ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date:	May 8, 2020
Findings Date:	May 8, 2020
Project Analyst:	Celia C. Inman
Assistant Chief:	Lisa Pittman
Project ID #: Facility: FID #: County: Applicant: Project:	F-11846-20 Sugar Creek Dialysis 150478 Mecklenburg Captree Dialysis, LLC Relocate no more than 1 dialysis station from Mint Hill Dialysis for a total of no more than 11 stations upon project completion

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.

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The applicant, Captree Dialysis, LLC (Captree), proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis and 21 dialysis stations at Mint Hill Dialysis upon project completion. Captree Dialysis, LLC is a joint venture between DVA Healthcare Renal Care Inc. (DVA) and The Presbyterian Hospital. DVA is also the owner of Mint Hill Dialysis. DaVita, Inc. is the parent company of DVA.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is no county need determination for additional dialysis stations in Mecklenburg County.

Table 9E: Dialysis Station Need Determination by Facility, page 172, shows there is no facility need determination for Sugar Creek Dialysis. Table 9B, page 160 of the 2020 SMFP identifies Sugar Creek Dialysis as both a new facility and a small facility (as defined in Condition 1(a) of the facility need determination methodology on page 115 of the SMFP) with a utilization rate of only 50% (20 patients / 10 stations = 2.0 patients per station per week). To meet Condition 1(a), "*The facility's "current" reported utilization must be at least 3.0 patients per station in a given week. For purposes of Condition 1 only, "current" means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted."* The applicant provides the December 31, 2019 in-center utilization of 28 patients. This utilization date meets the "no more than 90 days before" submission of the CON application date; however, serving 28 patients results in a utilization of only 2.8 patients per station per week, which is less than 3.0 patients per station per station per week standard. Thus, Sugar Creek Dialysis does not meet Condition 1a, and therefore, does not qualify to apply to add dialysis stations under the facility need determination.

Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

There is one policy in the 2020 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2, on page 20 of the 2020 SMFP states:

"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan, and
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan."

Both Sugar Creek Dialysis and Mint Hill Dialysis are in Mecklenburg County. Therefore, the application is conforming to Policy ESRD-2.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion because the relocation of one dialysis station within Mecklenburg County will have no effect on the number of dialysis stations within the county.

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

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The applicant proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis upon project completion. Mint Hill Dialysis will have 21 dialysis stations upon project completion. Both facilities are located in Mecklenburg County and share DVA as an owner and DaVita, Inc. as a parent company.

The following tables, summarized from Section A.4, pages 7-8 of the application, show the existing and proposed number of dialysis stations at Sugar Creek Dialysis and Mint Hill Dialysis.

Sugar Creek Dialysis		
Stations	Description	Project ID #
10	Total existing certified stations as of the July 2018 SDR	
+1	Stations to be added as part of this project	F-11846-20
11	Total stations upon completion of above project	

Mint Hill Dialysis		
Stations	Description	Project ID #
22	Total existing certified stations as of the July 2019 SDR	
-1	Stations to be deleted as part of another project	F-11846-20
21	Total stations upon completion of above projects	

As shown in the tables above, upon project completion, Sugar Creek Dialysis will be certified for 11 dialysis stations, and Mint Hill Dialysis will be certified for 21 dialysis stations.

Patient Origin

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as "the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties." Both facilities referred to in this application are in Mecklenburg County. Thus, the service area for this application is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the historical patient origin for Sugar Creek Dialysis for in-center (IC) dialysis patients as of December 31, 2019, as follows:

	IN-CENTER AS OF DECEMBER 31, 2019		HH / PD PATIENTS AS OF DECEMBER 31, 2019	
COUNTY	IC PATIENTS	% OF TOTAL	HH/PD PATIENTS	% OF TOTAL
Mecklenburg	24	85.6%	0	0.0%
Gaston	1	3.6%	0	0.0%
Guilford	1	3.6%	0	0.0%
South Carolina	1	3.6%	0	0.0%
Other States	1	3.6%	0	0.0%
Total	28	100.0%	0	0.0%

Source: Section C.2, page 19

In Section C.3, page 20, the applicant provides a table showing projected patient origin for Sugar Creek Dialysis in the second project year following project completion, which is summarized below:

	SECOND FULL FY IC PATIENTS (CY2022)		SECOND FULL FY HH / PD PATIENTS (CY2022)	
COUNTY	IC PATIENTS % OF TOTAL		HH/PD PATIENTS	% OF TOTAL
Mecklenburg	31	88.6%	0	0.0%
Gaston	1	2.9%	0	0.0%
Guilford	1	2.9%	0	0.0%
South Carolina	1	2.9%	0	0.0%
Other States	1	2.9%	0	0.0%
Total	35	100.0%	0	0.0%

Note: numbers may not sum due to rounding

The applicant does not currently offer home therapies and does not plan to offer home therapies following completion of the proposed project. In Section C.3(b), pages 20-21, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 21-22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that the Sugar Creek Dialysis census has been growing rapidly, increasing 40% during 2019.
- The applicant states that Sugar Creek Dialysis had an in-center patient census of 28 patients dialyzing on 10 stations, as of December 31, 2019, with a utilization rate of 70% or 2.8 patients per stations.
- The applicant states that physician constraints have limited available stations and treatment shifts in Mecklenburg County because patient census growth has outgrown nephrologist capacity.
- The applicant states that adding stations on current shifts is an efficient approach to bridging the gap with physician capacity.
- The applicant states that the projected patient utilization of 34 patients (page 21 of the application) clearly demonstrates the need the population to be served has for the one-station relocation proposed in this application.

The information is reasonable and adequately supported based on the following:

- The applicant adequately demonstrates the need the existing and proposed patients have for the services provided.
- The applicant adequately demonstrates the need to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis.

Projected Utilization

In Section C, pages 20-21, and Section Q Form C Assumptions and Methodology, the applicant provides the assumptions and methodology used to project in-center utilization, as summarized below:

- Sugar Creek Dialysis census, as of December 31, 2019 is 28 in-center patients, with 24 of those patients residing in Mecklenburg County.
- The applicant begins the projections for Sugar Creek Dialysis by using the December 31, 2019 in-center patient census of 24 Mecklenburg County patients.
- The applicant projects the Mecklenburg County patient census at Sugar Creek Dialysis will increase by the Mecklenburg County Five-Year Average Annual Change Rate (AACR) of 4.2 percent.
- The applicant assumes that four Mecklenburg County patients will transfer to Sugar Creek Dialysis from Mint Hill Dialysis by January 1, 2021.
- The 29 Mecklenburg County patients are projected forward at the Mecklenburg County AACR of 4.2 percent.
- The four patients from outside Mecklenburg County are added to the projections without any future growth.
- Operating Year 1 (OY1) = January 1 through December 31, 2021 (CY2021).

Operating Year 2 (OY2) = January 1 through December 31, 2022 (CY2022).

In Section C, page 21, and Section Q Form C Assumptions and Methodology, the applicant provides the projected utilization based on the above assumptions, as summarized in the following table:

24
24 X 1.042 = 25.008
25.008 + 4 = 29.008
.008 X 1.042 = 30.226
30.226 + 4 = 34.226
.226 X 1.042 = 31.496
31.496 + 4 = 35.496

The applicant projects to serve 34 in-center patients in CY2021, the first full operating year following project completion, and 35 in-center patients in CY2022. Thus, the applicant projects that Sugar Creek Dialysis will have a utilization rate of 77.27% or 3.1 patients per station per week (34 patients / 11 stations = 3.09 / 4 = 0.7727) in OY1. The projected utilization of 3.1 patients per station per week at the end of OY1 exceeds the minimum standard of utilization of 70% or 2.8 in-center patients per station per week (2.8 / 4 = 0.70) required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant begins the projections for Sugar Creek Dialysis based on the December 31, 2019 in-center patient census of 24 Mecklenburg County patients.
- The applicant projects the growth of the Mecklenburg County patient census at Sugar Creek Dialysis using the Mecklenburg County Five-Year AACR of 4.2 percent, as reported in the 2020 SMFP.
- The applicant assumes that four Mecklenburg County patients will transfer to Sugar Creek Dialysis from Mint Hill Dialysis by January 1, 2021.
- The applicant assumes no growth for the four patients from outside Mecklenburg County.

• The utilization rate by the end of CY2021, the first full operating year following project completion, is above the minimum standard of 2.8 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

Sugar Creek Dialysis does not offer home hemodialysis or peritoneal dialysis training nor does the applicant propose to add those services. In Section I, page 41, the applicant states those patients that require home hemodialysis or peritoneal dialysis will be referred to Charlotte East Dialysis. In Exhibit I-1, the applicant provides a copy of the home training agreement.

<u>Access</u>

In Section C.7, page 24, the applicant states:

"By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

•••

Sugar Creek Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons."

In Section L.3, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Projected Payor Mix CY2022				
Doumont Sourco	% of IC	% of HH	% of PD	
Payment Source	Patients	Patients	Patients	
Self-pay	0.0%	0.0%	0.0%	
Commercial Insurance*	7.1%	0.0%	0.0%	
Medicare*	78.6%	0.0%	0.0%	
Medicaid*	7.1%	0.0%	0.0%	
Other (specify)	7.1%	0.0%	0.0%	
Total	100.0%	0.0%	0.0%	

Sugar Creek Dialysis	
Projected Payor Mix CY2022	

Totals may not sum due to rounding

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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.

С

The applicant proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis and 21 dialysis stations at Mint Hill Dialysis upon project completion.

In Section D, pages 27-28, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced by relocating one station will be adequately met following completion of the project.

The applicant states that Mint Hill Dialysis had 55 patients (41 Mecklenburg County residents) dialyzing as of December 31, 2019. The applicant assumes that the 41 in-center Mecklenburg County residents dialyzing at Mint Hill Dialysis on December 31, 2019 will increase at 4.2 percent per year based on the Five-Year AACR for Mecklenburg County, as reported in Table 9C of the 2020 SMFP. The applicant projects that four Mecklenburg County patients will transfer their care from Mint Hill Dialysis to Sugar Creek Dialysis on January 1, 2021. The applicant serves 14 patients from other counties and assumes those patients will continue to dialyze at Mint Hill Dialysis but does not project any increase in the number of out-of-county patients to be served there. In Section D.2, page 28, the applicant projects the in-center patient census for Mint Hill Dialysis starting January 1, 2020 through December 31, 2022, summarized as follows:

The applicant begins with the Mecklenburg County in-center	
patients as of January 1, 2020.	41
The applicant projects the Mecklenburg County patients forward to	
December 31, 2020 using the Mecklenburg County AACR of 4.2	
percent.	41 X 1.042 = 42.722
The applicant subtracts four patients projected to transfer to Sugar	
Creek Dialysis with the relocation of the one dialysis station on	
January 1, 2021.	42.722 – 4 = 38.722
The applicant projects the Mecklenburg County in-center patients	
forward one year to December 31, 2021 using the Mecklenburg	
County AACR of 4.2 percent.	38.722 X 1.042 = 40.348
The applicant adds 14 patients from other counties. This is the	
ending census on December 31, 2021.	40.348 + 14 = 54.348
The applicant projects the Mecklenburg County in-center patients	
forward one year to December 31, 2022 using the Mecklenburg	
County AACR of 4.2 percent.	40.348 x 1.042 = 42.043
The applicant adds 14 patients from other counties. This is the	
ending census on December 31, 2022.	42.043 + 14 = 56.043

In Section D, page 28, the applicant projects the Mint Hill Dialysis patient population at the end of the first full fiscal year of the project, December 31, 2021, to be 54 in-center patients for a utilization of 64% or 2.57 patients per station, per week (54 / 21 = 2.57; 2.57 / 4 = 0.643). At the end of the second year, December 31, 2022, the applicant projects a utilization rate of 67% or 2.67 patients per station, per week (56 / 21 = 2.67; 2.67 / 4 = 0.666). On page 28, the applicant states:

"Given this projected growth of the in-center patient population, the facility will have sufficient capacity to ensure that the needs of the facility's patients will continue to be met."

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant begins its utilization projection with the existing Mecklenburg County patient census currently served at Mint Hill Dialysis.
- The applicant projects the Mecklenburg County in-center patient census at Mint Hill Dialysis will increase at the Mecklenburg County Five-Year AACR of 4.2 percent, as reported in the 2020 SMFP.
- The applicant projects the number of patients from other counties that are dialyzing at Mint Hill Dialysis will remain constant.

On page 29, the applicant states the proposed relocation of the station from Mint Hill Dialysis will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care and that the proposed relocation of stations will not have an effect upon access to care for any patient.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced through the relocation of one station will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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

The applicant proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis and 21 dialysis stations at Mint Hill Dialysis upon project completion.

In Section E, page 30, the applicant states that it considered the following alternatives related to serving the needs of the patients in the area:

- 1. Maintain the status quo the applicant states that this alternative was dismissed given the opportunity to align station utilization in a more optimal manner while avoiding any negative impact on operations at the facility losing the station.
- 2. Relocate more than one station though the applicant could demonstrate the need to relocate up to two stations, it determined that relocating one station would meet the future need at Sugar Creek Dialysis while protecting against increased future need at Mint Hill Dialysis.
- 3. Relocate stations from another DaVita facility the applicant provides a table on page 31 that shows there are seven DaVita facilities in Mecklenburg County from which stations could be relocated. The table shows each facility's utilization. The applicant states that relocation of stations from any facility other than Mint Hill Dialysis is not optimal: one facility is new; three facilities have current or pending relocations happening; and the other two facilities have higher utilization than Mint Hill Dialysis.

On page 31, the applicant states that the proposed project is a more effective alternative as it will provide additional capacity at Sugar Creek Dialysis and have the smallest impact on facility operations at the other facilities in Mecklenburg County.

The applicant adequately demonstrates that the alternative proposed in this application is the more effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided credible information to explain why it believes the proposed project is the more effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- **1.** Captree Dialysis, LLC shall materially comply with all representations made in the certificate of need application.
- 2. Pursuant to Policy ESRD-2, Captree Dialysis, LLC shall develop no more than one additional dialysis station at Sugar Creek Dialysis by relocating one dialysis station from Mint Hill Dialysis, for a total of no more than 11 in-center dialysis stations at Sugar Creek Dialysis upon project completion, which shall include any home hemodialysis or isolation stations.
- **3.** Upon completion of this project, DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify one dialysis station at Mint Hill Dialysis for a total of no more than 21 dialysis stations at Mint Hill Dialysis upon project completion.
- 4. Captree Dialysis, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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.

С

The applicant proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1(a), the applicant projects the total capital cost of the project as shown in the table below:

Ітем	AMOUNT
Non-medical Equipment	\$3,138
Furniture	\$1,135
Total	\$4,273

In Section F.3, pages 33-35, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because Sugar Creek Dialysis is an operational facility.

Availability of Funds

In Section F.2, page 32, the applicant states that the capital cost will be funded as shown in the table below.

Түре	SOURCE
Loans	0
DaVita, Inc. Accumulated Reserves or OE*	\$4,273
Other (Specify)	0
Total	\$4,273

*OE = Owner's Equity

Exhibit F-1 contains a letter dated January 15, 2020 from Chief Accounting Officer of DaVita, the parent company of Sugar Creek Dialysis, authorizing and committing cash reserves in the amount of \$4,273 for the capital costs of the project. Exhibit F-2 contains DaVita's Form 10-K for the Fiscal Year ended December 31, 2018 showing DaVita Inc. with a consolidated balance sheet total cash and cash equivalents of \$323,038,000, current assets exceeding \$8 billion, and equity of \$3.9 billion.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	OY 1 (CY2021)	OY 2 (CY2022)
Total In-Center Treatments	4,982	5,166
Total Gross Revenues (Charges)	\$1,619,527	\$1,679,453
Total Net Revenue	\$1,499,509	\$1,554,994
Average Net Revenue per Treatment	\$301	\$301
Total Operating Expenses (Costs) (From Form A)	\$1,179,889	\$1,418,385
Average Operating Expense per Treatment	\$237	\$275
Net Income	\$319,620	\$136,610

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. Total operating expenses for CY2021 are understated by \$143,000 because of an omission of 4.25 FTE positions for Patient Care Technician; however, the net income for CY2021 more than covers that deficit. The discussion regarding staffing in Criterion (7) is incorporated herein by reference. See Section Q 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.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates sufficient funds for the capital needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

С

The applicant proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis and 21 dialysis stations at Mint Hill Dialysis upon project completion. Both facilities are located in Mecklenburg County.

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as "the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties." Both facilities referred to in this application are in Mecklenburg County. Thus, the service area for this application is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

Currently, there are 25 existing and approved dialysis facilities in Mecklenburg County, ten of which are owned by DaVita, as shown in the following table:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018					
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization	
BMA Beatties Ford	FMC	Charlotte	32	95.31%	
BMA Nations Ford	FMC	Charlotte	28	79.46%	
BMA of East Charlotte	FMC	Charlotte	26	89.42%	
BMA West Charlotte	FMC	Charlotte	29	87.93%	
Brookshire Dialysis^^	DaVita	Charlotte	10	40.00%	
Carolinas Medical Center^^	CMC	Charlotte	9	33.33%	
Charlotte Dialysis	DaVita	Charlotte	34	81.62%	
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%	
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%	
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%	
FMC Charlotte	FMC	Charlotte	44	89.20%	
FMC Matthews	FMC	Matthews	21	114.29%	
FMC of North Charlotte	FMC	Charlotte	40	96.88%	
FKC Mallard Creek	FMC	Charlotte	0	0.00%	
FKC Regal Oaks	FMC	Charlotte	12	93.75%	
FKC Southeast Charlotte	FMC	Pineville	0	0.00%	
FMC Aldersgate^^	FMC	Charlotte	10	27.50%	
FMC Southwest Charlotte	FMC	Charlotte	13	92.31%	
Huntersville Dialysis	DaVita	Huntersville	14	92.86%	
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%	
Mountain Island Lake Dialysis	DaVita	Charlotte	0	0.00%	
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%	
South Charlotte Dialysis	DaVita	Charlotte	23	85.87%	
South Charlotte Dialysis	DaVita	Charlotte	0	0.00%	
Sugar Creek Dialysis^/^^	DaVita	Charlotte	10	50.00%	

Source: 2020 SMFP, Table B.

^ Designated as a new facility per Condition 1.a. in the facility need determination methodology

^^ Designated as a small facility per Condition 1.a. in the facility need determination methodology

In Section G, page 38, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

"The project proposes to relocate one station from Mint Hill Dialysis to Sugar Creek Dialysis so there is no duplication of services. The project better aligns dialysis station utilization to an area of higher patient concentration."

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant is proposing to relocate one station within Mecklenburg County. There will be no increase in the number of stations within the county.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing and/or approved dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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.

С

In Section Q Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the Sugar Creek Dialysis service, as illustrated in the following table:

Position	FTE Positions As of 12/31/19	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
RN	1.25	1.50	1.50
Patient Care Technician (PCT)*	3.75	0.00 [4.25]	4.25
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	0.50	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	8.00	5.00 [9.25]	9.25

Source: Section Q Form H

*The applicant appears to have a typographical error omitting the PCT FTE positions in OY1, which creates an error in the total OY1 FTE positions, which would reduce the total salaries cost by \$142,885.

The assumptions and methodology used to project staffing are provided in Section Q Form H Staffing. OY1 salary expense is approximately \$143,000 too low due to the omission of the 4.25 FTE positions for PCT for OY1, causing the total operating expenses to be \$143,000 short; however, this amount is more than covered by the \$320,000 net income shown for OY1. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 39-40, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 40, the applicant identifies Dr. James Wood as the medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating his intent to continue serving in that capacity.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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.

С

In Section I.1, page 41, the applicant includes a list of providers of the necessary ancillary and support services.

SUGAR CREEK DIALYSIS			
ANCILLARY AND SUPPORT SERVICES			
Services Provider			
Self-care training (in-center)	On site		
HH / PD training and follow-up	Charlotte East Dialysis		
Isolation – hepatitis	On site		
Psychological counseling	On site by RN		
Nutritional counseling	On site by RD		
Social Work services	On site by MSW		
Laboratory services	DaVita Laboratory Services, Inc.		
Acute dialysis in an acute care setting	Novant Presbyterian Hospital		
Emergency care	Novant Presbyterian Hospital		
Blood bank services	Novant Presbyterian Hospital		
Diagnostic and evaluation services	Novant Presbyterian Hospital		
X-ray services	Novant Presbyterian Hospital		
Pediatric nephrology	Novant Presbyterian Hospital		
Vascular surgery	Novant Presbyterian Hospital		
Transplantation services	Carolinas Medical Center		
Vocational rehabilitation & counseling	NC DHHS Division Vocational Rehab Services		
Transportation	Mecklenburg Transportation Services		

In Section I.1 and I.2, pages 41-42, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective January 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

The applicant does not propose to construct any new space associated with the relocation of one station as proposed in this application. Therefore, Criterion (12) is not applicable to this review.

(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;

С

In Section L, page 48, the applicant provides the historical payor mix for the last full operating year for its existing Sugar Creek Dialysis and Mint Hill Dialysis services, as shown in the tables below.

Doursont Sourco	% of IC	% of HH	% of PD	
Payment Source	Patients	Patients	Patients	
Self-pay	0.0%	0.0%	0.0%	
Commercial Insurance*	7.1%	0.0%	0.0%	
Medicare*	78.6%	0.0%	0.0%	
Medicaid*	7.1%	0.0%	0.0%	
Other (VA)	7.1%	0.0%	0.0%	
Total	100.0%	00.0%	0.0%	

Sugar Creek Dialysis Historical Payor Mix CY2019

Totals may not sum due to rounding

*Including any managed care plans

Payment Source	% of IC % of HH		% of PD	
	Patients	Patients	Patients	
Self-pay	1.8%	0.0%	0.0%	
Commercial Insurance*	10.9%	0.0%	0.0%	
Medicare*	81.8%	0.0%	0.0%	
Medicaid*	5.5%	0.0%	0.0%	
Other (VA)	0.0%	0.0%	0.0%	
Total	100.0%	0.0%	0.0%	

Mint Hill Dialysis Historical Payor Mix CY2019

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 47, the applicant provides comparison of the demographical information on Sugar Creek Dialysis patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total Sugar Creek Dialysis Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	34.5%	51.9%
Male	65.5%	39.1%
Unknown	0.0%	0.0%
64 and Younger	55.2%	89.8%
65 and Older	44.8%	11.2%
American Indian	0.0%	0.8%
Asian	3.4%	6.4%
Black or African-American	89.7%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	3.4%	57.5%
Other Race	3.4%	2.4%
Declined / Unavailable	0.0%	0.0%

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <u>https://www.census.gov/quickfacts/fact/table/US/PST045218</u>. Just enter in the name of the county.

On page 48, the applicant also provides the same comparison table based on the patients served at Mint Hill Dialysis.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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;

С

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 49, that it has no obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 49, the applicant states that no patient civil rights access complaints have been filed against Sugar Creek Dialysis or Mint Hill Dialysis within the last five years.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

С

In Section L.3, page 49, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

Projected Payor Mix CY2022				
Payment Source	% of IC	% of HH	% of PD	
Payment Source	Patients	Patients	Patients	
Self-pay	0.0%	0.0%	0.0%	
Commercial Insurance*	7.1%	0.0%	0.0%	
Medicare*	78.6%	0.0%	0.0%	
Medicaid*	7.1%	0.0%	0.0%	
Other (VA)	7.1%	0.0%	0.0%	
Total	100.0%	0.0%	0.0%	

Sugar Creek Dialysis Projected Payor Mix CY2022

Totals may not sum due to rounding

*Including any managed care plans

As shown is the table above, during the second year of operation, the applicant projects that 0.0% of in-center dialysis services will be provided to self-pay patients, 78.6% to Medicare patients, and 7.1% to Medicaid patients.

On pages 49-50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Sugar Creek Dialysis.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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.

С

In Section L.5, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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.

С

In Section M, page 51, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective January 1, 1987.
- (16) Repealed effective January 1, 1987.
- (17) Repealed effective January 1, 1987.
- (18) Repealed effective January 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.

С

The applicant proposes to relocate one dialysis station from Mint Hill Dialysis to Sugar Creek Dialysis for a total of 11 dialysis stations at Sugar Creek Dialysis and 21 dialysis stations at Mint Hill Dialysis upon project completion. Both facilities are located in Mecklenburg County.

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as "the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties." Both facilities referred to in this application are located in Mecklenburg County. Thus, the service area for this application is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

Per Table 9B in the 2020 SMFP, there are 25 existing and approved dialysis facilities in Mecklenburg County, ten of which are DaVita facilities, as shown in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018					
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization	
BMA Beatties Ford	FMC	Charlotte	32	95.31%	
BMA Nations Ford	FMC	Charlotte	28	79.46%	
BMA of East Charlotte	FMC	Charlotte	26	89.42%	
BMA West Charlotte	FMC	Charlotte	29	87.93%	
Brookshire Dialysis^^	DaVita	Charlotte	10	40.00%	
Carolinas Medical Center^^	CMC	Charlotte	9	33.33%	
Charlotte Dialysis	DaVita	Charlotte	34	81.62%	
Charlotte East Dialysis	DaVita	Charlotte	34	80.15%	
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	67.71%	
DSI Glenwater Dialysis	DSI	Charlotte	42	74.40%	
FMC Charlotte	FMC	Charlotte	44	89.20%	
FMC Matthews	FMC	Matthews	21	114.29%	
FMC of North Charlotte	FMC	Charlotte	40	96.88%	
FKC Mallard Creek	FMC	Charlotte	0	0.00%	
FKC Regal Oaks	FMC	Charlotte	12	93.75%	
FKC Southeast Charlotte	FMC	Pineville	0	0.00%	
FMC Aldersgate^^	FMC	Charlotte	10	27.50%	
FMC Southwest Charlotte	FMC	Charlotte	13	92.31%	
Huntersville Dialysis	DaVita	Huntersville	14	92.86%	
Mint Hill Dialysis	DaVita	Mint Hill	22	55.68%	
Mountain Island Lake Dialysis	DaVita	Charlotte	0	0.00%	
North Charlotte Dialysis Center	DaVita	Charlotte	36	72.92%	
South Charlotte Dialysis	DaVita	Charlotte	23	85.87%	
South Charlotte Dialysis	DaVita	Charlotte	0	0.00%	
Sugar Creek Dialysis^/^^	DaVita	Charlotte	10	50.00%	

Source: 2020 SMFP, Table B.

^ Designated as a new facility per Condition 1.a. in the facility need determination methodology

^^ Designated as a small facility per Condition 1.a. in the facility need determination methodology

In Section N, page 52, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

"The relocation of one station to Sugar Creek Dialysis will have no effect on competition in Mecklenburg County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita. The relocation of one station to Sugar Creek 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 others involved in the dialysis process to receive services."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections C, F, N and Q of the application and any exhibits)
- Quality services will be provided (see Sections C, N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Sections C, D, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective January 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.

С

In Section Q Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 100 dialysis facilities owned, operated, or managed by a DaVita related entity located in North Carolina.

In Section O.2, pages 54-55, the applicant states that, during the 18 months immediately preceding the submittal of the application, one facility, Waynesville Dialysis Center, had an incident related to quality of care that resulted in a finding of *"Immediate Jeopardy"*. The applicant further states that Waynesville Dialysis Center is currently in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective January 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.

С

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.
- -NA- Sugar Creek Dialysis is an existing facility.
- (b) An applicant proposing to increase the number of dialysis stations in:
 - (1) an existing dialysis facility; or
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;

shall document the need for the total number of dialysis stations in the facility based on 2.8 incenter patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- -C- In Section Q Form C, the applicant projects that Sugar Creek Dialysis will serve 34 in-center patients on 11 stations, or a rate of 3.09 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- -C- In Section C, pages 20-21, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.