

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 6, 2017

Findings Date: January 6, 2017

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11247-16

Facility: South Charlotte Dialysis

FID #: 955814

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add one dialysis station for a total of 23 stations upon completion of the project

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 South Charlotte Dialysis proposes to add one dialysis station for a total of 23 certified dialysis stations upon completion of the project.

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 South Charlotte Dialysis in the July 2016 SDR is 3.23 patients per station per week. This utilization rate was calculated based on 71 in-center dialysis patients and 22 certified dialysis stations as of December 31, 2015 (71 patients/ 22 stations = 3.23 patients per station per week). Application of the facility need methodology indicates that one additional station is 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		80.68%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		22
In-Center Patients as of 12/31/15 (SDR2)		71
In-Center Patients as of 6/30/15 (SDR1)		70
Step	Description	
	Difference (SDR2 - SDR1)	1
(i)	Multiply the difference by 2 for the projected net in-center change	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	.0286
	(ii) Divide the result of step (i) by 12	.0024
(iii)	Multiply the result of step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	.0286
(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	73.0306
(v)	Divide the result of step (iv) by 3.2 patients per station	22.8221
	and subtract the number of certified and pending stations to determine the number of stations needed	.8221

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2016 SDR. 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 one new station 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, Section N.1, page 49, 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 C.3, page 15, Section L, pages 43-46, Section N.1, page 49, 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, Section C.1, pages 13-14, and N.1, page 49. 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, South Charlotte Dialysis, proposes to add one dialysis station for a total of 23 certified dialysis stations upon completion of the project.

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 17, the applicant provides the historical patient origin for South Charlotte Dialysis as of December 31, 2015, which is summarized in the following table:

**South Charlotte Dialysis
Historical Patient Origin
12/31/15**

County	In-Center Patients
Mecklenburg	67
Union	2
Virginia	1
Other states	1
TOTAL	71

In Section C.1, page 13, the applicant provides the projected patient origin for South Charlotte Dialysis 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:

**South Charlotte Dialysis
 Projected In-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	77	81	95.1%	95.3%
Union	2	2	2.5%	2.4%
Virginia	1	1	1.2%	1.2%
Other states	1	1	1.2%	1.2%
Total	81	85	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 projected patient origin.

Analysis of Need

The applicant proposes to add one dialysis station to South Charlotte Dialysis for a total of 23 certified dialysis stations upon completion of the project pursuant to the 2016 SMFP Facility Need Methodology. In Section C.1, pages 13-14, the applicant provides the following assumptions to project utilization:

1. As reported in Table A of the July 2016 SDR, South Charlotte Dialysis had 71 in-center dialysis patients as of December 31, 2015. Of these 71 in-center patients, 67 were residents of Mecklenburg County and 10 [4] were residents of Union County and other states.
2. The number of in-center dialysis patients from Mecklenburg County only are projected forward from January 1, 2016 to December 31, 2019 by applying the Average Annual Change Rate (AACR) for Mecklenburg County of 5% each year.
3. No growth calculations are performed on the four patients residing outside Mecklenburg County.
4. OY1 is projected to be January 1, 2018 through December 31, 2018, calendar year 2018 (CY2018), and OY2 is projected to be January 1, 2019 through December 31, 2019 (CY2019).

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.	67
The Mecklenburg County in-center patient census is projected forward to December 31, 2016, increased by the Five Year AACR for Mecklenburg County of 5%.	$(67 \times 0.05) + 67 = 70.35$
The applicant adds four patients from outside Mecklenburg County. This is the ending census for December 31, 2016.	$70.35 + 4 = 74.35$
The Mecklenburg County in-center patient census is projected forward one year to December 31, 2017 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(70.35 \times 0.05) + 70.35 = 73.87$
The applicant adds four patients from outside Mecklenburg County. This is the ending census for December 31, 2017.	$73.87 + 4 = 77.87$
The Mecklenburg County in-center patient census is projected forward one year to December 31, 2018 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(73.87 \times 0.05) + 73.87 = 77.56$
The applicant adds four patients from outside Mecklenburg County for the ending census of OY1.	$77.56 + 4 = 81.56$
The census of Mecklenburg County in-center patients is projected forward one year to December 31, 2019 and is increased by the Five Year AACR for Mecklenburg County of 5%.	$(77.56 \times 0.05) + 77.56 = 81.44$
The applicant adds four patients from outside Mecklenburg County for the ending census of OY2.	$81.44 + 4 = 85.44$

The applicant states, on page 14, that South Charlotte Dialysis will have 81 in-center patients, rounded down, by the end of OY1 or 3.52 patients per station per week (81 patients/ 23 stations = 3.52). By the end of OY2, the applicant projects South Charlotte Dialysis will have 85 in-center patients, rounded down, or 3.70 patients per station per week (85 patients/ 23 stations = 3.70). 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, page 15, the applicant states that its policy is to make dialysis services available to 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 47, the applicant reports that 80.5% of South Charlotte Dialysis’s patients were Medicare or Medicaid recipients in CY2015. In Section L.1, page 44, the applicant projects that 80.5% 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 one additional station at South 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 21, the applicant states that one alternative would be to maintain the status quo, however, given the projected growth of the facility, this alternative would not be an effective alternative.

In Section E.2, page 21, the applicant states that the proposal to add one dialysis station to South Charlotte Dialysis will “*proactively address the issues of growth and access at the facility.*” In addition, the applicant states if one dialysis station is not added, a third shift would need to be added and this would not be convenient for the patients. Furthermore, the applicant states that the facility’s capacity would be “*maxed out*” and patient choice would be eliminated if the status quo was maintained. 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 South Charlotte Dialysis shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, South Charlotte Dialysis shall materially comply with the last made representation.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis shall develop and operate no more than one additional dialysis station for a total of no more than 23 certified stations upon completion of the project.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis shall install plumbing and electrical wiring through the walls for one additional dialysis station for a total of 23 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a South 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, South Charlotte Dialysis, proposes to add one dialysis station for a total of 23 certified dialysis stations upon completion of the project.

Capital and Working Capital Costs

In Section F.1, page 22, the applicant states that the project's capital costs will be \$3,338, listed under "*Construction Costs*" in line item, "*Equipment included in contract.*" The applicant provided clarifying information, stating that the capital cost amount should have been placed under "*Miscellaneous Costs*" in line item, "*Equipment/furniture not included above.*" In Sections F.11 and F.12, page 25, the applicant states there will be no start-up expenses or initial operating expenses since South Charlotte Dialysis is an existing facility.

Availability of Funds

In Section F.2, page 23, the applicant states it will finance the capital costs with accumulated reserves/owner's equity. Exhibit F-5 contains a letter dated September 12, 2016 from the Chief Accounting Officer for DaVita HealthCare Partners, Inc. (DaVita), the parent company of the applicant, which states that DaVita has committed cash reserves in the amount of \$3,338 for the proposed project. In supplemental information, the applicant provides the Securities and Exchange Commission Form 10-K for DaVita which indicates that as of December 31, 2015, it had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,948,238,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

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

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 used 79 in-center patients in operating year one and 83 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	71	74	72.5
CY2017	74	77	75.5
CY2018	77	81	79
CY2019	81	85	83

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

	OY1 (CY2018)	OY2 (CY2019)
Total Treatments	11,708	12,301
Total Gross Revenues (Charges)	\$4,180,903	\$4,392,288
Total Net Revenue	\$4,054,649	\$4,259,630
Total Operating Expenses (Costs)	\$3,322,408	\$3,471,765
Net Income	\$732,241	\$787,864

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 projections of costs and charges.

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, South Charlotte Dialysis, proposes to add one dialysis station for a total of 23 certified dialysis stations upon completion of the project.

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 eight dialysis facilities, Bio-Medical Applications (BMA) of North Carolina, Inc. operates 10 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 South Charlotte Dialysis	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 one in-center dialysis station at South Charlotte Dialysis for a total of 23 dialysis stations upon completion of the project. As of December 31, 2015, South Charlotte Dialysis was serving 71 patients on 22 dialysis stations, which is 3.23 patients per station per week or 80.68% 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 3.52 in-center patients per station per week (81 patients /23 dialysis stations = 3.52), which is 88.0% 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 one additional dialysis station 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 30, the applicant provides the current staffing for the facility, which includes 15.5 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project, which includes 16.5 FTE employees. In Section H.3, pages 31-32, the applicant describes its experience and process for recruiting and retaining staff, and states that it does not anticipate difficulties in hiring the required staff for this project. Exhibit I-3 contains a copy of a letter from Christopher Buehrig, M.D., stating 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 34, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-1 provides documentation regarding agreements for several ancillary and support services, including, but not limited to, acute dialysis, surgical services, transplantation, home training in hemodialysis and peritoneal dialysis, and laboratory services. In Section I.4, page 36, the applicant states that it has established relationships with healthcare providers and social service agencies in Mecklenburg County over the years. In addition, Exhibit I-3 contains a letter from the medical director of the facility that expresses his support for the proposed project. 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 47, the applicant reports that 80.5% of the in-center patients who received treatments at South Charlotte Dialysis in CY2015 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	0.0%
Medicare	23.4%
Medicaid	7.8%
Commercial Insurance	13.0%
Medicare/Commercial Insurance	40.2%
Medicare/Medicaid	9.1%
VA	6.5%
Total	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."

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 46, the applicant states:

“South 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 46, the applicant states it has had no civil rights equal access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1(b), page 52, the applicant projects that 80.5% of the in-center patients who will receive treatments at South Charlotte Dialysis in OY2, CY2019, 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:

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

Payor Source	In-Center
Private Pay	0.0%
Medicare	23.4%
Medicaid	7.8%
Commercial Insurance	13.0%
Medicare/Commercial Insurance	40.2%
Medicare/Medicaid	9.1%
VA	6.5%
Total	100.0%

In Section L.1, page 44, 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 47. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at South 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 46, the applicant describes the range of means by which a person will have access to the dialysis services at South 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 48, the applicant states that it has offered South Charlotte Dialysis as a training site for medical assisting students at Brookstone College. Exhibit M-1 contains a copy of a Student Training Agreement with Brookstone College of Business which offers numerous DaVita dialysis facilities, including South 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, South Charlotte Dialysis, proposes to add one dialysis station for a total of 23 certified dialysis stations upon completion of the project.

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 South Charlotte Dialysis	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 49, 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 50, 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- South 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, pages 13-14, the applicant projects to serve 81 in-center patients by the end of OY1, which is 3.52 patients per station per week ($81 / 23 = 3.52$). 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.

