ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: June 3, 2016
Findings Date: June 3, 2016

Project Analyst: Gloria C. Hale
Team Leader: Lisa Pittman

Project ID #: F-11155-16
Facility: Charlotte Dialysis
FID #: 955930
County: Mecklenburg
Applicant: DVA Healthcare Renal Care, Inc.
Project: Add eight dialysis stations for a total of 34 stations upon completion of this project and Project I.D. #F-11108-15 (relocate 10 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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.

C

DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon completion of this project and Project I.D. #F-11108-15 (relocate 10 stations).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of eight dialysis stations in Mecklenburg County. Therefore, based on the county need methodology, there is no need for additional stations in

Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Charlotte Dialysis in the January 2016 SDR is 3.50 patients per station. This utilization rate was calculated based on 126 in-center dialysis patients and 36 certified dialysis stations as of June 30, 2015 (126 patients / 36 stations = 3.50 patients per station). Application of the facility need methodology indicates that eight additional stations are needed for this facility, as illustrated in the following table:

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		87.50%
Certified Stations		36
Pending Stations		0
Total Existing and Pending Stations		**36**
In-Center Patients as of 6/30/15 (SDR2)		126
In-Center Patients as of 12/31/14 (SDR1)		113
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	13
	Multiply the difference by 2 for the projected net in-center change	26
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.2301
(ii)	Divide the result of step (i) by 12	0.0192
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.1152
(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	140.52
(v)	Divide the result of step (iv) by 3.2 patients per station	43.91
	and subtract the number of certified and pending stations to determine the number of stations needed	**8**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eight 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 eight new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles, page 39, of the 2016 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."

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, and Exhibit K. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 15, Section L, pages 44-48, and Exhibit L-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11, and N.1, page 50. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the January 2016 SDR and with *Policy GEN-3: Basic Principles*. Therefore, 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.

DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis, whose parent company is DaVita HealthCare Partners, Inc. (DaVita), proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon completion of this project and Project I.D. #F-11108-15 (relocate 10 stations).

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 18, the applicant provides the historical in-center patient origin for Charlotte Dialysis as of June 30, 2015, which is summarized in the following table:

Charlotte Dialysis
Historical Patient Origin
June 30, 2015

	# of In-Center Patients
Mecklenburg	120
Catawba	1
Gaston	3
Other States	2
Total	**126**

In Section C.1, page 13, the applicant provides the projected in-center patient origin for Charlotte Dialysis for the first two years of operation following project completion, as illustrated in the following table:

Charlotte Dialysis
Projected Patient Origin by County

	# of In-Center Patients CY2018	# of In-Center Patients CY2019	County Patients as a Percent of Total, CY2018	County Patients as a Percent of Total, CY2019
Mecklenburg	126	134	95.5%	95.7%
Catawba	1	1	0.8%	0.7%
Gaston	3	3	2.3%	2.1%
Other States	2	2	1.5%	1.4%
Total	**132**	**140**	**100.0%**	**100.0%**

The applicant provides the assumptions and methodology used to project patient origin on pages 13-14. The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to add eight dialysis stations to Charlotte Dialysis for a total of 34 certified dialysis stations upon completion of this project and Project I.D. #F-11108-15 (relocate ten stations) pursuant to the 2016 SMFP Facility Need Methodology.

As of June 30, 2015, as reported in the January 2016 SDR, the utilization rate at Charlotte Dialysis was 3.5 patients per station per week based on 126 in-center patients utilizing 36 certified dialysis stations.

In Section C.1, pages 13-14, the applicant provides the following assumptions used to project utilization for in-center patients:

1. Project I.D. #F-11108-15, if approved, will transfer 10 dialysis stations from Charlotte Dialysis to develop a new facility, Brookshire Dialysis, in Mecklenburg County. Eighteen in-center patients from Mecklenburg County dialyzing at Charlotte Dialysis are projected to transfer their care to Brookshire Dialysis upon certification of the facility.

2. The ending census for CY2017 will be 144 in-center patients, 138 from Mecklenburg County, based on growth. Eighteen Mecklenburg County in-center patients will transfer their care to Brookshire Dialysis, leaving 120 in-center patients from Mecklenburg County to begin CY2018.

3. Operating Year One and Operating Year Two are projected to be CY2018 and CY2019, respectively.

4. The Average Annual Change Rate (AACR) for Mecklenburg County of 5.8%, as reported in Table B of the January 2016 SDR, is used to project growth in in-center patients from Mecklenburg County. The period of growth begins July 1, 2015 and is calculated forward to December 31, 2019. No growth rates are applied for the six in-center patients from other counties and states.

Projected Utilization

In Section C.1, page 14, the applicant provides its methodology for projecting utilization for in-center patients for operating years one and two, as follows:

Charlotte Dialysis	In-Center Patients
Beginning census of Mecklenburg County in-center patients only, July 1, 2015	120
The census of Mecklenburg County in-center patients is projected forward six months to January 1, 2016, using one-half of the AACR for Mecklenburg County, 2.9%, then the six patients outside the county are added.	(120 x 1.029) + 6 = 129.48
The census of Mecklenburg County in-center patients is projected forward one year to January 1, 2017, using the AACR for Mecklenburg County, 5.8%, then the six patients outside the county are added.	(123.48 x 1.058) + 6 = 136.64
Eighteen patients from Mecklenburg County dialyzing at Charlotte Dialysis are subtracted from the census of Mecklenburg County in-center patients on January 1, 2018. The AACR for Mecklenburg County of 5.8% is then applied to the remaining Mecklenburg County patients and the six patients outside the county are added.	{(130.64 – 18) x 1.058} + 6 = 125.17
The ending census for Operating Year One, CY2018, is calculated by projecting the census of Mecklenburg County in-patients forward by 12 months using the AACR for Mecklenburg County of 5.8%, then adding the six patients outside the county.	(119.18 x 1.058) + 6 = 132.08
The ending census for Operating Year Two, CY2019, is calculated by projecting the census of Mecklenburg County in-center patients forward by 12 months using the AACR for Mecklenburg County of 5.8%, then adding the six patients from outside the county.	(126.08 x 1.058) + 6 = 139.39

The applicant states, on page 14, that Charlotte Dialysis will have 132 in-center patients, rounded down, by the end of operating year one for a utilization rate of 97.1%, or 3.88 patients per station per week (132 patients/ 34 stations = 3.88). Therefore, the applicant's projected utilization 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).

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for eight additional dialysis stations at Charlotte Dialysis.

Access to Services

In Section L.1(a), page 44, the applicant states that Charlotte Dialysis makes its services available to all persons without qualifications, and *"without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability."* In addition, on page 45, the applicant states that it assists uninsured or underinsured patients with applying for financial assistance. Lastly, the applicant projects, in Section L.1(b), page 45, that 92.9% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for eight additional stations at Charlotte Dialysis, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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 E.1, page 22, the applicant provides two alternatives for the proposed project, summarized as follows:

1) Maintain the Status Quo – the applicant states that this alternative was dismissed because it does not account for growth at the facility. Therefore, it is not the most effective alternative.

2) Relocate Stations from another DaVita Facility – the applicant states that only one of its six facilities in Mecklenburg County, South Charlotte Dialysis, is operating at less than 80% capacity. South Charlotte Dialysis is operating at 76.09%, according to the January 2016 SDR and the applicant states that if it were to relocate stations from there to Charlotte Dialysis, it could have a negative impact on the patients currently being served there due to the facility's growth rate. Therefore, this is not the most effective alternative.

The applicant concludes, on page 22, that its proposal to add eight dialysis stations to Charlotte Dialysis was chosen in order to *"help meet the growing demand for dialysis services…"* In addition, the proposal will allow the facility to meet the needs of dialysis patients during day shifts rather than having to create a third shift which is inconvenient.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis shall materially comply with all representations made in the certificate of need application and clarifying information provided. In those instances where representations conflict, DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis shall materially comply with the last made representation.**

2. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis shall develop and operate no more than eight additional dialysis stations for a total of no more than 34 certified stations upon completion of this project and Project I.D. #F-11108-15 (relocate ten stations), which shall include any isolation or home hemodialysis stations.**

3. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance 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.

C

The applicant proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon completion of this and Project I.D. #F-11108-15 (relocate ten stations).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant states that there will be no capital costs to develop this project. In addition, in Sections F.10 and F.11, pages 25-26, the applicant states there will be no start-up expenses or initial operating expenses for this project.

Financial Feasibility

In Section R, page 60, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Medicare	$230.39
Medicaid	$143.00
Commercial Insurance	$1,275.00
Medicare/Commercial	$230.39
Medicare/ Medicaid	$230.39
VA	$193.00

In Section C.1, page 14, and in the pro formas, the applicant provides tables for its projected beginning census, ending census, and average census for in-center patients, for operating years one and two. The applicant uses the average census for in-center patients to calculate its financial projections. The following table summarizes the census counts and census averages for each of the first two operating years of the project:

	Operating Year One	**Operating Year Two**
# of In-Center Patients		
Beginning Census	126	132
Ending Census	132	140 [139]
Average Census	129	136

*Correction provided by the Project Analyst is in brackets.

The applicant states, in Section R, page 59, *"The average number of patients for operating year 1 and 2 which were calculated in Section C of the application are used to project the number of treatments, operating revenue and some of the operating expenses in these pro formas."*

The applicant provided pro forma financial statements for the first two operating years of the project in Section R. In Form B of the pro formas, the applicant projects that revenues will exceed operating expenses in each of the first two operating years of the project, as shown in the following table:

	CY2018	**CY2019**
Gross Patient Revenue	$4,926,168	$5,193,271
Deductions from Gross Patient Revenue	$284,393	$299,830
Net Patient Revenue	$4,641,774	$4,893,441
Operating Expenses	$4,348,274	$4,506,163
Net Income	**$293,501**	**$387,278**

The Project Analyst notes that there is a discrepancy in the amount of income taxes reported by the applicant in Form A of the pro formas as compared to the calculation of income taxes based on the assumption provided for Form A. The assumption states that a rate of 39.225% of the profit is used to calculate income taxes. The Project Analyst calculates $122,624 and $159,816 in income taxes for operating years one and two, respectively, as compared to $19,118 and $20,155 reported by the applicant for those respective years. In clarifying information, the applicant states that it erroneously used a different income tax rate than what was stated in the assumption. However, after adjusting for these discrepancies, the applicant's proposed project still projects a positive net income in operating years one and two of $189,994 and $247,617, respectively.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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 add eight dialysis stations for a total of 34 certified dialysis stations upon completion of this project and Project I.D. #F-11108-15 (relocate ten stations).

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to the January 2016 SDR, there are 19 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities
June 30, 2015

Dialysis Facilities	Owner*	# of Patients	# of Certified Stations	Percent Utilization	CON Issued/Not Certified
BMA Beatties Ford	FMC	122	32	95.31%	11
BMA Nations Ford	FMC	114	24	118.75%	0
BMA of East Charlotte	FMC	85	25	85.00%	-4
BMA of North Charlotte	FMC	109	28	97.32%	8
BMA West Charlotte	FMC	95	29	81.90%	0
Carolinas Medical Center	CMHA	14	9	38.89%	0
Charlotte Dialysis	DVA	126	36	87.50%	0
Charlotte East Dialysis	DVA	104	26	100.00%	0
DSI Charlotte Latrobe Dialysis	DSI	56	19	73.68%	0
DSI Glenwater Dialysis	DSI	132	41	80.49%	0
FMC Charlotte	FMC	133	40	83.13%	0
FMC Matthews	FMC	99	21	117.86%	0
FMC of Southwest Charlotte	FMC	0	0	0.00%	10
FMC Regal Oaks	FMC	0	0	0.00%	12
FMC Aldersgate	FMC	0	0	0.00%	0
Huntersville Dialysis	DVA	0	0	0.00%	10
Mint Hill Dialysis	DVA	44	11	100.00%	0
North Charlotte Dialysis Center	DVA	134	35	95.71%	-14
South Charlotte Dialysis	DVA	70	23	76.09%	0

*FMC is Fresenius Medical Care Holdings, Inc., CMHA is Charlotte Mecklenburg Hospital Authority, DVA is DaVita HealthCare Partners, Inc., and DSI is DSI Renal Inc.

As illustrated above, DaVita (DVA) owns 6 of the 19 dialysis facilities in Mecklenburg County. Three FMC dialysis facilities and one DVA dialysis facility show zero patients and zero certified stations because they have received agency approval but have not been certified yet. Notwithstanding the facilities with zero patients, only three have utilization rates less than 80%. Therefore, most of the operational dialysis facilities in the county are reasonably well utilized.

According to Table B in the January 2016 SDR, there is a surplus of eight dialysis stations in Mecklenburg County. However, the applicant is applying for additional stations based on the facility need methodology. In Section C.1, page 14, the applicant demonstrates that Charlotte Dialysis will serve a total of 132 in-center patients on 34 dialysis stations at the end of operating year one (CY2018), for a utilization rate of 3.88 patients per station per week, or 97.1% of capacity (132/ 34 = 3.88; 3.88/4 = 97.1%). Therefore, the facility is expected to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Mecklenburg County. 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 H.1, page 31, the applicant demonstrates that there will be no change in staffing for the facility, as illustrated in the table below:

Charlotte Dialysis
Current and Proposed FTEs

Position	Current	Additional	Total
Medical Director*			
Registered Nurse	5	0	5
Patient Care Technician	13	0	13
Administrator	1	0	1
Dietitian	1	0	1
Social Worker	1	0	1
Administrative Assistant	1	0	1
Biomed Technician	1	0	1
Total FTEs	**23**	**0**	**23**

*This is an independent contractor, not an employee.

In Exhibit I-3, the applicant provides a letter from Dr. Joel Bruce, Medical Director of Charlotte Dialysis, dated February 15, 2016, indicating his support of the project and his willingness to continue to serve as Medical Director of the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. 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

In Section I.1, page 35, the applicant includes a list of providers of the necessary ancillary and support services for the proposed project. Exhibit I-1 contains a copy of a letter from the Facility Administrator for Charlotte Dialysis which states that the facility has established relationships with various healthcare providers and that it will continue to provide necessary services through existing agreements with them. A copy of the facility's existing laboratory services agreement and an agreement with Charlotte East Dialysis for home training for hemodialysis or peritoneal dialysis are also included in Exhibit I-1. The letter in Exhibit I-1

from the Facility Administrator and the letter from the facility's Medical Director in Exhibit I-3 demonstrate support for the project and coordination with the existing health care system. Therefore, the applicant adequately demonstrates 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

(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 L.1, page 44, the applicant states that its policy is to make dialysis services available to all persons, *"without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability."* In addition, the applicant states that it *"helps uninsured or underinsured patients with identifying and applying for financial assistance."* The applicant provides additional information regarding its financial policies for uninsured or underinsured patients on pages 45-46.

In Section L.7, page 48, the applicant provides the historical payor mix for Charlotte Dialysis, as follows:

Charlotte Dialysis
CY 2015

Payor Source	Percentage of In-Center Patients	Percentage of Total Patients
Medicare	32.3%	32.3%
Medicaid	5.5%	5.5%
Commercial Insurance	3.2%	3.2%
Medicare/Commercial	29.1%	29.1%
Medicare/Medicaid	26.0%	26.0%
VA	3.9%	3.9%
Total	**100.0%**	**100.0%**

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority	% Persons in Poverty*	% < Age 65 with a Disability	% < Age 65 without Health Insurance*
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014

	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: http://www.esrdnetwork6.org/utils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently 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;

In Section L.3, page 47, the applicant states,

> *"Charlotte Dialysis 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 L.6, page 47, the applicant states that it has not had any 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 L.1, page 45, the applicant provides the projected payor mix for the proposed services at Charlotte Dialysis for the second operating year (CY2019), as shown in the table below:

Charlotte Dialysis
Projected Payor Mix, CY2019

Payor Source	Percentage of In-Center Patients	Percentage of Total Patients
Medicare	32.3%	32.3%
Medicaid	5.5%	5.5%
Commercial Insurance	3.2%	3.2%
Medicare/Commercial	29.1%	29.1%
Medicare/Medicaid	26.0%	26.0%
VA	3.9%	3.9%
Total	**100.0%**	**100.0%**

As shown in the table above, the applicant projects that 92.9% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1, page 45, the applicant provides its assumptions used to project payor mix, stating that it is *"based on the sources of patient payment that have been received by the existing facility in the last full operating year."* The projected payor mix is the same as the applicant's historical payor mix provided in Section L.7, page 48. The applicant demonstrates that medically underserved populations would 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 L.4, page 47, the applicant describes the range of means by which a person will have access to the dialysis services at Charlotte Dialysis, including referrals from nephrologists with privileges at the facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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.

C

In Section M.1, page 49, the applicant states that Charlotte Dialysis has been offered as a clinical training site for medical assisting students at King's College. Exhibit M-2 contains a copy of a Student Training Agreement between King's College and several DaVita dialysis facilities, including Charlotte Dialysis, to offer the dialysis facilities as clinical training sites for students enrolled in the college's Medical Assistant and Medical Office Assistant programs. The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately supports a finding of conformity 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.

C

The applicant proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon completion of this project and Project I.D. #F-11108-15 (relocate ten stations).

On page 369, the 2016 SMFP defines the service area for dialysis stations as *"the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each*

of the 94 remaining counties is a separate dialysis station planning area." Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

Table A in the January 2016 SDR indicates that there are 19 dialysis facilities in Mecklenburg County, as follows:

Mecklenburg County Dialysis Facilities
June 30, 2015

Dialysis Facilities	Owner*	# of Patients	# of Certified Stations	Percent Utilization	CON Issued/Not Certified
BMA Beatties Ford	FMC	122	32	95.31%	11
BMA Nations Ford	FMC	114	24	118.75%	0
BMA of East Charlotte	FMC	85	25	85.00%	-4
BMA of North Charlotte	FMC	109	28	97.32%	8
BMA West Charlotte	FMC	95	29	81.90%	0
Carolinas Medical Center	CMHA	14	9	38.89%	0
Charlotte Dialysis	DVA	126	36	87.50%	0
Charlotte East Dialysis	DVA	104	26	100.00%	0
DSI Charlotte Latrobe Dialysis	DSI	56	19	73.68%	0
DSI Glenwater Dialysis	DSI	132	41	80.49%	0
FMC Charlotte	FMC	133	40	83.13%	0
FMC Matthews	FMC	99	21	117.86%	0
FMC of Southwest Charlotte	FMC	0	0	0.00%	10
FMC Regal Oaks	FMC	0	0	0.00%	12
FMC Aldersgate	FMC	0	0	0.00%	0
Huntersville Dialysis	DVA	0	0	0.00%	10
Mint Hill Dialysis	DVA	44	11	100.00%	0
North Charlotte Dialysis Center	DVA	134	35	95.71%	-14
South Charlotte Dialysis	DVA	70	23	76.09%	0

*FMC is Fresenius Medical Care Holdings, Inc., CMHA is Charlotte Mecklenburg Hospital Authority, DVA is DaVita HealthCare Partners, Inc., and DSI is DSI Renal Inc.

As illustrated in the table above, four dialysis facilities show 0% utilization because they have received agency approval but have not been certified yet. Twelve facilities are operating above 80% capacity and with the exception of the facilities that are not yet operational, only three have utilization rates less than 80%. Therefore, the operational dialysis facilities in the county are reasonably well utilized.

In Section N.1, page 50, the applicant discusses how any enhanced competition would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states that the proposed project will have no effect on competition, and, that while it could serve as an alternative for dialysis patients *"to select a provider that gives them the highest quality service and better meets their needs…,"* it is primarily seeking to serve existing patients and accommodate projected growth.

In addition, the applicant states, on page 50,

> *"The expansion of Charlotte Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other* [sic] *involved in the dialysis process to receive services."*

See also Sections B, C, E, F, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.

- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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.

C

In Exhibits O-2 and O-3, the applicant provides information on quality of care provided at DaVita's ESRD facilities in the state, including citations received during the 18 months immediately preceding the submittal of the application through the date of the decision, and their resolution. Three facilities had deficiencies of the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities, 42 CFR Part 494. One facility had one standard level deficiency, another had one immediate jeopardy citation, and one other facility had two standard level deficiencies. In Sections O.2 and O.3, page 51, and in Exhibits O-2 and O-3, the applicant states that each these facilities is back in full compliance with CMS Guidelines as of the date of submission of this application. Exhibits O-2 and O-3 contain copies of letters documenting that the facilities were determined to be back in compliance by the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has

provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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.

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.

-NA- Charlotte Dialysis is an existing facility.

(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 C.1, pages 13-14, the applicant projects 132 in-center patients dialyzing on 34 stations at the end of the first operating year for a utilization rate of 3.88 patients per station per week, thereby documenting the need for the additional stations. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 13-14, and Section C.7, pages 16-17. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.