

Exhibit A

TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208
(P) 704-335-0151, Ext. 255
(F) 866-480-7831

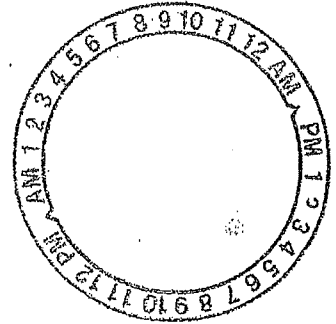
DaVita "he/she that gives life"

William L. Hyland
Director of Healthcare Planning

Letter of Intent – Expedited Review Request

September 9, 2011

Mr. Craig Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Human Resources
2704 Mail Service Center
Raleigh, NC 27699-2704



RE: Certificate of Need Application submitted by DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center to expand our existing facility by four stations in Charlotte/Mecklenburg County

Dear Mr. Smith:

Please accept this letter as our formal Letter of Intent for submitting a Certificate of Need Application for DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center/Mecklenburg County. The particulars are the following:

1. This project is for the expansion of the existing facility by four stations.
2. This project has a total projected capital expense of \$60,234. This figure includes the purchase of dialysis machines, dialysis chairs and individual TVs for the stations and other cost associated with the expansion of stations.
3. The anticipated filing date of this application is September 15, 2011.
4. We are requesting an **expedited review** of this Certificate of Need application due to significant increase in End Stage Renal Disease patient referrals by physicians to the North Charlotte Dialysis Center.

Sincerely,

William L. Hyland
Director of Healthcare Planning

VIII. CAPITAL COSTS AND FINANCING

1. Estimated Capital Costs of Proposed Project. In A, B, and C below, provide the projected capital costs as follows:

- (a) For a proposed new facility, the applicant must use the most accurate estimates available for the entire project.

RESPONSE: Not Applicable. The North Charlotte Dialysis Center is not applying to establish a new facility.

- (b) For an expansion or renovation of existing space, the applicant must use the most accurate estimates available for the proposed addition or renovation.

RESPONSE: We estimate that adding one station to the facility will require a capital expense of \$60,234.

- (c) List equipment which must be purchased or leased and the cost of each item that is included in the proposed project.

RESPONSE:	Dialysis Machines	\$11,935 each
	TVs	\$ 1,195 each
	Dialysis Chairs	\$ 970 each

- (d) For projects which do not fall into one of the above categories the applicant must call the project analyst to determine how to complete this section of the application.

RESPONSE: Not Applicable. This project falls within one of the stated categories.

Note: If the lessor is incurring any capital costs for the proposed project, e.g., upfitting of leased space, the lessor must complete Section VIII. See the "General Instructions" section of the application for further instructions regarding lessor/lessee arrangements and who must file for a certificate of need.

A.	Site Costs	Lessor	Lessee
	(1) Full purchase price of land		
	(2) Closing Costs		
	(3) Site Inspection and Survey		
	(4) Legal fees/subsoil investigation		
	(5) Other (Specify) Demolition		
	(6) Sub-Total Site Costs		0
B.	Construction Contract		
	(7) Site Preparation Costs		
	(8) Cost of Materials		
	(9) Cost of Labor		
	(10) Equipment Included in Contract.		
	* Combined costs		
	(11) Other (Specify) – Attorney Fees		
	(12) Sub-Total Construction Contract		0
C.	Miscellaneous Project Costs		
	(13) Building Purchase		
	(14) Dialysis Machines		47,740
	(15) (RO) water treatment equipment		
	(16) Equipment/Furniture not included above		1,746
	(17) Landscaping		
	(18) Architect/Engineering Fees		
	(19) Consultant Fees (Specify) \$		
	(20) Financing Costs (Bond, Loan, etc.)		
	(21) Interest During Construction		
	(22) Other: Dialysis Chairs		3,880
	Televisions		4,780
	Chairside Computer Terminals		2,088
	(23) Sub-Total Miscellaneous		60,234
	(24) Total Capital Costs of Project (Sum A-C above)		60,234

2. Anticipated Sources of Financing for the Project

Respond for all costs to be incurred to implement this project. The total financing should equal the total capital costs in VIII.1(23) above if the proposal is for a new facility or expansion/renovation of an existing facility.

Note: The total project financing is demonstrated below:

Specify Type	Lessor Amount(*)	Lessee Amount
(a) Conventional Loans		
(b) Cash Reserves		60,234
(c) Owner's Equity		
(d) Other (Specify) Bank Lease		
(e) Total		60,234

3. Submit copies of letter(s) from lending institution(s) which indicate a willingness to finance the proposed project (both construction and permanent financing). The letter(s) should include:

(a) Purpose of the Loan(s)

RESPONSE: Not Applicable.

(b) Proposed interest Rate(s) (Fixed or Variable)

RESPONSE: Not Applicable.

(c) Proposed Term (Period of the Loan(s))

RESPONSE: Not Applicable.

(d) Proposed Amount of Loan(s)

RESPONSE: Not Applicable.

(e) Verification that the lender has examined the financial position of the borrower and found it to be adequate to support the proposal. The examination should reflect other project activity, actual or proposed, that might relate to this specific proposal.

RESPONSE: Not Applicable.

4. Provide amortization schedule(s) for each loan setting forth:

(a) Amount of Principal,

(b) Term/Number of Payment Periods (long term loan may be annualized,)

(c) Amount of Interest, and

(d) Outstanding balance for each payment period.

RESPONSE: Not Applicable.

5. Submit documentation of the availability of accumulated reserves, such as, a letter from the appropriate official who is fiscally responsible for the funds.

RESPONSE: James Hilger, Chief Accounting Officer of DaVita Inc. and DVA Healthcare Renal Care, Inc., submitted a letter stating that the funds are available (See **Exhibit 15** of the application).

6. If not financing the project through commercial loan or accumulated reserve please describe the source of financing in detail and provide documentation of the commitment of the funds.

RESPONSE: Not Applicable.

7. (a) Supply copies of the two most recent audited financial reports of the applicant.

If audited statements are unavailable, please provide unaudited statements. If there are no statements for the subsidiary corporation, please provide parent company's statements, personal financial statements, or any other financial reports which document the financial security of the applicant.

RESPONSE: Corporate financial statements serve as **Exhibit 16**. The corporate financial statement included in this application provides audited financial statements for the years 2009 and 2010.

- (b) Indicate the line items on the reports to show the dollar amounts specifically available for this project.

RESPONSE: See **Exhibit 16** under the line item Cash and Cash Equivalents on page F-5, Line 1.

8. a) Discuss how the financing of this project will impact the financing associated with any other certificate of need projects that are approved and not operational or are currently under review.

RESPONSE: DVA Healthcare Renal Care, Inc., a wholly owned Company of DaVita Inc., a New York Stock Exchange listed Corporation. The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that have been approved previously or are currently under review.

- (b) List all projects that are under development or proposed for development in North Carolina, the respective capital costs of each, and the methods of financing.

RESPONSE: See **Exhibit 17** for a list of projects under development or proposed for development in North Carolina, the respective capital costs of each, and the method of financing.

- (c) Explain how the applicant is financially able to undertake all of these projects at this time.

RESPONSE: The parent corporation has sufficient moneys on hand to undertake all of these projects at this time as evidenced by its balance sheet. See **Exhibit 16**.

9. (a) Provide a copy of any equipment rental agreement related to the proposed project.

RESPONSE: The North Charlotte Dialysis Center does not propose to lease equipment in this project.

(b) Explain how the equipment and/or operating lease rates, as well as any management contract fees, were negotiated.

RESPONSE: Not Applicable.

(c) Provide supporting evidence that the lease and/or management contract amounts are reasonable from a prudent buyers perspective.

RESPONSE: Not Applicable.

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

¹ See 42 CFR §494.30(a)(1)(i)

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

- **F-8590-10 RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers – Concord** ["RAI"] proposes to develop a new 23-station dialysis facility in Concord in Cabarrus County. In Section I.8, page 3, the applicant states the facility will offer in-center hemodialysis on 21 stations, will include one separate room for patients requiring isolation, pursuant to CMS Guidelines,² and one additional separate room, to offer home hemodialysis training. The line drawing in Section II.12, page 27, and in Exhibit 23 show a total of 23 dialysis stations are proposed. The line drawing identifies 21 dialysis stations on the floor, one room separate for patients requiring isolation, and one room labeled for home hemodialysis purposes. Thus, the applicant proposes a total of 23 dialysis stations. The 2010 SMFP defines the need for a maximum of 23 dialysis stations in Cabarrus County. The applicant proposes to develop no more than 23 dialysis stations in Cabarrus County and therefore is conforming to the need determination in the 2010 SMFP.

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

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

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

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

Promote Safety and Quality

In Section II, page 21, the applicant states,

² See 42 CFR §494.30(a)(1)(i)

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

On page 22, the applicant states,

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

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

Document Plans for Access to Healthcare by Underserved

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

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

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

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

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

Maximize Healthcare Value

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

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

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

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

Promote Safety and Quality

In Section II, page 24, the applicant states,

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

On page 26, the applicant states,

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

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

Document Plans for Access to Healthcare by Underserved

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

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

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

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

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

On page 42, the applicant states:

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

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

Maximize Healthcare Value

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

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

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

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

F-8584-10 Copperfield Dialysis Center

Promote Safety and Quality

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

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

...

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

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

Document Plans for Access to Healthcare by Underserved

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

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

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

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

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

Maximize Healthcare Value

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

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

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

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

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

Promote Safety and Quality

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

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

In Section II, page 29, the applicant states,

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

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

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

Document Plans for Access to Healthcare by Underserved

In Section II, page 24, the applicant states,

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

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

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

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

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

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

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

Maximize Healthcare Value

In Section II, page 25, the applicant states,

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

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

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

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

C

Harrisburg Dialysis Center
Cabarrus County Dialysis
Copperfield Dialysis Center

NC

RAI Care Center-Concord

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

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

facility will dialyze 70 patients on 20 dialysis stations at the end of project year one, which is 3.5 patients per station, or a utilization rate of 87.5% [70 patients / 20 stations = 3.5 patients per station. 70 patients / (20 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
	(N-CTR PTS)	(HOME PTS)	(N-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.

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

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		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	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 [$118.2 \times 0.085 = 10.047 + 118.2 = 128.247$. $128.2 \times 0.085 = 10.897 + 128.2 = 139.097$]. On page 28, the applicant states Operating Year One is projected to be July 1, 2011- June 30, 2012; likewise, Operating Year Two is projected to begin July 1, 2012 and end on June 30, 2013. The applicant states the difference between the projected aggregate population of the Harrisburg and Copperfield dialysis centers and the projected total Cabarrus County in-center dialysis population is 78.6 in-center dialysis patients [212.2 Cabarrus County in-center dialysis patients as of June 30, 2012 – 133.6 in-center combined Harrisburg and Copperfield dialysis patients as of June 30, 2012 = 78.6 as of June 30, 2012].

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

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

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

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

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

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

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
Total	75	7	78	7	100.0%	100.0%

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

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

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

Demonstration of Need

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

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

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

...

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

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

On page 32, the applicant states,

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

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

- ◆ *Trinity Church Road is located near the population center of Cabarrus County.*
- ◆ *Trinity Church Road is easily accessible from the north and south via US Highway 601 and I-85 and from the east and west via NC Highway 73. It is also near the Cabarrus-Mecklenburg border which makes it a convenient location for residents of North Mecklenburg (for example, Huntersville) where there is no dialysis facility.*
- ◆ *The local nephrologists' practice in Cabarrus County is located at CMC-Northeast in Concord."*

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

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

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

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

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

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

...

The data also shows that ESRD is not just a Medicare-age disease. While 50.9% of the ESRD patients in ESRD Network 6 are over the age of 60, the remaining 49.1% are under the age 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

	HISTORICAL				PROJECTED	
	12/05	12/06	12/07	12/08	12/09	12/10
No. Patients	146	150	170	174	201	218.1
% Change*	-	2.7%	13.3%	2.4%	15.5%	8.5%

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

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

Cabarrus County Total Dialysis Patients Dialyzed in Cabarrus County Historical and Projected

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

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

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

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

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	OP. YEAR 1	OP. 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
RN (dc)	3.0
Pt. Care Technician (dc)	3.0
Bio-Med Tech	0.5
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0.5
Social Worker	0.5
Unit Secretary	1.0
Other - Reuse	1.0
TOTAL	15.5

*dc: direct care staff

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

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

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
Total	30	30	60
Total Hours Operation per Year (weekly hours x 52)			3,120

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
Total	11.5	2,080	23,920	3,120	7.7

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

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

MO/SHIFTS	NO. OF PATIENTS	FTE/SAT. 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-3581-10, 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 FTE'S YEAR 2
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 - Reuse	0.5
TOTAL	11.7

*dc: direct care staff

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

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

WEEKLY HOURS OF OPERATION				
DAY	MORNING	AFTERNOON	EVENING	TOTAL
Monday	3	3	2	8
Tuesday	3	3	0	6
Wednesday	3	3	2	8
Thursday	3	3	0	6
Friday	3	3	2	8
Saturday	3	3	0	6
Sunday	0	0	0	0
Total	18	18	6	42
Total Hours Operation per Year (weekly hours x 52)				2,148

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

	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	MON/WED/FRI PATIENTS	TUE/THUR/SAT PATIENTS
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'S/YEAR
RN (dc)	4.0
Pt. Care Technician (dc)	11.0
Bio-Med Tech	0.7
Medical Director	Contract Position
Admin (dc)	1.0
Dietician	0.7
Social Worker	0.7
Unit Secretary	1.0
Other - Reuse	1.5
TOTAL	20.6

*dc: direct care staff

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

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

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
Total	42	42	72
Total Hours Operation per Year (weekly hours x 52)			4,368

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

	# FTE'S	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
Total	15.7	2,080	32,656	4,368	7.5

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

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

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'S YEARS
RN (dc)	4.5
Pt Care Technician (dc)	7.0
Medical Director	1.0
Dietician	1.0
Social Worker	1.0
Unit Secretary	1.0
TOTAL	15.5

*dc: direct care staff

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

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

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:

	FTE'S	HRS/OP/FTE	TOTAL FTE HOURS (ANNUAL)	TOTAL HRS OF OPERATION (ANNUAL)	FTE HRS/RS OF OPERATION
RNs	4.5	2,080	9,360	2,496	3.7
Techs	7.0	2,080	14,560	2,496	5.8
Total	11.5	2,080	23,920	2,496	9.5

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

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

TIME/SHIFT	M/W/R 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 Type	Percentage
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 Type	Percentage
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%
Total	100.0%

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

F-8590-10, RAI Care Center-Concord – In Section VI.1(c), page 53, the applicant projects that 80.5% of its patients who will be served at the proposed facility will have all or some of their services paid for by Medicare or Medicaid. The applicant provides a table to show the projected payor mix. See the following table:

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

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C
 All Applicants

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

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

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

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

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

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

C
All Applicants

F-8577-10, Harrisburg Dialysis Center - In Section V.3 of the application, page 36, the applicant states *"Total Renal Care of North Carolina, LLC has sent correspondence on behalf of the Harrisburg Dialysis Center to Rowan Cabarrus Community College to offer the facility as a clinical rotation site for 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 XI.5(e), page 65 of the application, the applicant states the facility will have power and water available at the proposed location, and that the facility will comply with 42 CFR §405.2100. In Exhibit 9, the applicant provides a copy of the DaVita policy regarding water supply in dialysis facilities.
- NA- **Copperfield Dialysis Center** – Copperfield Dialysis Center is not a new facility.
- C- **RAI Care Center-Concord** – In Section XI.6(f), page 86, the applicant states a house currently exists on the site chosen for the dialysis facility, and therefore power and water are both available at the site.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

- C- **Harrisburg Dialysis Center** – In Exhibit 9, the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.
- C- **Cabarrus County Dialysis Center** - In Exhibit 8, the applicant provides a copy of a September 8, 2010 letter requesting that the Cabarrus County Dialysis Center be included in the back up service that currently provides service to the Harrisburg and Copperfield facilities. The applicant also provides a copy of a DaVita policy regarding actions to be taken in the even of a power outage.

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

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

- C- **RAI Care Center-Concord** – In Section XI.6(g), page 87, the applicant states the dialysis center will operate in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements. In Exhibit 22, the applicant provides a September 10, 2010 letter from the facility architect that confirms the plans conform to all regulatory requirements.

- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- **Harrisburg Dialysis Center** –The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 10 – 19, and in Section III, pages 25 - 30 of the application. All patients are projected to reside in Cabarrus County.
- C- **Cabarrus County Dialysis Center** - The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 11 - 14, and in Section III, pages 29 - 33 of the application. All patients are projected to reside in Cabarrus County.
- C- **Copperfield Dialysis Center** – The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 11 – 19, and Section III.7, pages 25 – 30 of the application. All patients are projected to reside in Cabarrus County.
- NC- **RAI Care Center-Concord** – The information regarding patient origin provided by the applicant are found in Section III.1, pages 30 – 38, and in Section III.7, pages 41 – 42 of the application. However, the applicant did not state assumptions or methodology to support its projections of patients proposed to be served; thus, the projections are unsupported and unreliable. See Criterion (3) for discussion.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- **Harrisburg Dialysis Center** – Harrisburg Dialysis Center is not a new facility.
- C- **Cabarrus County Dialysis Center** – The applicant states, in Section II.7, page 14, that all of the patients projected to dialyze at Cabarrus County dialysis facility will reside within 30 miles of the proposed facility, particularly since it will be centrally located in Concord.
- NA- **Copperfield Dialysis Center** – Copperfield Dialysis Center is not a new facility.
- C- **RAI Care Center-Concord** – The applicant states, in Section III.8, page 42, that 100% of the patients projected to dialyze at RAI Care Center-Concord will reside within 30 miles of the proposed facility.

- (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	PY1	PY2
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	PY1	PY2
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	PY1	PY2
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	PY1	PY2
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	PY1	PY2
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	PY1	PY2
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	PY1	PY2
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	PY1	PY2
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:

2008 Davie County Competitive Dialysis Review

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

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

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

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

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

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

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

- Improve patient outcomes*
- Provide patient and teammate training*

2008 Davie County Competitive Dialysis Review

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

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

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

"The development of DKC will have a favorable impact on 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.

2008 Davie County Competitive Dialysis Review

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

2008 Davie County Competitive Dialysis Review

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

2008 Davie County Competitive Dialysis Review

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.

2008 Davie County Competitive Dialysis Review

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:

2008 Davie County Competitive Dialysis Review

"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."*

2008 Davie County Competitive Dialysis Review

- *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

2008 Davie County Competitive Dialysis Review

years is reasonable, given the historical rate of growth for Davie County in-center dialysis patients and the likelihood that a majority of Davie County dialysis patients would prefer a facility closer to their homes.

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

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

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC – TRC
CA – WFU

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

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

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

C – Both Applications

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

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

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

2008 Davie County Competitive Dialysis Review

"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.

2008 Davie County Competitive Dialysis Review

	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	-
TOTAL	\$2,680,627	\$435,010

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

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

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

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

2008 Davie County Competitive Dialysis Review

	Year 1	Year 2
Projected Expenses	\$1,298,673	\$1,532,113
# of Dialysis Treatments	4,401	6,174
Average Cost per Treatment	\$295.09	\$248.16
Net Patient Revenue	\$1,644,328	\$2,242,347
# of Dialysis Treatments	4,401	6,174
Net Revenue per Treatment	\$373.63	\$363.19
Total Net Profit	\$78,395	\$342,615

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

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

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

C-TRC
CA-WFU

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

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

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

C – Both Applications

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

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

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

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

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

2008 Davie County Competitive Dialysis Review

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

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

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

C – Both Applications

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

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

2008 Davie County Competitive Dialysis Review

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.

2008 Davie County Competitive Dialysis Review

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.

2008 Davie County Competitive Dialysis Review

- (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;*

2008 Davie County Competitive Dialysis Review

- (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.*

2008 Davie County Competitive Dialysis Review

-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

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

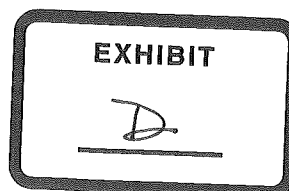
G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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

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*

Cape Fear Dialysis Center

Project I.D. # O-8252-08

Page 7

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%
TOTAL	95	0	97	0	100%	100%

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

$$\text{“January 1, 2008 – December 31, 2008 – 90 patients} \times 1.016 = 91.4 \text{ patients}”$$

*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.