

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 22, 2021

Findings Date: January 22, 2021

Project Analyst: Kim Meymandi

Team Leader: Fatimah Wilson

Project ID #: B-11980-20

Facility: Brevard Dialysis Center

FID #: 080169

County: Transylvania

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or DaVita) proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

Need Determination (Condition 2)

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 Transylvania County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the facility as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Brevard Dialysis Center on page 163 of the 2020 SMFP is 75.00 percent or 3.0 patients per station per week, based on 33 in-center dialysis patients and 11 certified dialysis stations (33 patients / 11 stations = 3.00; $3.00 / 4 = 75.00\%$).

As shown in Table 9E, page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to one additional station; thus, the applicant is eligible to apply to add up to one station during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than one new station to the facility, which is consistent with the 2020 SMFP calculated facility need determination for up to one station; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, 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.”

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5, pages 13-14; Section N, page 49, Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), page 15; Section L, pages 44-47; Section N, page 49, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c), page 15; Sections F and K, and Section N, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

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 based on 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 that the application is consistent with Policy GEN-3 because the applicant adequately demonstrates how Brevard Dialysis Center’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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than 1 dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

According to Table 9A on page 146 of the SMFP, Brevard Dialysis Center offers in-center (IC) and home peritoneal dialysis (PD) services. On page 19, the applicant states it will continue to offer IC and PD. The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Brevard Dialysis Center:

Brevard Dialysis Center

# OF STATIONS	DESCRIPTION	PROJECT ID #
13	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
1	# of stations to be added as part of this project	B-11980-20
0	# of stations to be deleted as part of this project	
0	# of stations previously approved to be added but not yet certified	
0	# of stations previously approved to be deleted but not yet certified	
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
14	Total # of stations upon completion of all facility projects	

As illustrated in the table above, in this application, the applicant proposes to add one dialysis station for a total of 14 stations upon project completion.

In Section A, page 5 the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with Brevard Dialysis Center to refer to itself or its facilities. References to DaVita should be interpreted to mean Brevard Dialysis Center 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility consists of Transylvania County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the patient origin for in-center (IC) and peritoneal dialysis (PD) patients at Brevard Dialysis Center for the last full operating year (CY2019), as summarized in the table below.

Brevard Dialysis Center Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# PD Patients	% PD Total
Transylvania	25.0	75.8%	3.0	60.0%
Henderson	5.0	15.2%	2.0	40.0%
Gaston	1.0	3.0%	0.0	0.0%
Other States	2.0	6.1%	0.0	0.0%
Total	33	100.0%	5	100.0%

Totals may not sum due to rounding

The following table summarizes projected patient origin for the second full operating year (CY2023) following project completion, as provided in Section C.3, page 20.

Brevard Dialysis Center Projected Patient Origin - CY2023

COUNTY	# IC PATIENTS	% IC Total	# PD Patients	% PD Total
Transylvania	37.0	82.2%	7.0	77.8%
Henderson	5.0	11.1%	2.0	22.2%
Gaston	1.0	2.2%	0.0	0.0%
Other States	2.0	4.4%	0.0	0.0%
Total	45.0	100.0%	9.0	100.0%

Totals may not sum due to rounding

In Section C, pages 20-24, the applicant provides the assumptions and methodology it used to project IC and PD patient origin. The applicant's assumptions are reasonable and adequately supported, based on the following:

- The applicant bases the projected patient origin on the historical patient origin of Brevard Dialysis Center.
- The applicant increases the number of projected future patients based on a reasonable growth rate considering the facility's growth rate.

Analysis of Need

In Section C.3, pages 20-22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 22, the applicant states that Section B clearly outlines the need for the expansion of Brevard Dialysis Center by one station, since the facility need methodology resulted in a determination of need for one additional station.

In Section Q Form C Utilization Assumptions and Methodology, the applicant provides information as to why the population projected to utilize the proposed services needs the proposed services, as summarized below:

- As of December 31, 2019, the facility had a patient census of 33 in-center patients dialyzing on 13 stations for a station utilization rate of 63.5%. This is due to two additional stations being certified on August 11, 2019, pursuant to Project ID# B-11688-19.
- Growing at 10%, significantly lower than the facility's 5-year Average Annual Change Rate (AACR) of 13%, the facility will have 41 in-center patients and operate at a utilization rate of 73.2% on the 14 dialysis stations at the end of the project's first operating year, thus showing the need for the proposed additional dialysis station.

The information is reasonable and adequately supported for the following reasons:

- The applicant demonstrates the need for the additional station at Brevard Dialysis based on its existing and future patient population.
- The applicant provides supporting documentation for its projected utilization in Section Q Form C.

Projected Utilization

In-Center Projected Utilization

In Section Q, the applicant provides the assumptions and methodology used to project IC utilization, which is summarized below.

Assumptions

- The applicant states that it projects patients forward from December 31, 2019 census data. On page 20, the applicant states that, on December 31, 2019, its in-center patient census was comprised of 25 Transylvania County patients and 8 patients from other North Carolina counties (Henderson and Gaston) and other states.
- The applicant states the Transylvania Average Annual Change Rate (AACR) published in Table 9C of the 2020 SMFP was 6.6%. However, the applicant states Brevard Dialysis Center has experienced an average growth rate of 13.0% over the same five-year time period, as illustrated in the following table:

	# of IC Patients	% Change
12/31/2015	21	
12/31/2016	28	33.3%
12/31/2017	27	-3.6%
12/31/2018	33	22.2%
12/31/2019	33	0.0%

The applicant states that given the historical growth in the facility over the past five years and as shown in the table above, it is reasonable and conservative to use a growth rate of 10.0% to project future utilization for the IC Transylvania County patients.

- The applicant assumes the IC patients from outside Transylvania County will continue to dialyze at Brevard Dialysis Center but does not assume any growth in these patients.
- The applicant states services will be offered as of December 31, 2021. Therefore, Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY2023, January 1-December 31, 2023.

In Section C.3, page 21, the applicant provides a table to illustrate the methodology used to project IC utilization, as shown below.

Methodology

The table below summarizes the applicant’s methodology based on the applicant’s stated assumptions.

Brevard Dialysis Center Projected Utilization		
	IC Stations	IC Patients
The applicant begins with the 33 patients dialyzing on 13 stations at the facility as of December 31, 2019.	13	33
The applicant projects Transylvania County patient census forward one year to December 31, 2020 using a growth rate of 10%.		$25 \times 1.10 = 27.5$
The applicant adds eight patients from counties other than Transylvania County for a year-end census as of December 31, 2020.		$27.5 + 8 = 35.5$
The applicant projects the Transylvania County patient census forward one year to December 31, 2021 using a growth rate of 10%.		$27.5 \times 1.10 = 30.25$
The applicant adds eight patients from counties other than Transylvania County for a year-end census as of December 31, 2021.		$30.25 + 8 = 38.25$
The project is projected to be certified on 1/1/2022. This is the station count at the beginning of OY1.	$13 + 1 = 14$	
The applicant projects the Transylvania County patient census forward a year to December 31, 2022 using a growth rate of 10%.		$30.25 \times 1.10 = 33.275$
The applicant adds eight patients from counties other than Transylvania County for a year-end census as of December 31, 2022. This is the projected ending census for Operating Year 1 (OY1) .		$33.275 + 8 = 41.275$
The applicant projects the Transylvania County patient census forward one year to December 31, 2023 using a growth rate of 10%.		$33.275 \times 1.10 = 36.603$
The applicant adds eight patients from counties other than Transylvania County for a year-end census as of December 31, 2023. This is the projected ending census for Operating Year 2 (OY2) .		$36.603 + 8 = 44.603$

The applicant projects to serve 41 in-center patients in OY1 and 45 in-center patients in OY2. Thus, the applicant projects that Brevard Dialysis Center will have a utilization rate of 73.2% or 2.9 patients per station per week ($41 \text{ patients} / 14 \text{ stations} = 2.929 / 4 = 0.732$ or 73.2%) in OY1 and a utilization rate of 80.0% or 3.0 patients per station per week ($45 \text{ patients} / 14 \text{ stations}$

= $3.2 / 4 = 0.800$ or 80.0%) by the end of OY2. The projected utilization of 2.9 patients per station per week at the end of OY1 and 3.2 patients per station per week at the end of OY2 exceeds the minimum standard of 2.8 in-center 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 begins the projections with the existing Brevard Dialysis Center patient census as of December 31, 2019.
- The applicant projects future utilization using a growth rate of 10%, which is less than the historical average growth rate experienced by the facility over the past five years.
- The utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Peritoneal Dialysis Projected Utilization

In Section Q, the applicant provides the assumptions and methodology used to project PD utilization, which is summarized below.

- The applicant begins its utilization projections with the patient facility census on December 31, 2019. On page 22, the applicant states that, its PD patient census was comprised of five PD patients.
- The applicant assumes that the Transylvania County PD patient population will increase by one patient per year during the period of growth in OY1 and OY2.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, pages 21-22, and the Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the PD patient census for OY1 and OY2, as summarized in the table below.

Brevard Dialysis Center PD Projected Utilization	
Starting point of calculations is Brevard Dialysis Center PD patients as of January 1, 2020.	5
The PD patient population of Brevard Dialysis Center is projected forward by one year to December 31, 2020, at a growth rate of one patient per year.	$5 + 1 = 6$
The PD patient population of Brevard Dialysis Center is projected forward by one year to December 31, 2021, at a growth rate of one patient per year.	$6 + 1 = 7$
The PD patient population of Brevard Dialysis Center is projected forward by one year to December 31, 2022, at a growth rate of one patient per year (end of OY1).	$7 + 1 = 8$
The PD patient population of Brevard Dialysis Center is projected forward by one year to December 31, 2023, at a growth rate of one patient per year (end of OY2).	$8 + 1 = 9$

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

- The applicant begins the projections with the existing PD patient census at Brevard Dialysis Center as of December 31, 2019.
- The applicant projects the home-training program at Brevard Dialysis Center will increase by at least one patient per year during the period of growth, which is reasonable.

Access to Medically Underserved Groups

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. ...

Brevard Dialysis Center 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 page 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	30.3%
People age 65 and older	69.7%
Medicare beneficiaries	87.9%
Medicaid recipients	6.1%
American Indian	0.0%
Asian	0.0%
Black or African-American	27.3%
Native Hawaiian or Pacific Islander	0.0%
Other Race	6.1%

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 service 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, ... persons [with disabilities], 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 no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

In Section E, page 29, 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 that maintaining the status quo is not an effective alternative due to the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states that Brevard Dialysis Center is the only dialysis facility operated by the applicant in Transylvania County. While the applicant operates in the three contiguous counties, the applicant states they cannot relocate stations to Brevard Dialysis Center because the 2020 SMFP indicates that there is a surplus of stations in Transylvania County.

The applicant adequately demonstrates that 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

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. Total Renal Care of North Carolina, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than one additional in-center dialysis station for a total of no more than 14 in-center stations at Brevard Dialysis Center upon completion of this project.
 3. 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 sixth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.
 4. 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 no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant provides a table to illustrate projected capital cost of the project, as shown in the table below:

ITEM	COST
Medical Equipment	\$14,850
Non-Medical Equipment	\$2,198
Furniture	\$5,600
Total	\$18,448

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant uses the DaVita Team' NC Project Manager partnered with Finance to develop the capital cost for the project.
- The Project Manager uses DaVita experience, a corporate model, and regional database with specific inputs for this project being furniture, fixtures and equipment.

In Section F.3, page 32, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Availability of Funds

In Section F, page 30, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$18,448	\$18,448
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$18,448	\$18,448

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F contains the Consolidated Financial Statements for the year ending December 31, 2019 that shows DaVita, Inc., parent company to Total Renal Care of North Carolina, LLC currently has \$1.1 billion in cash and cash equivalents and \$17 billion in total assets.
- The applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years 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 summarized in the table below.

Brevard Dialysis Center Projected Revenue and Operating Expenses

	OY 1 CY 2022	OY 2 CY 2023
Total In-Center Treatments	7,004	7,623
Total Gross Revenue (charges)	\$1,928,687	\$2,096,714
Total Net Revenue	\$1,834,829	\$1,994,562
Average Net Revenue per Treatment	\$262	\$262
Total Operating Expenses (costs)	\$1,634,946	\$1,718,631
Average Operating Expense per Treatment	\$233.43	\$225.45
Net Income / Profit	\$199,884	\$275,932

*Source: application Form F.2, Section Q
 Numbers may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant bases charges and expenses on historical revenue and expenses for DaVita’s North Carolina facilities.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for the reasons stated above.
- 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 revenues and operating expenses for the reasons stated above.

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

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Transylvania County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, there is one existing dialysis facility in Transylvania County, and it is owned and operated by DaVita. Information on the dialysis facility, from Table 9B of the 2020 SMFP, is provided in the table below:

Transylvania County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Brevard Dialysis Center	13	33	2.54	75.00%
Total	13	33		

Source: 2020 SMFP, Table 9B, page 163.

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Transylvania County. The applicant states:

“While adding stations at this facility does increase the number of stations in Transylvania 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 for the following reasons:

- There is a facility need determination in the 2020 SMFP at Brevard Dialysis Center for one dialysis station. The applicant proposes to add one station.
- The applicant adequately demonstrates that the proposed dialysis station is needed in addition to the existing 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.

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Brevard Dialysis Center, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	OY1 (1/1/2022 to 12/31/2022)	OY2 (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
RNs	1.75	1.75	1.75
Home Training Nurse	0.50	0.50	0.50
Technicians (PCT)	5.00	5.25	5.25
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Admin/Business Office	0.50	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
TOTAL	10.25	11.00	11.00

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating 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 based on the following:

- The applicant projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Brevard Dialysis Center.
- The increased costs are accounted for in the budgeted Operating Costs

- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- A letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services is provided.

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 described 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

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

Ancillary and Support Services

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On page 38, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On site
Hemodialysis training & follow-up	Asheville Kidney Center
Peritoneal dialysis training & follow-up	On site
Psychological counseling	On site by RN
Isolation – hepatitis	On site
Nutritional counseling	On site by RD
Social Work services	On site by MSW
Acute dialysis in an acute care setting	Mission Memorial Hospital
Emergency care	Mission Memorial Hospital
Blood bank services	Mission Memorial Hospital
Diagnostic and evaluation services	Mission Memorial Hospital
X-ray services	Mission Memorial Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Mission Memorial Hospital
Vascular surgery	Mission Memorial Hospital
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Accordius Health at Brevard
Transportation	Transylvania Transportation

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for dialysis patients located in or near Transylvania County and how these will be made available.
- The applicant describes how the necessary ancillary and support services will be coordinated with the existing health care system.

Coordination

In Section I, pages 38-39, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation of established relationships with local health care providers and for referrals. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients in the service area.
- The applicant has established relationships and agreements with the community health care and ancillary service providers where dialysis patients can receive appropriate referrals for necessary services and care related to their condition.

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.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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 ... persons [with disabilities], 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 45, the applicant provides the historical payor mix for Brevard Dialysis Center during the last full operating year (CY2019) for its existing services, as shown in the table below.

**Brevard Dialysis Center
 Historical Payor Mix CY 2019**

Payor Category	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	0.0	0.0%
Insurance*	1.0	3.0%	0.0	0.0%	0.0	0.0%
Medicare*	29.0	87.9%	0.0	0.0%	4.0	80.0%
Medicaid*	2.0	6.1%	0.0	0.0%	1.0	20.0%
Miscellaneous (Incl. VA)	1.0	3.0%	0.0	0.0%	0.00	0.00%
Total	33.0	100.00%	0.0	0.0%	5.0	100.00%

*Including any managed care plans

In Section L, page 44, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population in the Service Area*
Female	30.3%	51.8%
Male	69.7%	48.2%
Unknown	0.0%	0.0%
64 and Younger	30.3%	68.6%
65 and Older	69.7%	31.4%
American Indian	0.0%	0.5%
Asian	0.0%	0.7%
Black or African-American	27.3%	3.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	66.7%	93.4%
Other Race	6.1%	1.9%
Declined / Unavailable	0.0%	

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

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 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 ... persons [with disabilities] 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 45, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 45, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.3, page 46, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Brevard Dialysis Center
Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%
Insurance*	1.4	3.0%	0.0	0.0%
Medicare*	39.2	87.9%	7.2	80.0%
Medicaid*	2.7	6.1%	1.8	20.0%
Miscellaneous (incl. VA)	1.4	3.0%	0.0	0.0%
Total	44.7	100.0%	9.0	100.0%

Table may not sum due to rounding

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 0.0% of in-center dialysis services will be provided to self-pay patients, 87.9% to Medicare patients, and 6.1% to Medicaid patients. In addition, 80.0% and 20.0% of PD services will be provided to Medicare and Medicaid patients, respectively.

On page 46, 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, stating the payor mix is based upon recent facility history of actual treatment volumes. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of Brevard Dialysis Center.

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.5., pages 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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 48, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant offers the facility as a clinical learning site for students from Blue Ridge Community College.
- The applicant provides a copy of the letter sent to Blue Ridge Community College offering training opportunities 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 no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 14 stations upon project completion.

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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Transylvania County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, there is one existing dialysis facility in Transylvania County, and it is owned and operated by DaVita. Information on the dialysis facility, from Table 9B of the 2020 SMFP, is provided in the table below:

Transylvania County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	# IN-CTR PATIENTS	PATIENTS / STATION	PERCENT UTILIZATION
Brevard Dialysis Center	13	33	2.54	75.00%
Total	13	33		

Source: 2020 SMFP, Table 9B, page 163.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 49, the applicant states:

“The expansion of Brevard Dialysis Center will have no effect on competition in Transylvania 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. ”

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups in Section N, page 49, the applicant states:

“As discussed in Section B, 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 Brevard Dialysis Center 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.”

See also Sections B, C, F, L, N, O and Q of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and & the applicant’s record of providing quality care in the past (*if applicable*).
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on 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

In Section Q Form A Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility; Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back 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 July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (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- Brevard Dialysis Center 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 Form C in Section Q, the applicant projects that Brevard Dialysis Center will serve 41 in-center patients on 14 stations, or a rate of 2.9 patients per station per week or 73.2% ($41 / 14 = 2.929/4 = 0.732$ or 73.2%), as of the end of the first operating year (CY2022) following project completion. This exceeds the minimum performance standard requirement of 2.8 patients per station per week. 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, in Section Q, Form C, 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.