD is not met as evidenced by: Based on observations, fire safety reports review and staff interview, the facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or impassable.</p> <p>The findings include:</p> <p>Observation on 09/22/2010 at 1016 during tour of the facility's patient treatment area revealed that the facility had a total of sixteen (16) total stations for hemodialysis treatments. The facility hemodialysis station locations were against the four (4) walls of the patient treatment area. The observation of the facility's fire safety emergency evacuation route revealed that the facility had one emergency exit leading directly into a hallway from the patient treatment area. The exit route led to a door with a fire exit sign leading out to the facility's lobby area and main exit doors. The observation further revealed that there was no other exit location or emergency evacuation route in the patient treatment area. Observation revealed that only one (1) exit route/egress existed in the patient treatment area for patients, visitors and staff. No other doors or exits were observed in the patient treatment area.</p>	V 408	<p>V408- *The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0" ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes.</p> <p>A copy of Certificate of Occupancy has been requested from the city of Charlotte, original architect and general contractor. Going forward any fire inspections will be kept on file in the facility. FA is responsible for ongoing compliance with POC.</p> <p>*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 10-18-10. The fire system was ordered on the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.</p>	10-13-10	*12-31-10 for additional physical plant work

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(04) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(03) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(05) DATE SURVEY COMPLETED
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS		STREET ADDRESS, CITY, STATE, ZIP CODE 2204 WILKINSON AVENUE CHARLOTTE, NC 28208		
(04) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROPOSED PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(05) COMPLETION DATE
V 408	Continued From page 28 An interview on 09/22/2010 at 1110 with the facility's registered nurse in the patient treatment area revealed that there was only one way out of the patient treatment area of the facility. The interview revealed, "I have never thought about it, but if there was a fire, the only way out would be through the that area (staff indicating by pointing to the one exit) there." The interview revealed that the staff were trained in fire drills to use the one exit in the treatment area to evacuate the patients. The interview also revealed that the facility administration did not instruct the staff what to do if that one fire exit route was blocked with fire or other objects.  A review of the local fire marshal reports on 09/23/2010 revealed that no report could be found at the facility where any fire marshal or local fire inspection was done at the facility to determine fire safety compliance. No documentation could be produced by the facility that revealed any fire safety inspections were conducted at the facility.  An interview on 09/23/2010 at 1000 with the facility administrator and regulatory staff revealed that the facility could not find or produce a fire marshal or local county/city report for any past inspection of the facility's fire safety. The interview revealed that the facility should have one on file, but the administrative staff were unable to produce this document during the survey.	V 408		
V 417	494.80(a)(1) PE-FIRE SAFETY-LIFE SAFETY CODE 2000  (1) Except as provided in paragraph (a)(2) of this section, by February 9, 2009, The dialysis facility must comply with applicable provisions of the	V 417	1. The fire system was ordered on the day of the survey. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10 2. The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. 3. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. 4. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer device. cont pg 25	*10-22-10 for Fire system

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		CA) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342227	DC) MULTIPLE DISINTEGRATION A. BUILDING _____ B. WING _____	DE) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2500 GRANITE AVENUE CHARLOTTE, NC 28204	
04 ID PREFIX YAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE
V 417	Continued From page 24 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744 (a)(1)(b) of this chapter).  This STANDARD is not met as evidenced by: Based on observation on Thursday 09/30/10 between 8:30 AM and 11:00 AM the following was noted:  1) The facility did not have a fire alarm system nor was there any battery powered smoke detector found in the building. 2) The Server Room is lined with a plywood interior finish on the walls which does not comply with the required fire resistance rating for this area. 3) Facility is approximately 7600 sq. ft. in size and does not have a smoke barrier separating the building into two separate smoke compartments. 4) The facility has Bio Hazard Storage room is not self closing nor fire-rated. 5) The emergency battery operated light located next to the re-use room was not operational when tested. 6) The facility inservices the staff on Fire Drills each quarter in place of holding Fire drills being held at unexpected times under varying conditions. 7) There is storage in the front corridor next to the lobby to the side exit door, partially blocking the exit.	V 417	5. This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. 6. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIP/M. 7. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Routs will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. *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 10-18-10. The fire system was ordered the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.	*12-31-10 for additional physical plant work
V 463	484.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC  The patient has the right to-  (12) Receive the necessary services outlined in	V 463		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(K1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342827	(K2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(K3) DATE SURVEY COMPLETED  10/01/2010
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EASY DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 700 SHARON AVENUE CHARLOTTE, NC 28276
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(K4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(K5) COMPLETION DATE
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V 463	<p>Continued From page 28</p> <p>the patient plan of care described in §484.60;</p> <p>This STANDARD is not met as evidenced by: Based on facility policy review, clinical record review, patient interview and staff interview, the facility failed to include the patient in the facility's interdisciplinary team annual meeting involving the patient's plan of care for 2 of 7 sampled patient records (Patient #1,2).</p> <p>The findings include:</p> <p>A review of the facility policy "Patient Assessments and Plan of Care" (revision date 03/2010) revealed "The patient plan of care will be completed by the facility's interdisciplinary team, including patient or personal representative and be signed by team members including the patient or the patient's personal representative."</p> <p>A review on 09/22/2010 of the open clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2008. The review of the clinical record revealed that an "Annual Care Plan" meeting was scheduled for Wednesday 03/03/2010 for the patient. A review of the form inviting the patient was found in the clinical record of the patient. The review of the form revealed that the facility's clinician signed the staff signature portion and dated it 03/03/2010 but failed to obtain a patient signature that she would either attend or not attend the meeting. The space was not completed and left blank but the staff member (dieter) had signed the staff signature witness section. No documentation was found where the patient received individualized care and a chance to participate in her plan of</p>	V 463	<p>V463- Policy #1-01-07 Patient Assessment and Plan of Care" was reviewed with the interdisciplinary team (IT) with emphasis on the need to include the patient/patient designee in the development of the plan of care unless the patient declines. Each patient will be given a written and verbal invitation to the care plan meeting as care plans become due. Patients will be asked to sign invitation and note if they will attend. If patient declines the invitation the plan of care a member of the IDT will review with them and ask for their signature on the plan. If the patient refuses to sign, this will be noted in the record as well. FA/designee will audit all plans of care completed x 3 months and then 10% of those completed quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.</p>	10-18-10
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342227	(X) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 1308 SHAWAN AVENUE CHARLOTTE, NC 28203		
(X) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X) COMPLETION DATE	
V 453	Continued From page 26 care meeting.  An interview with patient #8 on 09/22/2010 at 1040 during the facility tour and observation revealed that the patient had not been invited by the facility staff to her plan of care meetings. The interview revealed "I am usually told they happened, but the staff does not really invite me to attend. I would try to make it if possible. I usually sign the paper after the meeting happens."	V 453			
V 502	484.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS  The patient's comprehensive assessment must include, but is not limited to, the following:  (1) Evaluation of current health status and medical condition, including co-morbid conditions.  This STANDARD is not met as evidenced by: Based on facility policy review, clinical record review and staff interview, the facility failed to ensure that registered nurses met the clinical needs of patients by failing to document and reassess as needed (PRN) medication administration in 5 of 5 sampled patients receiving PRN medication (Patients #1,2,3,4,6).	V 502	V502- The Required documentation for the administration of PRN medication to include the reason given and effectiveness of the medication was reviewed with RN's. Facility Administrator will monitor documentation of PRN meds once a week for 3 weeks then complete random audits quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342527	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3204 WILSON AVENUE CHARLOTTE, NC 28205		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
V 502	<p>Continued From page 27</p> <p>The findings include:</p> <p>1. A review on 08/22/2010 of the clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2008 for chronic hemodialysis. A review of the patient treatment sheets for 08/16/2010 and 08/27/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1700 and on 08/27/2010 at 1430 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 08/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.</p> <p>2. A review on 08/23/2010 of the clinical record for patient #2 revealed that the patient was admitted to the facility on 10/20/2008 for chronic hemodialysis. A review of the patient treatment sheets for 08/24/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/24/2010 at 1140 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 08/23/2010 at</p>	V 502			

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/CLINICAL IDENTIFICATION NUMBER 343237	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/01/2010
NAME OF PROVIDER OR SUPPLIER CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3284 SHARON AVENUE CHARLOTTE, NC 28208	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 502	Continued From page 28 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.  3. A review on 09/23/2010 of the clinical record for patient #3 revealed that the patient was admitted to the facility on 12/26/2009 for chronic hemodialysis. A review of the patient treatment sheets for 08/18/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1422 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.  4. A review on 09/22/2010 of the clinical record for patient #4 revealed that the patient was admitted to the facility on 03/11/2010 for chronic hemodialysis. A review of the patient treatment sheets for 09/20/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 09/20/2010 at 1807 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No	V 502	V686 The facility will ensure qualified charge nurse is designated for each shift during hemodialysis treatments. The opening nurse is designated as the charge nurse for the day and this will be identified on the daily schedule on an ongoing basis. FA is responsible for ongoing compliance with POC.	10-15-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/07/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 2000 SHARON AVENUE CHARLOTTE, NC 28204	
DAI ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	PER COMPLETION DATE
V 602	Continued From page 29 other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 08/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.  5. A review on 08/23/2010 of the clinical record for patient #8 revealed that the patient was admitted to the facility on 07/21/2008 for chronic hemodialysis. A review of the patient treatment sheets for 08/19/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1443 the patient was administered the medication "Loporanide (and diuretic medication) 2 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 08/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.	V 602	V750 Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height will also be installed around the medication prep area to further designate this space as a clean area. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift, 3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need appropriate cleaning and disinfecting of vascular clamps. cont. pg 31	10-18-10
V 688	484.140(b)(3)(i)-(ii) PG-CHARGE NURSE-12 MO NURSING'S MO DIALYSIS  The charge nurse responsible for each shift must: (i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in this State in which he or she is employed; (ii) Have at least 12 months experience in providing nursing care, including 3 months of	V 688		

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		PROVIDER/CLIA IDENTIFICATION NUMBER 242537	MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	DATE SURVEY COMPLETED 10/01/2010
NAME OF PROVIDER OR SUPPLIER CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3804 SHAWAN AVENUE CHARLOTTE, NC 28204	
(14) ID PREFIX TAG	BRIEF STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETION DATE
V 656	<p>Continued From page 30</p> <p>experience in providing nursing care to patients on maintenance dialysis;</p> <p>This STANDARD is not met as evidenced by: Based on facility policy review and staff interview, the facility failed to designate a charge nurse for each shift during hemodialysis treatments.</p> <p>The findings include:</p> <p>A review of the facility policy "Teammate Qualifications, License and Adequate Teammate Staffing" (revision date of 12/2008) revealed "Charge Nurse Standards: The charge nurse responsible for each shift will be a registered nurse, licensed practical nurse/vocational nurse who meets the practice requirements in each State in which he or she is employed."</p> <p>An interview on 09/22/2010 at OAH with the facility administrator revealed that the facility does not currently have a designated charge nurse during the hemodialysis treatments. The interview revealed "We do not have enough patients to have an established charge nurse. All of the staff knows we have a nurse that can handle things and who to report problems to."</p> <p>An interview on 09/22/2010 at 1900 with the facility administrator revealed that the facility does not have a official charge nurse but everyone knows the nurse role. The interview revealed that each shift does not have any formal or assigned charge nurse.</p>	V 656	<p>V750 cont. 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.</p> <p>The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. 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.</p> <p>Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation.</p> <p>Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward.</p> <p>*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 10-18-10. The fire system was ordered the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. cont pg 12</p>	10-18-10
V 750	494.180 CFC-GOVERNANCE	V 750		*10-22-10 for Fire system

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(C1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(C2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(C3) DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 7204 WILLOW AVE CHARLOTTE, NC 28208	
(C4) ID PREFIX TAG	DIAGNOSTIC STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	(C5) PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(C6) COMPLETION DATE
V 760	Continued From page 31 This CONDITION is not met as evidenced by: Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility's governing body failed to provide oversight and have systems in place to ensure the facility implemented and maintained an effective infection control program; and failed to ensure that the facility maintained a physical environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Renalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to conduct fire drills at unexpected times under varying conditions each quarter in place of only inservice staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure safe and effective care for all dialysis patients, and the safety of staff and visitors.	V 750	V750 cont. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.  The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer device. cont pg 33	*12-31-10 for additional physical plant work

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		Q11 PROVIDER/APPURCHUA IDENTIFICATION NUMBER:  348527	Q2 MULTIPLE CONSTRUCTION A. BUILDINGS _____ B. WARD _____	Q3 DATE SURVEY COMPLETED  10/01/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3211 SHARON AVE CHARLOTTE, NC 28205	
Q4 ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	IR PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	Q40 COMPLETION DATE
V 750	<p>Continued From page 32</p> <p>The findings include:</p> <p>A. For findings causing the Condition for Infection Control to be not met, see V110 and its associated tags. reprocessing, and failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood fingered external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area.</p> <p>-Cross refer to 494.30 Infection Control Condition- Tag V0110</p> <p>B. The facility failed to maintain a physical environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is</p>	V 750	<p>V750 cont. This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits.</p> <p>Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM.</p> <p>Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee.</p> <p>Please review the attached MSDS Sheet for Renalin, Section 16 for Other Information. The NFPA Flammability Classification for this chemical is 0, thereby qualifying as a low hazard in accordance with NFPA 101 Section 6.2.2.2.</p> <p>NFPA 101 Section A6.2.2.4 for High Hazardous contents are described as the following "contents include occupancies where flammable liquids are handled or used or are stored under conditions involving possible release of flammable vapors; where grain dust, wood flour, or plastic dust, aluminum or magnesium dust, or other explosives are produced; where hazardous chemicals or explosives are manufactured, stored, or handled under conditions producing flammable fumes; and other situations of similar hazards."</p> <p>cont pg 34</p>	<p>10/07/10</p> <p>09/30/10</p> <p>12-31-10 for additional physical plant work</p>

OCT-09-2010 15:07

PRINTED: 10/09/2010  
FORM APPROVED  
FORM NO. 0998-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  346527	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  10/07/2010
NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS			STREET ADDRESS, CITY, STATE, ZIP CODE 3804 CHARCON AVENUE CHARLOTTE, NC 28205	
(X4) ID PREFIX TAG  V 750	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG  V 750	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COMPLETION DATE
V 750	Continued From page 33 approximately 7600 square feet in size, failed to have a hazardous storage area that is 1 hour fire rated construction and unattended when storing twelve (12) cases of highly flammable material (Hentain that is used for disinfection of dialyzers; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to remove storage in the front corridor of the facility next to the lobby at the side exit door; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers.  -Cross refer to 484.50 Physical Environment Condition- Tag V0400	V 750	V750 cont. The Storage Room is classified as a Low Hazard area in accordance with Section 6.2.2.2. Due to this, NFPA 101 Section 8.4.1 will require this area as well as the Janitor's Closet to be upgraded to the Minimum 1 Hour Fire Resistant Rating. This will be accomplished by upgrading the existing Non-Rated Partition and Doors according to the attached Sketches.  The attached Sketches are respectfully submitted for your review and comments. Should you require additional information, please contact our office.  The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL**  
**PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY**

**CENTERS FOR MEDICARE & MEDICAID SERVICES**  
 ID: OB2211  
 Facility ID: 001554

1. MEDICARE/MEDICAID PROVIDER NO. (L) 342627 STATE VENDOR OR MEDICAID NO. (L2)		3. NAME AND ADDRESS OF FACILITY (L3) CHARLOTTE EAST DIALYSIS (L4) 3204 SHARON AMITY (L5) CHARLOTTE, NC (L6) 28205			4. TYPE OF ACTION: <u>6</u> (L8) 1. Initial 2. Recertification 3. Termination 4. CHOW 5. Validation 6. Complaint 7. On-Site Visit 9. Other 8. Full Survey After Complaint	
EFFECTIVE DATE CHANGE OF OWNERSHIP (L9) DATE OF SURVEY <u>04/15/2009</u> (L34) ACCREDITATION STATUS: ___ (L10) 0 Unaccredited 1 JCAHO 2 AOA 3 Other		7. PROVIDER/SUPPLIER CATEGORY <u>09</u> (L7) 01 Hospital      05 HHA      09 ESRD      13 FTIP 02 SNF/NF/Dual      06 LAB      10 NF      14 CORF 03 SNF/NF/Distinct      07 X-Ray      11 IMR      15 ASC 04 SNF      08 OPT/SP      12 RHC      16 HOSPICE			FISCAL YEAR ENDING DATE: (L35) 12/31	
1. LTC PERIOD OF CERTIFICATION From (a): To (b): 2. Total Facility Beds (L18) 13. Total Certified Beds (L17)		10. THE FACILITY IS CERTIFIED AS: X A. In Compliance With Program Requirements Compliance Based On: <u>X 1. Acceptable POC</u> B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: <u>A1*</u> (L12) And/Or Approved Waivers Of The Following Requirements: ___ 2. Technical Personnel      ___ 6. Scope of Services Limit ___ 3. 24 Hour RN      ___ 7. Medical Director ___ 4. 7-Day RN (Rural SNF)      ___ 8. Patient Room Size ___ 5. Life Safety Code      ___ 9. Beds/Room				
14. LTC CERTIFIED BED BREAKDOWN 18 SNF (L37)      18/19 SNF (L38)      19 SNF (L39)      ICF (L42)      IMR (L43)					15. FACILITY MEETS 1861 (e) (1) or 1861 (j) (1): YES (L15)	

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):  
 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 plan of correction was requested. Refer to intake #NC00054102.

17. SURVEYOR SIGNATURE <u>Ralph M. Purvis</u> Date: <u>06/01/2009</u> (L19)		18. STATE SURVEY AGENCY APPROVAL <u>[Signature]</u> <u>6/2/09</u> Date: (L20)	
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**PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY**

19. DETERMINATION OF ELIGIBILITY ___ 1. Facility is Eligible to Participate ___ 2. Facility is not Eligible (L21)		20. COMPLIANCE WITH CIVIL RIGHTS ACT: 21. 1. Statement of Financial Solvency (HCFA-2572) 2. Ownership/Control Interest Disclosure Stmt (HCFA-1513) 3. Both of the Above:	
22. ORIGINAL DATE OF PARTICIPATION (L24)		23. LTC AGREEMENT BEGINNING DATE (L41)	
25. LTC-EXTENSION DATE: (L27)		24. LTC AGREEMENT ENDING DATE (L25) 27. ALTERNATIVE SANCTIONS A. Suspension of Admissions: (L44) B. Rescind Suspension Date: (L45)	
28. TERMINATION DATE: (L28)		26. TERMINATION ACTION: (L30) <u>VOLUNTARY</u> <u>00</u> 01-Merger, Closure 02-Dissatisfaction W/ Reimbursement 03-Risk of Involuntary Termination 04-Other Reason for Withdrawal 05-Fail to Meet Health/Safety 06-Fail to Meet Agreement 07-Provider Status Change 08-Active	
31. RO RECEIPT OF CMS-1539 (L32)		29. INTERMEDIARY/CARRIER NO. <u>00000</u> (L31) 30. REMARKS 32. DETERMINATION OF APPROVAL DATE (L33) DETERMINATION APPROVAL	

Department of Health and Human Services  
 Medicare/Medicaid/CLIA Complaint Form

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number 3 4 2 6 2 7		Facility Name and Address CHARLOTTE EAST DIALYSIS 3204 SHARON AMITY CHARLOTTE, NC 28205		3. Date Complaint Received 0 3 0 6 0 9 M M D D Y Y	
4. Receiving Component 1 State Survey Agcy. 1 2 RO		5. Date Acknowledged 0 3 2 7 0 9 M M D D Y Y		6A. Source of Complaint 1 <input checked="" type="checkbox"/> 1 Resident/Patient Family 2 <input type="checkbox"/> 2 Ombudsman 3 <input type="checkbox"/> 3 Facility Employee/Ex-Employ 4 <input type="checkbox"/> 4 Anonymously 5 <input type="checkbox"/> 5 Other	
7. Allegations 1 <input type="checkbox"/> 0 6 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>		7A. Category 1 Resident Abuse 2 Resident Neglect 3 Resident Rights 4 Patient Dumping 5 Environment 6 Care or Services 7 Dietary 8 Misuse of Funds/Property 9 Certification/Unauthorized Testing 10 Proficiency Test 11 Falsification of Records / Reports 12 Unqualified Personnel 13 Quality Control 14 Specimen Handling 15 Diagnostic 16 Fraud/False Billing 17 Fatality/Transfusion Fatality 18 Other (Specify) 19 Life Safety Code 20 State Monitoring		7B. Findings (To be completed following investigation) 1 <input type="checkbox"/> 0 2 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
8. Action (if multiple actions, indicate earliest action) 1 Investigate within 2 working days 2 Investigate within 10 working days 3 Investigate within 45 working days 4 Investigate during next onsite 5 Referral (Specify) 6 Other Action (Specify) 7 None		7C. Number of Complainants per Allegation 1 <input type="checkbox"/> 0 1 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>			

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by 1 <input checked="" type="checkbox"/> 1 State Survey Agency 2 <input type="checkbox"/> 2 RO 3 <input type="checkbox"/> 3 Other (Specify)		10. Complaint Survey Date 0 4 1 5 0 9 M M D D Y Y		11. Findings (Under 7B Above)	
12. Proposed Actions Taken by SA or RO 1: <input type="checkbox"/> 0 4 2: <input type="checkbox"/> 3: <input type="checkbox"/>		1. Recommend Termination (23-day) 2. Recommend Termination (90-day) 3. Recommend Intermediate Sanction 4. POC (No Sanction) 5. Fine 6. Denial of Payment for New Admissions 7. License Revocation 8. Reciprocity 9. Provisional License 10. Special Monitor 11. Directed POC 12. Limitation of Certificate 13. Suspension of Certificate 14. Revocation of Certificate 15. Injunction 16. Civil Monetary Penalty		17. TA & Training for Unsuccessful PT 18. State Onsite Monitoring 19. Suspension of Part of Medicare Payments 20. Suspension of All Medicare Payments 21. None 22. Other (Specify) 23. Enforcement Action	
13. Date of Proposed Action 0 4 1 5 0 9 M M D D Y Y		14. Parties Notified and Dates 1 Facility 2 Complainant 3 Representative 4 Other (Specify)		15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567) 0 4 1 6 0 9 0 4 2 1 0 9 M M D D Y Y M M D D Y Y	

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt M M D D Y Y		17. CMS RO/MSA Action 1 None 2 Termination (23-day) 3 Termination (90-day) 4 Intermediate Sanction 5 Move Routine Survey Date Forward 6 Limitation of Certificate 7 Suspension of Certification 8 Revocation of Certificate 9 Injunction 10 Civil Monetary Penalty 11 TA & Training For Unsuccessful PT 12 Cancellation of Medicare Approval 13 Other (Specify) 14 Enforcement Action		18. Date of Final Action Sign-off M M D D Y Y	
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APR-24-2009 FRI 02:43 PM DAV CHAR EAST

FAX NO. 70453181.

Rm 5/27/09 P. 01

RECEIVED APR 29 2009

PRINTED: 04/15/2009  
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OMB NO. 0938-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  C 04/15/2009
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AMITY CHARLOTTE, NC 28205
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 147	<p>494.30(a)(2) CDC RR-10 AS ADOPTED BY REFERENCE</p> <p>Recommendations for Placement of Intravascular Catheters in Adults and Children</p> <p>I. Health care worker education and training  A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections.  B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.</p> <p>II. Surveillance  A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.</p> <p>Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.</p> <p>VI. Catheter and catheter-site care  B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].</p> <p>This STANDARD is not met as evidenced by: Based on the facility's policies and procedures, clinical record review, and staff interview, the facility's staff failed to change or clean an exit site</p>	V 147	See Attached	5/15/09

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Charles Deppa* TITLE: RN/FA (X6) DATE: 4-24-09

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  C 04/15/2009
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NAME OF PROVIDER OR SUPPLIER  CHARLOTTE EAST DIALYSIS	STREET ADDRESS, CITY, STATE, ZIP CODE 3204 SHARON AMITY CHARLOTTE, NC 28205
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 147	<p>Continued From page 1 of a patient's central venous catheter dressing 7 of 16 hemodialysis treatments (Patient #1).</p> <p>The findings include:</p> <p>Review of the facility's policy "Central Venous Catheter (CVC) Care" (revised on 04/2009) revealed that the purpose of the care was to reduce the risk of infection in the patient and to reduce trauma to the catheter and exit site while minimizing blood loss. The policy review also revealed that cuffed catheters with well-healed exit sites may not require a dressing but still require examination and cleaning of exit site each treatment.</p> <p>A clinical record review on 04/15/2009 for patient #1 revealed that the 32 year old patient had his first dialysis treatment at the facility 12/30/2004. The review revealed that the patient had "CVC right side femoral catheter" used for his hemodialysis treatments at the facility. The review of the patient's post treatment flow sheets on the dates of 03/10/2009, 03/26/2009, 03/28/2009, 04/04/2009, 04/07/2009, 04/11/2009 and 04/14/2009 revealed that no staff either changed the patient's CVC dressing or documented cleaning of the patient's dressing after his hemodialysis treatments. No documentation was found in the patient's clinical record where the facility's administration or the patient's physician was made aware of the patient not having his CVC catheter cleaned after each hemodialysis treatment.</p> <p>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.</p>	V 147	<ol style="list-style-type: none"> <li>1. An in-service on Central Venous Catheter changes and initiation of treatment was Completed on 4-15-09 by the vascular Access Manager with attendance all pct's and RNs</li> <li>2. Teammates will be observed by RN or Facility Administrator to assure company guidelines are adhered to. Teammates will be observed on 3 occasions.</li> <li>3. Bi-weekly meetings between RN's and Facility Administrator will be held to discuss any concerns or issues pertaining to any patient or teammate.</li> <li>4. Teammates and RN's are instructed to document any event that is a variation from company policy and procedure and/or any Physicians order</li> <li>5. MD was fully aware of pt's refusal of dressing changes. On several MD visits, MD verbalized to pt. the importance of dressing changes performed in-center by RN</li> </ol>	5-15-09

APR-24-2009 FRI 02:44 PM DAL CHAR EAST

FAX NO. 70453181

P. 03

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  342627	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  C 04/15/2009
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NAME OF PROVIDER OR SUPPLIER  
  
CHARLOTTE EAST DIALYSIS

STREET ADDRESS, CITY, STATE, ZIP CODE  
3204 SHARON AMITY  
CHARLOTTE, NC 28205

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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V 147	<p>Continued From page 2</p> <p>The interview also revealed that the staff should make the administration aware if the patient was refusing the medication and cleaning of the CVC catheter exit site.</p> <p>Reference intake #NC00054102.</p>	V 147		
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SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

The reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, MD 21207; or to the Office of Management and Budget, Paperwork Reduction Project (0838-0583), Washington, D.C. 20503.

Provider/Supplier Number 42627	Provider/Supplier Name CHARLOTTE EAST DIALYSIS
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Type of Survey (select all that apply)

A				
---	--	--	--	--

- 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)

D				
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- A Routine/Standard Survey (all providers/suppliers)
- B Extended Survey (HHA or Long Term Care Facility)
- C Partial Extended Survey (HHA)
- D Other Survey

SURVEY TEAM AND WORKLOAD DATA

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

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. 15546	04/15/2009	04/15/2009	1.00	0.00	4.00	0.00	11.00	2.50
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00  
 Total SA Clerical/Data Entry Hours..... 0.50  
 Total RO Supervisory Review Hours..... 0.00  
 Total RO Clerical/Data Entry Hours..... 0.00

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

**END STAGE RENAL DISEASE APPLICATION/NOTIFICATION AND SURVEY AND CERTIFICATION REPORT**  
**PART I - APPLICATION - TO BE COMPLETED BY FACILITY**

1. Name of Facility: Davita East

2. Provider Number: 342621

3. Street Address: Charlotte / 3204 N. Sharon Amity

4. City: Charlotte

5. County: MECKLENBURG

6. State: NC

7. ZIP Code: 28205

8. Telephone No.: (704) 531-1590

9. Facsimile No.: (704) 531-8122

10. Fiscal Year Ending Date: 12/31/10

11. Name/Address/Telephone Number of Authorized Official

Name: CHARLES STEPPARD Address: 3204 N. Sharon Amity Charlotte NC 28205 Telephone No.: (704) 531-1590

12. Type of Application/Notification: (v1) (check all that apply and specify in Remarks section [see item 27])

1. Initial  2. Expansion to new location  3. Change of ownership

4. Change of location  5. Expansion in current location  6. Change of services/operations

7. Other (specify) Recertification

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)

15. Is this Facility SNF-Based (check one)

(v5)  Yes  No If Yes, SNF provider number (v6)

16. Is this facility owned and/or managed by a multi-facility organization? (v7)  Yes  No If Yes, name and address of parent organization

Name: DAVITA DIALYSIS 1423 Pacific Ave Tacoma Washington 98401

17. Services Provided: (v9) (check all that apply and specify in Remarks section [see item 27])

1. Hemodialysis  2. Peritoneal Dialysis  3. Transplantation

4. Home Training: Hemodialysis  5. Home Support: Hemodialysis

Peritoneal Dialysis  Peritoneal Dialysis

18. Is Reuse Practiced? (v10)  Yes  No

19. Reuse System (v11) (check all that apply)

1. Manual  2. Semi-Automated  3. Automated

20. Germicide (v12) (check all that apply)

1. Formalin  2. Heat  3. Gluteraldehyde  4. Peracetic Acid Mixture

5. Other (specify) RENALIN

21. Number of Dialysis Patients

(v13) 78 Total Patients = (v14)  Hemodialysis + (v15)  Peritoneal Dialysis

22. Number of Stations (check all that apply and include isolation stations under Total Stations)

(v16) 16 Total Stations = (v17)  Hemodialysis + (v18)  Hemodialysis Training

(v19)  Yes  No

23. Does the facility have isolation stations?

24. Total Number of Patients (enter number of dialysis facility patients treated on each shift for full week prior to submission of this form)

A. SUNDAY				B. MONDAY				C. TUESDAY				D. WEDNESDAY			
1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
				16	16	14		16	16			16	16	14	
E. THURSDAY				F. FRIDAY				G. SATURDAY							
1	2	3	4	1	2	3	4	1	2	3	4				
16	16			16	16	14		16	16						

25. Total Number of patients followed at home (v20) \_\_\_\_\_

Department of Health and Human Services/Medicaid/CLIA Complaint Form

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

<b>1. Medicare/Medicaid Identification Number</b> 3 4 2 6 2 7		<b>Facility Name and Address</b> CHARLOTTE EAST DIALYSIS 3204 SHARON AMITY CHARLOTTE, NC 28205		<b>3. Date Complaint Received</b> 0 3 0 6 0 9 M M D D Y Y	
<b>4. Receiving Component</b> 1 State Survey Agency 1 2 RO		<b>5. Date Acknowledged</b> 0 3 2 7 0 9 M M D D Y Y		<b>6A. Source of Complaint</b> 1 <input checked="" type="checkbox"/> 1 Resident/Patient Family 2 <input type="checkbox"/> 2 Ombudsman 3 <input type="checkbox"/> 3 Facility Employee/Ex-Employ 4 <input type="checkbox"/> 4 Anonymous 5 <input type="checkbox"/> 5 Other	
<b>7. Allegations</b> 1 <input type="checkbox"/> 0 6 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>		<b>7.A. Category</b> 1 Resident Abuse 2 Resident Neglect 3 Resident Rights 4 Patient Dumping 5 Environment 6 Care or Services 7 Dietary 8 Misuse of Funds/Property 9 Certification/Unauthorized Testing 10 Proficiency Test 11 Falsification of Records / Reports 12 Unqualified Personnel 13 Quality Control 14 Specimen Handling 15 Diagnostic Erroneous Test Results 16 Fraud/False Billing 17 Fatality/Transfusion Fatality 18 Other (Specify)		<b>7.B. Findings (To be completed following investigation)</b> 1 <input type="checkbox"/> 0 2 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>	
<b>8. Action (if multiple actions, indicate earliest action)</b> 1 Investigate within 2 working days 2 Investigate within 10 working days 3 Investigate within 45 working days 4 Investigate during next onsite 5 Referral (Specify) 6 Other Action (Specify) 7 None		<b>7.C. Number of Complainants per Allegation</b> 1 <input type="checkbox"/> 0 1 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>		<b>19 Life Safety Code</b> <b>20 State Monitoring</b>	

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

<b>9. Investigated by</b> 1 <input checked="" type="checkbox"/> 1 State Survey Agency 2 <input type="checkbox"/> 2 RO 3 <input type="checkbox"/> 3 Other (Specify)		<b>10. Complaint Survey Date</b> 0 4 1 5 0 9 M M D D Y Y		<b>11. Findings (Under 7B Above)</b>	
<b>12. Proposed Actions Taken by SA or RO</b> 1 <input type="checkbox"/> 0 4 2 <input type="checkbox"/> 3 <input type="checkbox"/>		1 Recommend Termination (23-day) 2 Recommend Termination (90-day) 3 Recommend Intermediate Sanction 4 POC (No Sanction) 5 Fine 6 Denial of Payment for New Admissions 7 License Revocation 8 Receivership		9 Provisional License 10 Special Monitor 11 Directed POC 12 Limitation of Certificate 13 Suspension of Certificate 14 Revocation of Certificate 15 Injunction 16 Civil Monetary Penalty 17 TA & Training for Unsuccessful PT 18 State Onsite Monitoring 19 Suspension of Part of Medicare Payments 20 Suspension of All Medicare Payments 21 None 22 Other (Specify) 23 Enforcement Action	

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

<b>13. Date of Proposed Action</b> 0 4 1 5 0 9 M M D D Y Y		<b>14. Parties Notified and Dates</b> 1 Facility 2 Complainant 3 Representative 4 Other (Specify)		<b>15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567)</b> 0 4 1 6 0 9 0 4 2 1 0 9 M M D D Y Y      M M D D Y Y	
<b>16. Date of CMS/MSA Receipt</b> M M D D Y Y		<b>17. CMS RO/MSA Action</b> <input type="checkbox"/>		6 Limitation of Certificate 7 Suspension of Certification 8 Revocation of Certificate 9 Injunction 10 Civil Monetary Penalty 11 TA & Training For Unsuccessful PT 12 Cancellation of Medicare Approval 13 Other (Specify) 14 Enforcement Action	
		1 None 2 Termination (23-day) 3 Termination (90-day) 4 Intermediate Sanction 5 Move Routine Survey Date Forward		<b>18. Date of Final Action Sign-off</b> M M D D Y Y	



**END STAGE RENAL DISEASE APPLICATION/NOTIFICATION AND SURVEY AND CERTIFICATION REPORT**

**PART I - APPLICATION - TO BE COMPLETED BY FACILITY**

1. Name of Facility: Davita East Charlotte

2. Provider Number: 342627

3. Street Address: 3204 N. Sharon Amity Rd.

4. City: Charlotte

5. County: MECKLENBURG

6. State: NC

7. ZIP Code: 28205

8. Telephone No.: (704) 531-1990

9. Facsimile No.: (704) 531-8122

10. Fiscal Year Ending Date: 12/31

11. Name/Address/Telephone Number of Authorized Official

Name: CHARLES SHEPARD Address: 3204 N. Sharon Amity Rd. Charlotte NC. Telephone No.: (704) 531-1990

12. Type of Application/Notification: (v1) (check all that apply and specify in Remarks section [see item 27])

1. Initial  2. Expansion to new location  3. Change of ownership

4. Change of location  5. Expansion in current location  6. Change of services/operations

7. Other (specify) COMPLAINT

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)

15. Is this Facility SNF-Based (check one) (v5)  Yes  No If Yes, SNF provider number (v6)

16. Is this facility owned and/or managed by a multi-facility organization? (v7)  Yes  No If Yes, name and address of parent organization (v8) Name: Address:

17. Services Provided: (v9) (check all that apply and specify in Remarks section [see item 27])

1. Hemodialysis  2. Peritoneal Dialysis  3. Transplantation  4. Home Training:  5. Home Support:

Hemodialysis  Hemodialysis

Peritoneal Dialysis  Peritoneal Dialysis

18. Is Reuse Practiced? (v10)  Yes  No

19. Reuse System (v11) (check all that apply)  1. Manual  2. Semi-Automated  3. Automated

20. Germicide (v12) (check all that apply)  1. Formalin  2. Heat  3. Glutaraldehyde  4. Peracetic Acid Mixture  5. Other (specify) \_\_\_\_\_

21. Number of Dialysis Patients (v13) 72 Total Patients = (v14) 72 Hemodialysis + (v15) \_\_\_ Peritoneal Dialysis

22. Number of Stations (check all that apply and include isolation stations under Total Stations) (v16) 16 Total Stations = (v17) 16 Hemodialysis + (v18) \_\_\_ Hemodialysis Training

23. Does the facility have isolation stations? (v19)  Yes  No

24. Total Number of Patients (enter number of dialysis facility patients treated on each shift for full week prior to submission of this form)

A. SUNDAY				B. MONDAY				C. TUESDAY				D. WEDNESDAY			
1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
				16	16	9		14	13			16	16	7	
E. THURSDAY				F. FRIDAY				G. SATURDAY							
1	2	3	4	1	2	3	4	1	2	3	4				
14	13			16	14	5		14	13						

25. Total Number of patients followed at home (v20) 0

26. Staffing (list full-time equivalents)	(v21) <input checked="" type="checkbox"/> Registered Nurse	7.00	(v22) <input type="checkbox"/> Licensed Practical Nurse	---
	(v23) <input checked="" type="checkbox"/> Social Worker	25	(v24) <input checked="" type="checkbox"/> Dietitian	25
	(v25) <input checked="" type="checkbox"/> Technicians	7.00	(v26) <input checked="" type="checkbox"/> Others	25

27. Remarks: (Use this space for explanatory statements for Items 1-26)

I certify that the information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my belief. I understand that incorrect or erroneous statements may cause the Request for Approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 405.2100 and 405.2180, respectively.

Signature of Authorized Official <i>Charles Deppa</i>	Title RN / Administrator	Date 4-15-09
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**PART II TO BE COMPLETED BY STATE AGENCY**

9. ESRD Provider Number (if the facility has a provider number) 3 4 2 6 2 7

D. Network Number (v27) 0 6

1. State Region (v28) NCC      32. State County Code (v29) 590

3. Type of Survey (v30) (check all that apply)     Initial     Complaint     Recertification     Other

4. Survey Protocol (v31) (check all that apply)     Basic     Initial     Supplemental     Combination

5. Surveyor Name/Number (print) <i>Ralph Mills, RN, BSN</i>	Professional Discipline (print) <i>Registered Nurse</i>

i. Date of Survey  
April 15, 2009

According to the Paperwork Reduction of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0360. The time required to complete this information collection is 20 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: I/A Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.