

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: January 25, 2017
Findings Date: January 25, 2017

Project Analyst: Gloria C. Hale
Team Leader: Fatimah Wilson

Project ID #: F-11252-16
Facility: North Charlotte Dialysis Center
FID #: 060083
County: Mecklenburg
Applicant: DVA Healthcare Renal Care, Inc.
Project: Add 9 dialysis stations for a total of 36 stations upon completion of this project and Project I.D. #F-11019-15 (relocate 4 stations to Copperfield Dialysis Center) and Project I.D. #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C.Gen.Stat. § 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. (DaVita) d/b/a North Charlotte Dialysis Care Center (North Charlotte) proposes to add nine dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. #F-11019-15 (relocate four stations to Copperfield Dialysis Center) and Project I.D. #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis).

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 July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for 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 North Charlotte in the July 2016 SDR is 3.71 patients per station per week. This utilization rate was calculated based on 152 in-center dialysis patients and 41 certified dialysis stations as of December 31, 2015 (152 patients / 41 stations = 3.71 patients per station per week). Application of the facility need methodology indicates that 19 additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		92.68%
Certified Stations		41
Pending Stations*		0
Total Existing and Pending Stations		41
In-Center Patients as of 12/31/15 (SDR2)		152
In-Center Patients as of 6/30/15 (SDR1)		134
Step	Description	
(i)	Difference (SDR2 - SDR1)	18
	Multiply the difference by 2 for the projected net in-center change	36
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	.2687
(ii)	Divide the result of step (i) by 12	.0224
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	.2687
(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	192.8424
(v)	Divide the result of step (iv) by 3.2 patients per station	60.2633
	and subtract the number of certified and pending stations to determine the number of stations needed	19.2633

As shown in the table above, the potential number of stations needed is 19 stations, however the applicant is proposing to add nine 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 nine new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3, on page 39, 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-1(g). 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 L, pages 44-45, and Exhibits 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) and (d), page 11, and Section N, 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 July 2016 SDR and Policy GEN-3. 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.

C

The applicant, North Charlotte, proposes to add nine dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. #F-11019-15 (relocate four stations to Copperfield Dialysis Center) and Project I.D. #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis).

Patient Origin

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 patient origin for North Charlotte as of December 31, 2015, which is summarized in the following table:

**North Charlotte
Historical Patient Origin
December 31, 2015**

County	In-Center
Mecklenburg	140
Cabarrus	3
Gaston	1
Lincoln	1
South Carolina	1
Other states	6
TOTAL	152

In Section C.1, page 13, the applicant provides the projected patient origin for North Charlotte for operating year one (OY1), January 1, 2018 – December 31, 2018, and OY2, January 1, 2019 – December 31, 2019, following completion of the project as follows:

**North Charlotte Dialysis
 Projected Patient Origin**

County	OY1 1/1/18 – 12/31/18	OY2 1/1/19 – 12/31/19	County Patients as Percent of Total OY1	County Patients as Percent of Total OY2*
Mecklenburg	150	157	92.6%	92.9%
Cabarrus	3	3	1.9%	1.8%
Gaston	1	1	0.6%	0.6%
Lincoln	1	1	0.6%	0.6%
South Carolina	1	1	0.6%	0.6%
Other states	6	6	3.7%	3.6%
Total	162	169	100.0%	100.0%

*Total may not foot due to rounding.

The applicant provides the assumptions and methodology used to project in-center patient origin in Section C.1, pages 13-14. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, page 7, the applicant demonstrates the need for the additional dialysis stations through the use of the facility need methodology. The applicant demonstrates that North Charlotte qualifies for an additional 19 stations, however in Section A.6, page 3, it states it is proposing to add nine stations. In Section C.1, pages 13-14, the applicant provides the following assumptions:

1. As of December 31, 2015, there were 152 in-center dialysis patients at North Charlotte, as reported in Table A of the July 2016 Semiannual Dialysis Report (SDR). Of these, 140 patients were residents of Mecklenburg County and 12 were residents from outside of the county, including Cabarrus, Gaston, Lincoln counties, South Carolina, and other states.
2. In Project I.D. #F-011019-15, Total Renal Care of North Carolina, LLC, a subsidiary of DaVita, will relocate four dialysis stations from North Charlotte to Copperfield Dialysis in Cabarrus County. No patients are projected to transfer from North Charlotte Dialysis as a result of this project.
3. In Project I.D. #F-011108-15, DaVita will relocate 10 dialysis stations from North Charlotte to develop Sugar Creek Dialysis, formerly University City Dialysis, in Mecklenburg County. Eleven in-center patients are expected to transfer their care to Sugar Creek Dialysis on January 1, 2018 upon certification.

4. In-center patient projections are increased annually for Mecklenburg County residents only, applying the Average Annual Change Rate (AACR) of 5.0% for Mecklenburg County, beginning January 1, 2016 to December 31, 2019. No growth calculations are applied to the 12 in-center patients living outside Mecklenburg County.
5. The proposed project is to be completed on December 31, 2017.
6. The applicant projects that OY1 will be Calendar Year (CY) 2017 [2018] and OY2 will be Calendar Year (CY) 2018 [2019].

Projected Utilization

The applicant provides its methodology in Section C.1, page 14, as follows:

	In-Center
The applicant begins with the Mecklenburg County in-patient census at the facility on January 1, 2016.	140
The Mecklenburg County in-center patient census is projected forward to December 31, 2016, increased the Five Year AACR for Mecklenburg County of 5%.	$(140 \times 0.05) + 140 = 147$
The 12 in-center patients from outside Mecklenburg County are added for the ending census of CY2016.	$147 + 12 = 159$
The census of Mecklenburg County in-center patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2017.	$(147 \times 0.05) + 147 = 154.35$
The 12 in-center patients from outside Mecklenburg County are added for the ending census of CY2017.	$154.35 + 12 = 166.35$
Eleven in-center patients from Mecklenburg County transfer to Sugar Creek Dialysis and are, therefore, subtracted from the Mecklenburg County patient census.	$154^* - 11 = 143$
The census of Mecklenburg County in-center patients is increased by the Five Year AACR for Mecklenburg County of 5% to project the census forward one year to December 31, 2018.	$(143 \times 0.05) + 143 = 150.15$
The 12 in-center patients from outside Mecklenburg County are added for the ending census of OY1, CY2018.	$150.15 + 12 = 162.15$
The census of Mecklenburg County in-center patients only is projected forward one year and increased by the Five Year AACR for Mecklenburg County of 5% to December 31, 2019.	$(150.15 \times 0.05) + 150.15 = 157.66$
The 12 in-center patients from outside Mecklenburg County are added for the ending census of OY2, CY2019.	$157.66 + 12 = 169.66$

*The applicant rounds down to the nearest whole number of in-center patients.

The applicant projects to serve 162 in-center patients or 4.5 patients per station per week ($162 \text{ patients} / 36 \text{ dialysis stations} = 4.50$) by the end of OY1 and 169 in-center patients or 4.69 patients per station per week ($169/36 = 4.69$) by the end of OY2. 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).

Access

In Section C.3, page 15, the applicant states that its policy is to make dialysis services available all residents in the service area, “...without regard to race, sex, age, or handicap....regardless of ethic or socioeconomic situation.” In Section L.7, page 48, the applicant reports that 88.2% of North Charlotte’s patients were Medicare or Medicaid recipients in CY2015. In Section L.1, page 45, the applicant projects that 88.2% 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 its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for nine additional stations at North Charlotte, 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 states that one alternative, maintaining the status quo, was considered prior to submitting this application for the proposed project. However, this alternative was dismissed due to the growth rate of the facility. Furthermore, the applicant states in Section E.2, page 22, that maintaining the status quo would necessitate an inconvenient third shift or no option at all for the growing numbers of patients projected to dialyze at the facility. Therefore, this was not the most effective alternative.

In Section E.2, page 22, the applicant states that the proposed project will “ensures that the facility will proactively address the issues of growth and access at the facility.” Therefore, the proposed alternative represented in the application is the most effective alternative to meet the identified need.

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 the 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 North Charlotte Dialysis Center shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center shall develop and operate no more than nine additional dialysis stations for a total of no more than 36 certified stations upon completion of this project and the following projects: #F-011019-15 (relocate 4 stations to Copperfield Dialysis Center) and #F-011108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis), which shall include any isolation or home hemodialysis stations.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center shall install plumbing and electrical wiring through the walls for nine additional dialysis stations for a total of no more than 36 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a North Charlotte Dialysis Center 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, North Charlotte Dialysis, proposes to add nine dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. #F-11019-15 (relocate four stations to Copperfield Dialysis Center) and Project I.D. #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant states that the project will not incur any capital costs. In Sections F.10-F.12, pages 25-26, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since North Charlotte Dialysis is an existing facility.

Financial Feasibility

In Section R, Form C of the pro formas, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

Allowable Charges

Payor	In-Center Charge
Self Pay/Indigent/ Charity	*
Commercial Insurance	\$1,275.00
Medicare	\$230.39
Medicaid	\$143.00
Medicare/Commercial	\$230.39
Medicare/Medicaid	\$230.39
VA	\$193.00

*The applicant does not provide an allowable charge for self-pay/indigent/charity.

In Section R, Form C, the applicant states in its assumptions that it uses the average number of in-center patients to calculate its revenues for the first and second years of the project. The applicant uses 158.5 in-center patients in operating year one and 165.5 in-center patients in operating year two. The applicant provides its beginning and ending census for interim operating years, CY2016 and CY2017, and first and second operating years of the project, CY2018 and CY2019, as follows:

In-center Patients

Year	Beginning census	Ending census	Average number of patients
CY2016	152	159	155.5
CY2017	159	166	162.5
CY2018	155	162	158.5
CY2019	162	169	165.5

In Section R, Form B, the applicant projects operating expenses and revenues, respectively, summarized as follows:

	OY1 (CY2018)	OY2 (CY2019)
Total Treatments	23,490	24,527
Total Gross Revenues (Charges)	\$7,054,926	\$7,366,613
Deductions from Gross Revenues	\$342,037	\$357,151
Total Net Revenue	\$6,712,889	\$7,009,462
Total Operating Expenses (Costs)	\$5,747,081	\$5,979,521
Net Income	\$965,808	\$1,029,941

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant, North Charlotte Dialysis, proposes to add nine dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. #F-11019-15 (relocate four stations to Copperfield Dialysis Center) and Project I.D. #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis).

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 July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County. Of these, 16 are operational, four are under development, and one has certified stations

but is not yet operational. The applicant or its parent company owns and operates 10 of the 21 dialysis facilities in Mecklenburg County. DVA Healthcare Renal Care, Inc. (DaVita) owns and operates eight facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (DMC) operates one facility, as shown in the table below.

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2015**

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA North Charlotte	BMA	Charlotte	28	102.68%
BMA of East Charlotte	BMA	Charlotte	25	85.00%
BMA of North Charlotte	BMA	Charlotte	28	103.57%
BMA West Charlotte	BMA	Charlotte	29	87.07%
Brookshire Dialysis	DaVita	Charlotte	10	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	88.89%
Charlotte East Dialysis	DaVita	Charlotte	26	108.65%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	55.21%
DSI Glenwater Dialysis	DSI	Charlotte	41	81.71%
FMC Charlotte	BMA	Charlotte	43	82.56%
FMC Matthews	BMA	Matthews	21	117.86%
FMC of Southwest Charlotte*	BMA	Charlotte	10	0.00%
FMC Regal Oaks*	BMA	Charlotte	12	0.00%
FMC Aldersgate*	BMA	Charlotte	10	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	12	93.75%
North Charlotte Dialysis Center	DaVita	Charlotte	41	92.68%
South Charlotte Dialysis	DaVita	Charlotte	22	80.68%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.

**Facility has certified stations but is not yet operational.

As shown in the table above, all five of DaVita's eight facilities that are operational are operating above 80% utilization (3.2 patients per station per week) and three are operating above 90% utilization. DaVita's three remaining dialysis facilities are under development. Only two of the 16 operational dialysis facilities in the county are operating below 80% utilization, a DSI facility and a CMC facility.

The applicant proposes to add nine in-center dialysis stations at North Charlotte Dialysis for a total of 36 dialysis stations upon completion of the project. As of December 31, 2015, North Charlotte Dialysis was serving 152 patients on 41 dialysis stations, which is 3.71

patients per station per week or 92.68% of capacity. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve in Section C.1, pages 13-14, of the application. At the end of OY1, the applicant projects utilization will be 4.50 in-center patients per station per week (162 patients /36 dialysis stations = 4.50), which is 112.5% of capacity. 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 the need to develop nine additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations 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.

C

In Section H.1, page 31, the applicant provides the current staffing for the facility, which includes 24 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project, which includes 25 FTE employees, illustrated as follows:

North Charlotte Dialysis Current and Proposed FTEs			
Position	Current	Additional	Total
Medical Director*			
Registered Nurse	5	0	5
Patient Care Technician	14	0	14
Administrator	1	1	2
Dietitian	1	0	1
Social Worker	1	0	1
Administrative Assistant	1	0	1
Biomed Technician	1	0	1
Total FTEs	24	0	25

In Section H.3, pages 32-33, the applicant describes its methods for recruiting and retaining staff. In Section I-3, the applicant states that Dr. Joel Bruce will serve as medical director of North Charlotte Dialysis. A copy of a letter of support from Dr. Bruce is provided in Exhibit I-3 which also includes a statement regarding his willingness to continue serving as the Medical Director for 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. Exhibit I-1 contains a letter from the Facility Administrator of North Charlotte Dialysis stating that the facility will continue to have agreements in place with Carolinas Medical Center and Novant Health Presbyterian Medical Center for various ancillary and support services, including, but not limited to, x-ray services, acute dialysis, transplantation and surgical services. Exhibit I-1 also contains copies of agreements with Charlotte East Dialysis and DaVita Laboratory Services, Inc. for home dialysis training and laboratory services, respectively. In Section I.4, page 37, the applicant states that it has established relationships with health care providers and social service agencies in Mecklenburg County over the years and that the facility will continue these relationships. 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.7, page 48, the applicant reports that 88.2% of the in-center patients who received treatments at North Charlotte had some or all of their services paid for by Medicare or Medicaid in CY2015. The table below shows the historical (CY2015) payment source for the facility for in-center patients:

Payment Source	In-Center
Private Pay	0%
Medicare	31.6%
Medicaid	6.6%
Commercial Insurance	7.4%
Medicare/Commercial Insurance	25.0%
Medicare/Medicaid	25.0%
VA	4.4%
Total	100.00%

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."

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://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.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;

C

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

“North 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. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 47, the applicant states there have been no civil rights equal access complaints filed within the past 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

C

In Section L.1(b), page 45, the applicant projects that 88.2% of the in-center patients who will receive treatments at North Charlotte Dialysis in OY2, calendar year (CY) 2019, will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payment source for the facility for in-center patients:

**North Charlotte Dialysis
Projected Payor Source, OY2 (CY2019)**

Payment Source	Percent of In-Center Patients
Private Pay	0.0%
Medicare	31.6%
Medicaid	6.6%
Commercial Insurance	7.4%
Medicare/Commercial Insurance	25.0%
Medicare/Medicaid	25.0%
VA	4.4%
Total	100.0%

In Section L.1, page 45, the applicant provides the assumptions used to project payor mix. The applicant's projected payment source percentages are the same as the facility's historical (CY2015) payment source percentages as reported by the applicant in Section L.7, page 48. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at North Charlotte Dialysis. 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 North Charlotte Dialysis. Access to dialysis services will be granted upon referral by a nephrologist with privileges at the facility. Patients who contact the facility for access will be referred to a qualified nephrologist for evaluation and admission. 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 it has offered North Charlotte Dialysis as a training site for medical assisting students at Brookstone College. Exhibit M-2 contains a copy of a Student Training Agreement with Brookstone College of Business which offers numerous DaVita dialysis facilities, including North Charlotte Dialysis, as

training sites for the college's students. The information provided is reasonable and adequately supports a determination that 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.

C

The applicant, North Charlotte Dialysis, proposes to add nine dialysis stations for a total of 36 certified dialysis stations upon completion of this project and Project I.D. #F-11019-15 (relocate four stations to Copperfield Dialysis Center) and Project I.D. #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis).

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 July 2016 SDR, there are 21 dialysis facilities in Mecklenburg County. Of these, 16 are operational, four are under development, and one has certified stations but is not yet operational. The applicant or its parent company, DaVita, owns and operates eight facilities in Mecklenburg County. BMA owns and operates 10 dialysis facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2015**

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
BMA Beatties Ford	BMA	Charlotte	32	99.22%
BMA North Charlotte	BMA	Charlotte	28	102.68%
BMA of East Charlotte	BMA	Charlotte	25	85.00%
BMA of North Charlotte	BMA	Charlotte	28	103.57%
BMA West Charlotte	BMA	Charlotte	29	87.07%
Brookshire Dialysis	DaVita	Charlotte	10	0.00%
Carolinas Medical Center	CMC	Charlotte	9	27.78%
Charlotte Dialysis	DaVita	Charlotte	36	88.89%
Charlotte East Dialysis	DaVita	Charlotte	26	108.65%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	55.21%
DSI Glenwater Dialysis	DSI	Charlotte	41	81.71%
FMC Charlotte	BMA	Charlotte	43	82.56%
FMC Matthews	BMA	Matthews	21	117.86%
FMC of Southwest Charlotte*	BMA	Charlotte	10	0.00%
FMC Regal Oaks*	BMA	Charlotte	12	0.00%
FMC Aldersgate*	BMA	Charlotte	10	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	12	93.75%
North Charlotte Dialysis Center	DaVita	Charlotte	41	92.68%
South Charlotte Dialysis	DaVita	Charlotte	22	80.68%
University City Dialysis*	DaVita	Charlotte	10	0.00%

*Facility under development.

**Facility has certified stations but is not yet operational.

As shown in the table above, five of DaVita’s eight facilities that are operational are operating above 80% utilization (3.2 patients per station per week) and three are operating above 90% utilization. DaVita’s three remaining dialysis facilities are under development. Only two of the 16 operational dialysis facilities in the county are operating below 80% utilization, a DSI facility and a CMC facility.

In Section N.1, page 50, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The expansion of South 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, K, L, and N and 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 the 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 discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are 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 Exhibit F-8, the applicant identifies the kidney disease treatment centers it or an affiliated company owns or are under development in North Carolina. In Exhibit O-3 the applicant identifies four of its facilities, Southeastern Dialysis Center – Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West Dialysis, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states, in Section O.3, page 51, and Exhibit O-3, that all four facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .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- North Charlotte Dialysis 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 C.1, page 13, the applicant projects to serve 162 in-center patients by the end of OY1, which is 4.5 patients per station per week ($162 / 36 = 4.5$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 13-14, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

