

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 13, 2012  
PROJECT ANALYST: Gene DePorter  
ASSISTANT CHIEF: Martha Frisone

PROJECT I.D. NUMBER: F-8746-11/ DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center/ Add two dialysis stations for a total of 34 stations/ Mecklenburg County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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The applicant, DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center (CDC), operates 31 certified dialysis stations at 2321 West Morehead Street in Charlotte. This application [Project ID # F 8746-11] is a request for two additional dialysis stations for a total of 34 stations upon completion of the project.

The 2011 State Medical Facilities Plan (2011 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2011 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 dialysis stations in Mecklenburg County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Charlotte Dialysis Center in the July 2011 SDR is 4.19 patients per station, which is an occupancy rate of 105%. This utilization rate was calculated based on 109 in-center dialysis patients and 26 certified dialysis stations as of December 31, 2010 [109 patients / 26 stations = 4.19 patients per station]. In Project ID # F-8570-10 the

applicant was approved to add 4 stations for a total of 31 stations. Those stations were not developed as of December 31, 2010. They were developed as of June 30, 2011. The additional station approved in Project I.D. # F-8643-11 was certified as of December 23, 2011. Thus as of December 23, 2011, the facility is certified for 32 stations. The occupancy rate at 32 stations (assuming 109 in-center patients) is 85% [ $109/32= 3.4$ ;  $3.4/4 = 0.85$ ].

Application of the facility need methodology indicates an additional station is needed for this facility, as illustrated in the following table.

**Table 1**  
**DVA Charlotte Dialysis Center**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2010		105%
Certified Stations		26
Pending Stations		6
<b>Total Existing and Pending Stations</b>		<b>32</b>
In-Center Patients as of 12/31/10 (SDR2)		109
In-Center Patients as of 6/30/10 (SDR1)		106
Step	Description	Result
	Difference (SDR2 – SDR1)	3
(i)	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/10	0.0566
(ii)	Divide the result of step (i) by 12	0.0047
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the July 2011 SDR(12/31/2010) until the end of calendar year 2010 (12 months)	0.0566
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	115.1698
(v)	Divide the result of step (iv) by 3.2 patients per station	35.9906
	and subtract the number of certified and pending stations as recorded in SDR2 [31] to determine the number of stations needed	<b>4</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add only, two new stations, which is less than the facility need determination for dialysis stations.

Of the 109 in-center patients utilizing the facility as of 12/31/2010; 103 patients reside in Mecklenburg County and 6 patients reside in Gaston County.

Policy GEN-3: Basic Principles, on page 40 in the 2011 SMFP is applicable to this review. Policy GEN-3 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.”*

### **Promote Safety and Quality**

In Section II.3, pages 16-17, the applicant states how the proposed plan will insure 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 RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. The 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. Our Quality Management Program includes the following Quality Programs:*

- *Quality Improvement Methodology – utilizing outcome-driven, patient-centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*

- *Quality Assessment Audit Program – systematically utilizing a Comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*  
*Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).*

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

- *Improve patient outcomes*
- *Provide patient and staff training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards”*

The applicant adequately demonstrates the proposal will promote quality and safety.

### **Promote Equitable Access**

In Section VI.1 (b), page 29, the applicant's Source of Payment Table illustrates that 84.9% of its patients have historically been Medicaid or Medicare recipients. In Section VI.1(c), page 30, the applicant projects to continue to serve the same payer mix upon project completion. Further in Section VI.1 (a), page 29, the applicant states:

*“Charlotte Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

The applicant adequately demonstrates how the proposal will promote equitable access.

### **Maximize Healthcare Value**

In Section III.9, page 22, the applicant states how the addition of two certified stations will allow Charlotte Dialysis Center to maximize healthcare value. The applicant states:

*“The Charlotte 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 Charlotte 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 Charlotte Dialysis Center utilizes the reuse process that contains cost 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 Charlotte Dialysis Center has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- The Charlotte Dialysis Center Bio-medical Technician assigned to the facility conducts 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 Charlotte Dialysis Center also has 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 proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, page 40 of the 2011 SMFP states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.”*

The capital cost of the proposed project is \$32,041 which will be funded through Cash Reserves (Reference Exhibit 14.-Capital Funds Certification Letter). Therefore, Policy GEN-4 is not applicable.

The application is consistent with the facility need determination in the July 2011 SDR and Policy GEN 3. Consequently, the application is conforming to this criterion.

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

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The applicant, DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center, proposed to add two dialysis stations for a total of 34 stations upon completion of Project I.D. # F-8643-11 (add one station) and this project. This application was filed in October 2011. As of December 23, 2011, the additional station approved in Project I.D. # F-8643-11 has been certified. See the January 2012 SDR.

**Population to be Served**

In Section IV.1, page 23, the applicant identifies the population it served, as of December 31, 2010, as illustrated in the table below.

**Table 2  
Charlotte Dialysis Center  
Current In-Center Patient Population**

<b>County of Residence</b>	<b># of Patients Dialyzing In-Center</b>	<b>Percentage</b>
Mecklenburg	103	94.5%
Gaston	6	5.5%
<b>Total</b>	<b>109</b>	<b>100.0%</b>

In Section III.7, page 20, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

**Table 3**  
**Charlotte Dialysis Center**  
**In-Center and Home Dialysis Projections**  
**Operating Years 1 and 2**

County	Operating Year 1 FY 2012/2013		Operating Year 2 FY 2013/2014		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis	In-Center Patients	Home Dialysis	Year 1	Year 2
Mecklenburg	113	46	119	48	94.1%	94.4%
Gaston	6	4	6	4	5.9%	5.6%
Total	119	50	125	52	100.0%	100.0%

Section III. 7, page 20.

The applicant adequately identified the population to be served.

**Need Analysis**

In Section III.7, pages 20-21, the applicant states:

*“The Charlotte Dialysis Center had 109 in-center patients as of December 31, 2010 based on information included on Page 11 of the July 2011 Semiannual Dialysis Report (SDR). This is a station utilization of 85% based on 32 certified stations in the facility. Of the 109 in-center patients cited in the SDR, 103 of those patients lived in Mecklenburg County. The other 6 patients live in Gaston County. The Charlotte Dialysis Center is applying for a two-station expansion.*

*The July 2011 SDR indicates on page 20 that Mecklenburg County has experienced an average annual change rate of 5.1% for the past five years.*

*We have grown the patient population of the Charlotte Dialysis Center patients beginning July 1, 2011 through the projected operating year 2. The calculations below begin with 103 in-center patients living in Mecklenburg County:*

*July 1, 2011-June 30, 2012 – 103 patients X 1.051=108.253*

*July 1, 2012-June 30, 2013 – 108.253 patients X 1.051=113.773903*

*July 1, 2013-June 30, 2013 – 113.773903 patients X 1.051=119.567372*

*July 1, 2012 – June 30, 2012 (operating year 1)*

*July 1, 2013-June 30, 2013 (operating year 2)*

*We have chosen not to grow the number of Gaston County patients who are currently receiving their dialysis treatments at Charlotte Dialysis Center.*

*The Charlotte Dialysis Center is projected to have 119 in-center patients (113 Mecklenburg County in-center patients and 6 Gaston County in-center patients) at the end of operating year 1 for a utilization rate of 87.5% or 3.5 patients per station and 125 in-center patients (119 Mecklenburg County in-center patients and 6 Gaston County in-center patients) at the end of operating year 2 for a utilization rate of 92% or 3.7 patients per station."*

The number of home trained patients is determined in the same manner. See page 21 of the application.

The applicant projects to serve 119 in-center patients or 3.5 patients per station ( $119/34 = 3.5$ ) by the end of Year 1 and 125 in-center patients or 3.7 patients per station ( $125/34 = 3.7$ ) by the end of Year 2 for the proposed 34 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Proposed utilization is based on reasonable and supported assumptions regarding continued growth. Note: even if the number of in-center patients did not increase, the facility would average 3.2 patients per station per week with 34 stations [ $109/34 = 3.205$ ].

In summary, the applicant adequately identified the population to be served and demonstrated the need for the additional two stations based on the population it proposes to serve. 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.

NA

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

CA



In Section III.9, page 22, the applicant discusses the two alternatives it considered to meet the need for the proposed services. The first alternative is to do nothing. The second is to apply for a two station addition. The applicant selected the second alternative. The application is conforming to the facility need methodology for additional stations. See Criterion (1) for discussion. Further, the applicant demonstrated the need for two additional stations based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrated that the proposal to add two dialysis stations is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **DaVita Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall materially comply with all representations made in the certificate of need application.**
  2. **DaVita Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall develop no more than two additional stations for a total of 34 stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
  3. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall install plumbing and electrical wiring through the walls for no more than a total of 34 dialysis stations, including any home hemodialysis training or isolation stations.**
  4. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 37, the applicant projects the total capital cost of the project will be \$32,041, including \$23,711 for dialysis machines, \$4,000 for furniture, \$1,940

for dialysis chairs, and \$2,390 for televisions. The applicant projects no initial start-up costs or initial operating expenses. The applicant states the capital costs for the proposed project will be funded by cash reserves from DaVita Inc., the parent company of DVA Healthcare Renal Care, Inc.

Exhibit 14 includes a letter dated September 12, 2011 from the Senior Vice President of DaVita Inc., which states:

*"I am the Senior Vice President of DaVita Inc., the parent and owner of DVA Healthcare Renal Care, Inc. We are submitting a Certificate of Need application to expand our Charlotte Dialysis Center by two ESRD dialysis stations.*

*The project calls for a capital expenditure of \$32,041. This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$32,041 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 DVA Healthcare Renal Care, Inc."*

In Exhibit 15, the applicant provides the audited financial statements for DaVita Inc. As of December 31, 2009, DaVita Inc. had \$539,459,000 in cash and cash equivalents, \$7,558,236,000 in total assets and \$2,194,159 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

**Table 4**  
**Net Revenue and Operating Expenses**

	Project Year 1- 2008	Project Year 2- 2009
Net Revenue	\$7,699,452	\$8,071,319
Operating Expenses	\$6,854,291	\$7,166,792
Profit	\$845,161	\$ 904,527

The applicant adequately demonstrated that the proposal is based on reasonable projections regarding revenues and operating costs. Therefore, the application is conforming to this criterion.

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

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The applicant proposes to add two dialysis stations to the existing facility for a total of 34 stations upon completion of the proposed project. The applicant adequately demonstrated the need for two additional stations based on the number of in-center patients it proposes to serve. Furthermore, based on the number of in-center patients currently being served (as of December 31, 2010), the facility would average 3.2 patients per station per week with 34 stations [ $109/34 = 3.205$ ]. Thus the facility needs two additional stations to serve its current in-center patients. See Criteria (1) and (3) for additional discussion. Consequently, the applicant adequately demonstrated that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

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The information regarding staffing 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.

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

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In Section VI.1 (a), page 29, the applicant states that Charlotte Dialysis Center provides services to all residents “*without qualifications.*” Furthermore, on page 29, the applicant states:

*“Charlotte 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. Charlotte Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need. The facility also operates a third shift Monday, Wednesday and Friday.*

*Charlotte 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 under-served persons.”*

The applicant further states the following in Section VI.1 (d), page 30 of the application:

*“The Charlotte Dialysis Center maintains an open-door policy of accepting all patients, regardless of ability to pay, who develop end stage renal disease while residing in the service area of the Charlotte Dialysis Center.”*

In Section VI.1 (b), page 29, the applicant indicates that 84.9 percent of patients at Charlotte Dialysis Center have some or all of their services paid for by Medicare or Medicaid. The table below illustrates the payer mix for the facility.

**Table 5**  
**Historical Payer Mix**

Payer Source	Percentage
Medicare	27.4%
Medicaid	4.1%
Medicare/Medicaid	22.6%
Commercial Insurance	11.7%
VA	3.4%
Medicare/Commercial	30.8%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2008-2009, respectively. The data in the table was obtained on December 20, 2011. More current data, particularly with regard to the estimated uninsured percentages, was not available.

**Table 6**  
**Percent Medicaid and Uninsured**

County	Total # of Medicaid Eligible's as % of Total Population	Total # of Medicaid Eligible's Age 21 and older as % of Total Population	% Uninsured CY 2008& 2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg	15.0%	38.9%	20.1%
Statewide	16.5%	44.3%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Charlotte Dialysis Center.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible's who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage

of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of November 2011, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that it provides 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;

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In Section VI.1 (f), page 30, the applicant states:

*"Charlotte Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993."*

In Section VI.6 (a), page 32, the applicant states, *"There have been no civil rights equal access complaints filed within the last five years."* Therefore, the application is conforming to this criterion.

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

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In Section VI.1(c), page 30, the applicant does not anticipate a change in the payer mix resulting from this proposal, as illustrated in the table below.

**Table 7**  
**Projected Payer Mix**

Payer Source	Percentage
Medicare	27.4%
Medicaid	4.1%
Medicare/Medicaid	22.6%
Commercial Insurance	11.7%
VA	3.4%
Medicare/Commercial	30.8%
<b>Total</b>	<b>100.0%</b>

As illustrated in Table 6 above, the applicant projects that 84.9 percent of patients at Charlotte Dialysis Center will have some or all their services paid for by Medicare or Medicaid.

The applicant demonstrated that it will provide adequate access to the elderly and the 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.

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In Section VI.5 (a), page 31, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologists with privileges at the Charlotte Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Mecklenburg County or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Charlotte Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Charlotte Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Charlotte Dialysis Center transfer and transient policies.”*

The applicant adequately demonstrates that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.



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

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Exhibit 10 contains a copy of a letter to the President of Central Piedmont Community College from the Director of Healthcare Planning for DaVita offering the use of Charlotte Dialysis Center as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the service area. Therefore, 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.

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See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that Charlotte Dialysis Center's addition of two dialysis stations for a total of 34 stations will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The Charlotte Dialysis Center adequately demonstrates the need to add two dialysis stations. The proposal is a cost-effective alternative to meet the demonstrated need for additional dialysis stations at Charlotte Dialysis Center (see Criteria (1), (3), (4) and (5) for additional discussion);
- The applicant has and will continue to provide quality services (see Criteria (7), (8) and (20) for additional discussion);
- The applicant has and will continue to provide adequate access to medically underserved populations (see Criterion (13) for additional discussion).

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.

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The applicant currently provides dialysis services at Charlotte Dialysis Center. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Charlotte Dialysis Center operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. 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

The Criteria and Standards for End Stage Renal Disease Services 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 in 10A NCAC 14C .2200. The specific findings are discussed below.

**.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 Sections III.2, IV.1, and January 2011 SDR.

*.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, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*  
-C- See Section IV.7, page 24.

(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:*

- .2202(b)(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- Charlotte Dialysis Center is an existing facility.
- .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 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- Charlotte Dialysis Center is an existing facility.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- Charlotte Dialysis Center is an existing facility.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Section XI.6 (f), page 52, and Exhibit 7.

.2202(b)(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- Charlotte Dialysis Center is an existing facility.

.2202(b)(6) *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 9-17, and Section VII, pages 33-36.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- See Section III.7, pages 20-21.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- Charlotte Dialysis Center is an existing facility.

.2202(b)(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- See Section VI.1 (d), page 30.

### **.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 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- Charlotte Dialysis Center is an existing facility.

.2203(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- In Section III.7, pages 20-21, the applicant projects to serve 119 in-center patients or 3.5 patients per station [ $119 / 34 = 3.5$ ] by the end of Year 1 for the proposed 34-station facility.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section III.7, pages 20-21, the applicant provided the assumptions and methodology used to project utilization of two additional stations. See Criterion (3) for discussion.

### **.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; N/A*  
-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 25.

**.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 33-36.

.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 35, and Exhibit 13.