

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 2, 2020

Findings Date: October 2, 2020

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: F-11930-20

Facility: Sugar Creek Dialysis

FID #: 150478

County: Mecklenburg

Applicant: Captree Dialysis, LLC

Project: Add no more than 10 stations pursuant to Condition 1 of the facility need methodology for a total of no more than 21 stations upon completion of this project and Project I.D. #F-11846-20 (relocate 1 station)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Captree Dialysis, LLC (hereinafter referred to as “Captree” or “the applicant”) d/b/a Sugar Creek Dialysis (Sugar Creek) proposes to add 10 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of 21 stations upon completion of this project and Project I.D. #F-11846-20 (relocate one station).

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 not a county need determination for additional dialysis stations in Mecklenburg County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2020 SMFP if the facility is a “new” facility or a “small” facility (or both) as defined in the 2020 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “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. In Section B, page 11, the applicant states it was serving 42 in-center patients on 10 certified stations on its current reporting date of July 1, 2020. This is a utilization rate of 105 percent, or 4.2 patients per station per week. According to Table 9B on page 160 of the 2020 SMFP, Sugar Creek is defined as both a new and a small facility.

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 20 additional stations are needed at this facility, as illustrated in the following table.

1	# of In-center Patients as of the Current Reporting Date	42
2	# of In-Center Patients as of the Previous Reporting Date	28
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	14
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.50
5	Multiply Line 4 by 2 (Annual Growth Rate)	1.00
6	Multiply Line 5 by Line 1 (New Patients)	42.00
7	Add Line 6 to Line 1 (Total Patients)	84.00
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	30.00
9	# of Stations as of the Current Reporting Date [^]	10.00
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	20.00

[^] Include all stations that were: 1) certified; 2) CON approved but not yet certified; and 3) previously applied for but not yet approved.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Sugar Creek is 20 stations, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” The applicant proposes to add 10 new stations; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on pages 30-31 of the 2020 SMFP, 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.”

In Section B, pages 13-16, the applicant explains why it believes its application is consistent with Policy GEN-3. On pages 15-16, the applicant states:

“For all its patients – current patients as well as those included in the projected utilization – DaVita is committed to:

- *promoting a culture of safety;*
- *ensuring industry-leading quality of care;*
- *promoting equitable access; and*
- *maximizing healthcare value.*

..., established policy and procedure will continue to guide this commitment.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates how Sugar Creek’s projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need.

(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 proposes to add 10 dialysis stations to Sugar Creek pursuant to Condition 1 of the facility need methodology for a total of 21 stations following completion of this project and Project I.D. #F-11846-20 (relocate 1 station).

According to Table 9A on page 135 of the 2020 SMFP, Sugar Creek does not offer home peritoneal or home hemodialysis training and support. The applicant does not propose to offer home peritoneal or home hemodialysis training and support as part of the current application.

In Section A, page 5, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with Captree to refer to itself or its facilities. References to DaVita should be interpreted to mean Captree unless otherwise specified.

Patient Origin

On page 113, the 2020 SMFP defines the service area 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Sugar Creek – Current and Projected Patient Origin				
	Current (12/31/2019)		Projected (OY 2 – CY 2023)	
County	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	24	85.6%	62	88.6%
Gaston	1	3.6%	1	1.4%
Guilford	1	3.6%	1	1.4%
South Carolina	1	3.6%	0	0.0%
Other States	1	3.6%	3	4.3%
Cleveland	0	0.0%	1	1.4%
Union	0	0.0%	1	1.4%
Virginia	0	0.0%	1	1.4%
Total	28	100.0%	70	100.0%

Table may not foot due to rounding.

Source: Section C, pages 19-20

In Section C, pages 20-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 20-22, the applicant states the facility began offering services in July 2018. The applicant states its patient population increased from 20 to 28 patients between December 31, 2018 and December 31, 2019, an annual growth rate of 40 percent. The applicant states that as of June 30, 2020, the in-center patient population had increased to 42 patients – an increase of 50 percent over the patient population six months prior and equivalent to a 100 percent annual growth rate. The applicant states its current utilization rate is 105 percent based on a maximum utilization rate of four patients per station per week.

In Project I.D. #F-11846-20, the applicant was approved to relocate one station to Sugar Creek from Mint Hill Dialysis. As part of the project, the applicant projected four in-center dialysis patients residing in Mecklenburg County will transfer care to Sugar Creek on January 1, 2021, when the relocated station is projected to be certified, and that will increase the patient population at Sugar Creek.

The applicant states that, despite the 4.2 percent Mecklenburg County Average Annual Change Rate (AACR) published in the 2020 SMFP, Sugar Creek’s patient population increased by 40 percent during its first full fiscal year (CY 2019) and the patient population has increased by 50 percent over the patient population six months ago.

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

- Sugar Creek’s utilization rate is 105 percent based on an in-center patient population of 42 patients dialyzing on 10 stations.
- Sugar Creek’s patient population increased by 40 percent during CY 2019 and has increased by 50 percent during the first six months of 2020.

Projected Utilization

On Form C and the Form C Utilization subsection in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

Sugar Creek – Historical and Projected Patient Utilization				
	Historical (12/31/2019)		Projected (OY 2 – CY 2023)	
County	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	24	85.6%	62	88.6%
Gaston	1	3.6%	1	1.4%
Guilford	1	3.6%	1	1.4%
South Carolina	1	3.6%	0	0.0%
Other States	1	3.6%	3	4.3%
Cleveland	0	0.0%	1	1.4%
Union	0	0.0%	1	1.4%
Virginia	0	0.0%	1	1.4%
Total	28	100.0%	70	100.0%

Table may not foot due to rounding.

In Section C, pages 20-21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant begins its utilization projections with the patient facility census on June 30, 2020. On page 20, the applicant states that, on June 30, 2020, it was serving 34 Mecklenburg County patients and eight patients from other North Carolina counties and other states.
- Because Sugar Creek's patient population has grown at annual rates of 40 percent or higher, the applicant projects growth of the Mecklenburg County patient population at an annual rate of 15 percent, instead of using the 4.2 percent AACR for Mecklenburg County as published in the 2020 SMFP.
- The applicant assumes that, as part of Project I.D. #F-11846-20 (relocate one station from Mint Hill Dialysis), four in-center patients residing in Mecklenburg County will transfer their care to Sugar Creek on January 1, 2021, when the relocated station from Mint Hill Dialysis is expected to be certified.
- The applicant assumes no population growth for the patients residing in other North Carolina counties and other states dialyzing at Sugar Creek but assumes the patients will continue to dialyze at Sugar Creek and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 21, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

Sugar Creek Projected Utilization	
Starting point of calculations is Mecklenburg County patients dialyzing at Sugar Creek on June 30, 2020.	34
Mecklenburg County patient population is projected forward by six months to December 31, 2020, using one-half of the 15% projected annual growth rate.	$34 \times 1.075 = 36.550$
Four Mecklenburg County patients are projected to transfer care to Sugar Creek on January 1, 2021, when the station to be relocated from Mint Hill Dialysis (Project I.D. #F-11846-20) is projected to be certified.	$36.550 + 4 = 40.550$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the 15% projected annual growth rate.	$40.550 \times 1.15 = 46.633$
The patients from other NC counties and other states are added. This is the projected census on January 1, 2022 and the starting census for this project.	$46.633 + 8 = 54.633$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the 15% projected annual growth rate.	$46.633 \times 1.15 = 53.627$
The patients from other NC counties and other states are added. This is the projected census on December 31, 2022 (OY1).	$53.627 + 8 = 61.627$
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the 15% projected annual growth rate.	$53.627 \times 1.15 = 61.671$
The patients from other NC counties and other states are added. This is the projected census on December 31, 2023 (OY2).	$61.671 + 8 = 69.671$

The applicant projects to serve 62 patients on 21 stations, which is 2.95 patients per station per week ($62 \text{ patients} / 21 \text{ stations} = 2.95$), by the end of OY1 and 70 patients on 21 stations, which is 3.33 patients per station per week ($70 \text{ patients} / 21 \text{ stations} = 3.33$), by the end of OY2. This exceeds the minimum of 2.8 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 reasonable and adequately supported for the following reasons:

- The applicant projects utilization using an annual growth rate lower than the facility's historical growth rate.
- The applicant accounts for the dialysis station and four patients projected to transfer to Sugar Creek as part of Project I.D. #F-11846-20.
- The applicant does not project growth for the patients residing outside of Mecklenburg County dialyzing at Sugar Creek.

Access

In Section C, page 23, 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 [disability]. We will serve patients regardless of ethnic or socioeconomic situation.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. ...

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, disabled persons, elderly and other under-served persons.”

On pages 23-24, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table. The applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY 2019 and projected patient population in CY 2023.

Medically Underserved Groups	% of Total Patients
Women	34.5%
People age 65 and older	44.8%
Medicare beneficiaries	82.1%
Medicaid recipients	7.1%
American Indian	0.0%
Asian	3.4%
Black or African-American	89.7%
Native Hawaiian or Pacific Islander	0.0%
Other Race	3.4%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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 add 10 dialysis stations to Sugar Creek pursuant to Condition 1 of the facility need methodology for a total of 21 stations following completion of this project and Project I.D. #F-11846-20 (relocate 1 station).

In Section E, pages 29-30, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo was not an effective alternative because of the growth rate of the patient population at the facility.
- Relocate Stations from Another DaVita Facility: the applicant states every other DaVita facility in Mecklenburg County is either new, close to capacity, or already involved in projects to relocate existing stations; therefore, this is not an effective alternative.

On page 30, the applicant states its proposal is the most effective alternative because it meets the need, based on the growth rate of the patient population at the facility, for additional dialysis services at Sugar Creek.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 1 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 10 additional in-center dialysis stations for a total of no more than 21 in-center stations at Sugar Creek Dialysis upon completion of this project and Project I.D. #F-11846-20 (relocate 1 station).**
- 3. The certificate holder shall install plumbing and electrical wiring through the walls for a combined total of no more than 21 stations.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on April 1, 2021. The second progress report shall be due on July 1, 2021 and so forth.**

5. The certificate holder 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.

C

The applicant proposes to add 10 dialysis stations to Sugar Creek pursuant to Condition 1 of the facility need methodology for a total of 21 stations following completion of this project and Project I.D. #F-11846-20 (relocate 1 station).

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$189,065 to be used for medical equipment, non-medical equipment, and furniture. In Section Q, the applicant provides the assumptions used to project the capital cost. In Section F, page 33, the applicant states there are no projected start-up expenses or initial operating expenses because Sugar Creek is an existing and operational facility.

Availability of Funds

In Section F, page 31, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., authorizing the use of accumulated reserves for the capital needs and any other needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2019, DaVita, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
Sugar Creek	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	8,615	9,729
Total Gross Revenues (Charges)	\$2,800,444	\$3,162,700
Total Net Revenue	\$2,800,444	\$3,162,700
Average Net Revenue per Treatment	\$325	\$325
Total Operating Expenses (Costs)	\$2,078,550	\$2,249,304
Average Operating Expense per Treatment	\$241	\$231
Net Income/(Loss)	\$721,894	\$913,396

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. 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
- 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 cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - 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.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add 10 dialysis stations to Sugar Creek pursuant to Condition 1 of the facility need methodology for a total of 21 stations following completion of this project and Project I.D. #F-11846-20 (relocate 1 station).

On page 113, the 2020 SMFP defines the service area 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 27 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 27 of these dialysis facilities is provided below:

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

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the 2020 SMFP lists both the existing operational facility and the replacement facility.

***Facility which is dedicated exclusively to providing HH and PD training and support.

In Section G, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County:

“While adding stations at this facility does increase the number of stations in Mecklenburg County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- The applicant proposes to increase the number of dialysis stations in Mecklenburg County based on Condition 1 of the facility need determination in the 2020 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Mecklenburg County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

C

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

Sugar Creek Current and Projected Staffing			
	Current	Projected	
	12/31/19	OY 1 (CY 2022)	OY 2 (CY 2023)
Administrator	1.00	1.00	1.00
Registered Nurses	1.25	2.50	2.75
Patient Care Technicians	3.75	8.00	8.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Office	0.50	1.00	1.00
Biomed Technician	0.50	0.50	0.50
TOTAL	8.00	14.00	14.25

Adequate costs for the health manpower and management personnel proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 38-39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3. In Section H, page 39, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing support for the proposed project and stating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- 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.

C

In Section I, page 40, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

Sugar Creek – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	Charlotte East Dialysis Charlotte East Dialysis Charlotte East Dialysis
Isolation – hepatitis	On site
Psychological counseling	On site (by registered nurse)
Nutritional counseling	On site (by registered dietician)
Social Work services	On site (by MSW)
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Mecklenburg Transportation System

The applicant provides supporting documentation in Exhibit I-1.

In Section I, page 41, the applicant describes its existing relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

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 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

The applicant does not propose to construct any new space or renovate any existing space. 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;

C

In Section L, page 47, the applicant provides the historical payor mix during CY 2019 for its existing services at Sugar Creek, as shown in the table below.

Sugar Creek Historical Payor Mix CY 2019		
Payment Source	# Patients	% Patients
Self-Pay	0.0	0.0%
Insurance*	2.0	7.1%
Medicare*	22.0	78.6%
Medicaid*	2.0	7.1%
Other (VA)	2.0	7.1%
Total	28.0	100.0%

*Including any managed care plans

In Section L, page 46, the applicant provides the following comparison.

Sugar Creek	% of Patients Served During CY 2019	% of the Population of Mecklenburg County
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%

Sources: RTC-MA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 47, that Sugar Creek has no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 47, the applicant states that during the last five years no patient civil rights access complaints have been filed against Sugar Creek.

Conclusion

The Agency reviewed the:

- Application
- 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

C

In Section L, page 48, 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.

Sugar Creek Projected Payor Mix CY 2023		
Payment Source	# Patients	% Patients
Self-Pay	0.0	0.0%
Insurance*	5.0	7.1%
Medicare*	54.7	78.6%
Medicaid*	5.0	7.1%
Other (VA)	5.0	7.1%
Total	70 (69.7)	100.0%

Table may not foot due to rounding.

*Including any managed care plans

As shown in the table above, during the applicant's second full fiscal year following project completion, the applicant projects to provide 78.6 percent of services to Medicare patients and 7.1 percent of services to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- 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.

C

In Section L, pages 48-49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- 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.

C

In Section M, page 50, 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
- 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 July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add 10 dialysis stations to Sugar Creek pursuant to Condition 1 of the facility need methodology for a total of 21 stations following completion of this project and Project I.D. #F-11846-20 (relocate 1 station).

On page 113, the 2020 SMFP defines the service area 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell,*

and Yancey counties.” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 27 existing and approved facilities which provide dialysis and/or dialysis home training and support in Mecklenburg County, 23 of which are operational. Information on all 27 of these dialysis facilities is provided below:

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

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location; the 2020 SMFP lists both the existing operational facility and the replacement facility.

***Facility which is dedicated exclusively to providing HH and PD training and support.

In Section N, page 51, 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 expansion of 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.

...

..., DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Sugar Creek Dialysis will enhance accessibility to dialysis for current and projected 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N, and Q of the application and any exhibits)
- Quality (see Sections B, C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

- (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

On Form A in Section Q, 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 a total of 110 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, pages 53-54, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident resulting in an Immediate Jeopardy violation occurred in one of these facilities. The applicant states that all the problems have been corrected and the facility is back in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 110 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 July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 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 is an existing facility. Therefore, this Rule is not applicable to this review.

- (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 in-center 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 C, page 21, and on Form C in Section Q, the applicant projects that Sugar Creek will serve 62 patients on 21 stations, or a rate of 2.95 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 20-21, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.