

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 24, 2021

Findings Date: June 24, 2021

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: E-12044-21

Facility: Catawba County Dialysis

FID #: 160450

County: Catawba

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

Project: Add no more than five dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 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, also known as DaVita (hereinafter referred to as “the applicant” or “TRC”) proposes to add no more than five (5) dialysis stations to Catawba County Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 21 in-center dialysis stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of the 2021 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 9C, the county need methodology shows there is no county need determination for additional dialysis stations in Catawba 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 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Catawba County Dialysis in Table 9A, page 120 of the 2021 SMFP is 95.0%, or 3.8 patients per station per week, based on 38 patients and 10 certified stations [$38 / 10 = 3.8$; $3.8 / 4 = 0.95$].

As shown in Table 9D, page 138, there is a potential need for up to five (5) additional stations based on the facility need methodology for dialysis stations; thus, the applicant is eligible to apply to add up to five (5) dialysis stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than five (5) new dialysis stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to five (5) stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, page 29 of the 2021 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 17-20, the applicant explains why it believes its application is consistent with Policy GEN-3. On pages 19-20, the applicant summarizes:

“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.*

As discussed in Sections B-3(a), (b), & (c), established policy and procedure will continue to guide this commitment.”

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 17-18; Section N, page 64; Section O, pages 66-68; 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, page 19; Section L, pages 60-61; Section N, page 64; 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, page 19; Section K, pages 53-55; and Section N, page 64. 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 Condition 2 of the facility need methodology in the 2021 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately documents how the project will continue to promote safety and quality in the delivery of end stage renal disease (ESRD) services in Catawba County.
 - The applicant adequately documents how the project will continue to promote equitable access to ESRD services in Catawba County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended in Catawba County.

- (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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology in the 2021 SMFP for a total of no more than 21 stations upon project completion.

In Project ID #E-11882-20, the applicant was awarded a certificate of need to add six (6) in-center stations to the facility, bringing the total number of certified in-center dialysis stations to 16. Those stations were certified effective August 30, 2020, subsequent to data submission for the 2021 SMFP.

Patient Origin

On page 113, the 2021 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.*” Catawba County Dialysis is located in Catawba County. Thus, the service area for this facility is Catawba County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical patient origin for Catawba County Dialysis for calendar year (CY) 2020:

Catawba County Dialysis Historical Patient Origin, CY 2020

COUNTY	IN-CENTER PATIENTS		PERITONEAL PATIENTS	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Catawba	29	70.7%	13	52.0%
Alexander	2	4.9%	0	0.0%
Burke	6	14.6%	2	8.0%
Caldwell	3	7.3%	8	32.0%
Cleveland	1	2.4%	0	0.0%
Lincoln	0	0.0%	1	4.0%
Rutherford	0	0.0%	1	4.0%
Total	41	100.0%	25	100.0%*

Source: Section C, page 21

* The applicant placed the number “41” in this section of the table on page 21; the Project Analyst determined it was a typographical error and does not affect the substantive material in the table.

The following table illustrates projected patient origin for Catawba County Dialysis for the second project year (PY), CY 2024:

Catawba County Dialysis Projected Patient Origin, CY 2024

COUNTY	IN-CENTER PATIENTS		PERITONEAL PATIENTS	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Catawba	56.225	82.40%	17	58.62%
Alexander	2	2.90%	0	0.00%
Burke	6	8.80%	2	6.90%
Caldwell	3	4.40%	8	27.59%
Cleveland	1	1.50%	0	0.00%
Lincoln	0	0.00%	1	3.45%
Rutherford	0	0.00%	1	3.45%
Total	68.225	100.00%	29	100.0%

Source: Section C, page 22

In Sections C and Q, pages 22-24 and 72-74, respectively, the applicant provides the assumptions and methodology used to project patient origin at the facility. The applicant’s assumptions are reasonable and adequately supported because they are based on the facility’s actual historical utilization.

Analysis of Need

In Section C.4, page 25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“There is a facility need determination of five stations for Catawba County Dialysis, which had 16 existing stations as of August 2020. In Section C, Question 3 we demonstrate that an additional 5 stations will be well utilized by the population to be served, the current and projected in-center patients of Catawba County Dialysis. ... the additional stations provide opportunities to open appointment times on the more desirable first shift.”

In Sections C and Q, pages 22-27 and 72-74, respectively, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states its first project year will be CY 2023 and the second project year will be CY 2024.
- The applicant states the Five Year Average Annual Change Rate (AACR) for Catawba County as published in the 2021 SMFP is 6.1%. The applicant states Catawba County Dialysis has been open for three years, and has experienced patient census growth in that time of nearly 30%, as shown in the following table from page 23:

**Catawba County Dialysis Patient Census
 CY 2018-CY 2020**

YEAR	IN-CTR PATIENT CENSUS	ANNUAL CHANGE RATE
CY 2018	25	--
CY 2019	38	52.0%
CY 2020	41	7.9%
3 Year AACR		29.9%

The applicant’s calculation of 29.9% is an average of the two growth rates experienced from 201-2019 and from 2019-2020; the overall growth from 2018 to 2020 was 64% $[(41 / 25) - 1 = 0.64]$. The applicant demonstrates growth in the facility census since the facility began serving patients.

- To be conservative, the applicant projects growth of the Catawba County patient population by 18%, which is higher than the 6.1% Catawba County Five Year AACR in the 2021 SMFP but lower than the facility’s actual 29.9% historical growth rate over the last two calendar years.
- The applicant assumes the patients who reside outside of Catawba County will continue to dialyze at the facility, but the applicant does not assume any growth in patients from those counties and adds them to the calculations when appropriate.

Projected Utilization – In-Center Patients

In Section C, page 23, and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for PY1 and PY2, as summarized in the following table:

	IN-CENTER STATIONS	IN-CENTER PATIENTS
Begin with the 41 in-center patients on 16 stations as of 12/30/2020	16	41
Project Catawba County patient census forward one year to 12/30/2021 using 18% growth rate.		$19 \times 1.18 = 34.22$
Add 12 in-center patients from outside Catawba County. This is the ending census as of 12/30/21.		$34.22 + 12 = 46.22$
Project Catawba County patient census forward one year to 12/30/2022 using 18% growth rate.		$34.22 \times 1.18 = 40.38$
Add 12 in-center patients from outside Catawba County. This is the ending census as of 12/30/22.		$40.38 + 12 = 52.38$
Proposed certification of this project is 1/1/2023; this is the station count at the beginning of PY 1 (CY 2023).	$16 + 5 = 21$	
Project Catawba County patient census forward one year to 12/30/2023 using 18% growth rate.		$40.38 \times 1.18 = 47.65$
Add 12 in-center patients from outside Catawba County. This is the ending census as of 12/30/23, PY 1.		$47.65 + 12 = 59.65$
Project Catawba County patient census forward one year to 12/30/2024 using 18% growth rate.		$47.65 \times 1.18 = 56.22$
Add 12 in-center patients from outside Catawba County. This is the ending census as of 12/30/24, PY 2.		$56.22 + 12 = 68.22$

The applicant rounds the number of patients to the nearest whole number, and projects that Catawba County Dialysis will dialyze 60 patients on 21 stations at the end of PY 1, for a utilization rate of 2.86 patients per station per week, or 71.4% [$60 / 21 = 2.86$; $2.86 / 4 = 0.714$]. In PY 2, the applicant projects to dialyze 68 patients on 21 in-center stations, which is 3.24 patients per station per week, or 81.0% utilization [$68 / 21 = 3.24$; $3.24 / 4 = 0.8095$]. The projected utilization of 2.86 patients per station per week at the end of PY1 exceeds the minimum standard of 2.8 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

Projected Utilization – Peritoneal Dialysis

In Section C, page 24, and in Form C Utilization subsection of Section Q, the applicant provides the methodology and assumptions used to project the patient census for PY1 and PY2, as summarized below:

- The applicant states it begins projections of peritoneal dialysis (PD) patients with the PD patient population at Catawba County Dialysis as of December 30, 2020, as reported in the facility’s ESRD Data Collection Form. That facility census was 25 PD patients, 13 of whom lived in Catawba County and 12 of whom lived outside Catawba County.
- The applicant states PY 1 begins January 1, 2023 and PY 2 begins January 1, 2024. PY 1 is CY 2023 and PY 2 is CY 2024.
- The applicant begins its calculations as of January 1, 2021 and projects forward each year to December 31, 2024. The applicant states the Catawba County PD home program trained 14 PD patients in 2020. The applicant states not all PD patients remain on a PD program for a variety of reasons.
- The applicant assumes growth in the PD patient population of one PD patient per year, as illustrated in the following table from page 24:

PROJECTIONS	START DATE	# PTS BEGIN	# PTS END	AVG # PTS IN YEAR
Interim Period	1/1/2021	25	26	25.5
Interim Period	1/1/2022	26	27	26.5
First Project Year	1/1/2023	28	28	27.5
Second Project Year	1/1/2024	28	29	28.5

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

- The applicant begins the in-center and PD patient projections with the existing Catawba County patient census at Catawba County Dialysis as of December 31, 2020.

- The applicant projects in-center utilization using a growth rate for the dialysis facility that is less than the actual historical growth rate for the facility during its first two (2) full years of operation.
- The applicant assumes the patients residing outside of Catawba County will continue to dialyze at Catawba County Dialysis and are added to the projections without any future growth through the first two (2) operating years of the project.
- The projected utilization rate by the end of PY1 exceeds the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 28, the applicant states:

“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.

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. ...

Catawba County 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 page 29, 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 CY2020 and projected patient population payor mix in CY2024.

MEDICALLY UNDERSERVED GROUPS	% OF TOTAL PATIENTS
Low income persons	87.8%
Racial and ethnic minorities	22.4%
Women	40.3%
Persons with disabilities	100.0%
Persons 65 and older	59.7%
Medicare beneficiaries	80.5%
Medicaid recipients	7.3%

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 based on the following:

- The applicant currently serves the needs of medically underserved groups that utilize ESRD services.

- The applicant has implemented policies to prevent discrimination.

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 all the reasons described above.

- (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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 stations upon project completion.

In Section E, page 36, 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 given the growth rate at the facility.
- *Relocate stations from another DaVita facility* – The applicant states there are no other DaVita facilities in Catawba County, nor in any contiguous counties; therefore, there are no DaVita facilities from which to relocate dialysis stations.

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 applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria. Therefore, the application can be approved.

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 2021 SMFP, the certificate holder shall develop no more than five (5) additional in-center dialysis stations for a total of no more than 21 in-center stations at Catawba County Dialysis upon project completion.**
- 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 fourth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on February 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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 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:

Catawba County Dialysis Capital Cost

ITEM	COST
Medical Equipment	\$74,250
Non-Medical Equipment	\$7,444
Furniture	\$7,000
Total	\$88,694

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 states the costs are based on the input from the North Carolina project manager and the applicant’s finance department.
- In Section F, page 38, 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 37, 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
Cash/Cash Equivalents/Accumulated reserves or OE *	\$88,694	\$88,694
Bonds	\$ 0	\$ 0
Other (Specify)	\$ 0	\$0
Total Financing	\$88,694	\$88,694

* 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.2 contains the Consolidated Financial Statements for the year ending December 31, 2020, that shows DaVita, Inc., parent company to Total Renal Care of North Carolina, LLC currently has \$324 million in cash and cash equivalents and \$16 billion in total assets.

Financial Feasibility

The applicant provides pro forma financial statements for the first two (2) 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 (2) operating years of the project, as summarized in the table below.

	OY 1 CY 2023	OY 2 CY 2024
Total Combined In-Center and PD Treatments	12,376.74	13,699.05
Total Gross Revenue (charges)	\$4,226,840.65	\$4,643,877.72
Total Net Revenue	\$4,003,607.69	\$4,396,794.90
Average Net Revenue per Treatment	\$323.48	\$320.96
Total Operating Expenses (costs)	\$2,587,367.16	\$2,748,060.50
Average Operating Expense per Treatment	\$209.05	\$200.60
Net Income / Profit	\$1,416,240.53	\$1,648,734.40

Source: Forms C and F.1a, Section Q

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 applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant’s accounting department projected the financial feasibility of the proposed project and adjusted the reporting of some of its 2020 data into a single line item and reported it as Total Adjustments to Revenue in its calculations for Total Net Revenue.
- Projected utilization is based on reasonable and adequately supported assumptions. 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 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.

C

The applicant proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 stations upon project completion.

On page 113, the 2021 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.”* Catawba County Dialysis is located in Catawba County. Thus, the service area for this facility is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 120 of the 2021 SMFP, the applicant operates one of four (4) dialysis facilities in Catawba County. Information from Table 9A of the 2021 SMFP is provided below:

DIALYSIS FACILITY	PROVIDER	CERTIFIED STATIONS 12/31/19	# IN-CTR PATIENTS	PATIENTS / STATION / WEEK	PERCENT UTILIZATION
Catawba County Dialysis*	DaVita	10	38	3.80	95.0%
FMC Dialysis Services of Hickory	BMA	33	112	3.39	84.8%
FMC of Catawba Valley	BMA	25	96	3.84	96.0%
Fresenius Kidney Care Newton	BMA	15	21	1.4	35.0%
Total		83	267		

Source: 2021 SMFP, Table 9A, page 120 and page 43 of the application.

*Catawba County Dialysis is currently licensed for 16 dialysis stations pursuant to Project ID #E-11882-20.

In Section G, page 43, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Catawba County. The applicant states:

“Based on the facility need methodology in the 2021 SMFP under Condition 2, Catawba County Dialysis qualifies to add up to five dialysis stations.

...While adding stations at this facility does increase the number of stations in Catawba 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 2021 SMFP at Catawba County Dialysis for five (5) additional dialysis stations. The applicant proposes to add five (5) stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

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.

- (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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 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 Catawba County Dialysis, as illustrated in the following table:

POSITION	CURRENT FTE STAFF	PROJECTED FTE STAFF	PROJECTED FTE STAFF
	As of 12/31/2020	OY1 (CY 2023)	OY2 (CY 2024)
Administrator	1.00	1.00	1.00
RNs	2.00	2.75	2.75
Home Training Nurse	0.50	1.00	1.00
Technicians (PCT)	6.00	8.00	8.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Admin./Business Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
TOTAL	12.00	15.25	15.25

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 45-46, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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 Catawba County Dialysis.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- The applicant provides supporting documentation of their annual in-service training as well as courses offered by DaVita’s School of Clinical Education continuing education program.

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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 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 pages 47-50, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the providers of the ancillary and support services for Catawba County Dialysis.
- The applicant provides documentation identifying providers the dialysis facility has agreements in place with to offer ancillary and supporting services to its patients.

Coordination

In Section I, page 50, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. 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 Catawba County and in North Carolina.
- The applicant has established relationships and agreements with community health care providers and social service agencies and can provide appropriate referrals for necessary services and care related to their patients' conditions.

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

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 proposes to add no more than five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 stations upon project completion.

The applicant does not propose to

- construct any new space
- 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 57, the applicant provides the historical payor mix for Catawba County Dialysis during the last full operating year (CY 2020) for its existing services, as shown in the table below.

Catawba County Dialysis Historical Payor Mix, CY 2020

Payor Category	In-Center		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.00	0.0%	0.00	0.0%
Insurance*	2.00	4.9%	4.00	16.0%
Medicare*	33.00	80.5%	20.00	80.0%
Medicaid*	3.00	7.3%	0.00	0.0%
Other (Incl. VA)	3.00	7.3%	1.00	4.0%
Total	41.00	100.0%	25.00	100.0%

*Including any managed care plans

In Section L, page 58, the applicant provides the following comparison.

	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population in the Service Area *
Female	40.3%	51.2%
Male	59.7%	48.9%
Unknown	0.0%	0.0%
64 and Younger	40.3%	81.7%
65 and Older	59.7%	18.3%
American Indian	0.0%	0.6%
Asian	4.5%	4.5%
Black or African-American	16.4%	8.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	77.6%	74.9%
Other Race	1.5%	2.0%
Declined / Unavailable	0.0%	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 59, 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 59, the applicant states that during the last 18 months immediately preceding the application deadline that 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, page 60, 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:

Catawba County Dialysis Projected Payor Mix, CY 2024

Payor Category	In-Center		PD Patients	
	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.00	0.0%	0.00	0.0%
Insurance*	3.33	4.9%	4.64	16.0%
Medicare*	54.91	80.5%	23.20	80.0%
Medicaid*	4.99	7.3%	0.00	0.0%
Other (VA)	4.99	7.3%	1.16	4.0%
Total	68.22	100.0%	29.00	100.0%

*Including any managed care plans

The applicant identified the second full fiscal year as CY 2020; the Project Analyst determined it is a typographical error and does not affect the substantive analysis.

As shown in the table above, in the second full year of operation, the applicant projects that 80.5% of in-center dialysis services will be provided to Medicare patients, and 7.3% to Medicaid patients. In addition, for PD services the applicant projects that 80% of dialysis services will be provided to Medicare patients and 0% will be provided to Medicaid patients.

On pages 60-61, 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 patient payment that has been received by the existing facility in the last fiscal year. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Catawba County Dialysis.

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 61, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L.5.

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 63, 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-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant submits supporting documentation showing the facility has offered its location to Catawba Valley Community College as a clinical learning site for nursing students.

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 five (5) dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 21 stations upon project completion.

On page 113, the 2021 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.”* Catawba County Dialysis is located in Catawba County. Thus, the service area for this facility is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 120 of the 2021 SMFP, the applicant operates one of four (4) dialysis facilities in Catawba County. Information from Table 9A of the 2021 SMFP is provided below:

Catawba County Dialysis Facilities

DIALYSIS FACILITY	PROVIDER	CERTIFIED STATIONS 12/31/19	# IN-CTR PATIENTS	PATIENTS / STATION / WEEK	PERCENT UTILIZATION
Catawba County Dialysis*	DaVita	10	38	3.80	95.0%
FMC Dialysis Services of Hickory	BMA	33	112	3.39	84.8%
FMC of Catawba Valley	BMA	25	96	3.84	96.0%
Fresenius Kidney Care Newton	BMA	15	21	1.4	35.0%
Total		83	267		

Source: 2021 SMFP, Table 9A, page 120 and page 43 of the application.

*Catawba County Dialysis is currently licensed for 16 dialysis stations pursuant to Project ID #E-11882-20.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 64, the applicant states:

“The expansion of Catawba County Dialysis will have no effect on competition in Catawba 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 64, the applicant states:

“The expansion of Catawba County 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... As discussed in Section B and Section O, DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients. As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

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.
- 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 O Facilities, 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 108 of this type of facility located in North Carolina.

In Section O, page 68, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care resulting in a finding of “*Immediate Jeopardy*” occurred in any of its facilities. 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 or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of*

operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

- NA- Catawba County Dialysis 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 23, and Form C in Section Q, the applicant projects that Catawba County Dialysis will serve 60 in-center patients on 21 stations, or a rate of 2.857 patients per station per week or 71.4% ($60 / 21 = 2.857$; $2.857 / 4 = 0.7142$ or 71.4%), as of the end of the first operating year (CY 2023) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

- C- In Section C, pages 22-27, in Section Q, Form C, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.