

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 22, 2020

Findings Date: May 22, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: E-11882-20

Facility: Catawba County Dialysis

FID #: 160450

County: Catawba

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

Project: Add no more than six dialysis stations pursuant to facility need for a total of no more than 16 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care, LLC (the applicant) proposes to add no more than six dialysis stations to the existing facility (Catawba County Dialysis) pursuant to facility need for a total of no more than 16 dialysis stations upon project completion.

Need Determination

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

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2020 SMFP if the facility is a “new” facility or a “small” facility (or both) as defined in the 2020 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. In Section B, page 11, the applicant states it was serving 38 in-center patients on 10 certified stations on its current reporting date of December 31, 2019. This is a utilization rate of 95%, or 3.8 patients per station per week. According to Table 9B page 152 of the 2020 SMFP, Catawba County Dialysis is defined as both a new and small facility.

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 10 additional stations are needed at this facility, as illustrated in the following table.

Catawba County Dialysis Facility Need Methodology		
1	# of In-center Patients as of the Current Reporting Date	38
2	# of In-Center Patients as of the Previous Reporting Date	30
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	8
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.27
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.53
6	Multiply Line 5 by Line 1 (New Patients)	20.27
7	Add Line 6 to Line 1 (Total Patients)	58.27
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	20.81
9	# of Stations as of the Current Reporting Date	10.00
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	10.81

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Catawba County Dialysis is 11, based on rounding allowed in Condition 1.b.(vii). Condition 1a.(c) of the facility need methodology states, “*The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.*” The applicant proposes to add six new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2020 SMFP, Policy GEN-3 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, pages 13-14; Section N.2, page 49; Section O, pages 51-52, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 14-15; Section C.7, page 23; Section L, pages 44-47; Sections N.2. page 49, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 15; Section F, pages 30-32; Section K, page 41-42; Section N.2, page 49; Section Q; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

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

“DaVita’s goal is to create a “Culture of Safety” in all of its facilities and to make this a core part of how we function. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients, communication of clear expectations of staff, and complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients.

...

Catawba County Dialysis will help uninsured/underinsured patients with identifying and applying 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.

...

The parent corporation, DaVita, operates over 2,700 dialysis facilities nationwide and has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. All of

the products utilized in the facility purchased as a result of the proposed project, from office supplies to drugs to clinical supplies, will be purchased under these contracts.”

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:

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

C

The applicant proposes to add six dialysis stations to the existing facility for a total of no more than 16 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area is Catawba County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC) and peritoneal dialysis (PD) patients at Catawba County Dialysis (CCD).

Catawba County Dialysis Current Patient Origin				
County	Last Full Operating Year CY 2019			
	# of IC Patients	% of Total	# of PD Patients	% of Total
Catawba	22	57.9%	8	47.06%
Alexander	3	7.9%	1	5.88%
Burke	9	23.7%	1	5.88%
Caldwell	3	7.9%	5	29.41%
Cleveland	1	2.6%	0	0.00%
Lincoln	0	0.0%	2	11.76%
Total	38	100.0%	17	100.00%

Source: Section C, page 19

Catawba County Dialysis Projected Patient Origin				
County	2nd Full Operating Year CY 2023			
	# of In-Center Patients	% of Total	# of PD Patients	% of Total
Catawba	31	66.0%	12	57.14%
Alexander	3	6.4%	1	4.76%
Burke	9	19.1%	1	4.76%
Caldwell	3	6.4%	5	23.81%
Cleveland	1	2.1%	0	0.00%
Lincoln	0	0.0%	2	9.52%
Total	48	100.0%	21	100.00%

Source: Section C, page 20

In Section C, pages 19-22 and Section Q, Form C, the applicant provides the assumptions and methodology used to project IC and PD patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 22, the applicant references Section B, Question 3 of its application wherein it demonstrates that up to 10 additional dialysis stations are needed at Catawba County Dialysis based on application of the facility need methodology. The applicant discusses the need for additional dialysis stations based on CCD's patient growth rate over the last year. The applicant states:

- Projections begin with the 38 IC patients at the facility as of December 31, 2019. This information was reported on the December 2019 ESRD Data Collection forms submitted to the Agency. Of the 38 IC patients, 22 lived in the Catawba County and 16

lived outside of the service area (Alexander, Burke, Caldwell, Cleveland and Lincoln Counties).

- The applicant begins its projections with the 22 IC patients residing in Catawba County. The applicant does not project growth for the 16 IC patients living outside the service area.
- The Five-Year Average Annual Change Rate (AACR) for Catawba County is 7.8%, as published in the 2020 SMFP. However, on page 20, the applicant states that it experienced a 52% growth rate of IC patients between December 2018 and December 2019. This growth rate is evidenced by ESRD data collection forms for December 2018 and 2019. Thus, the applicant uses a conservative growth rate of 10.0% which is less than the historical growth rate of 52% for IC patients during the first year of operation at the facility but slightly higher than the 7.8% AACR for the county.
- The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

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

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

In-Center Projected Utilization

In Section C, page 21 and Section Q, Form C, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table.

	In-Center Stations	In-Center Patients
The applicant begins with the 38 patients dialyzing on 10 stations at the facility as of 12/31/2019.	10	38
The facility's Catawba County patient census is projected forward a year to 12/31/2020 and is increased by 10.0%.		$22 \times 1.10 = 24.20000$
The 16 patients from outside Catawba County are added to the facility's census. This is the ending census as of 12/31/2020.		$24.20 + 16 = 40.20$
The facility's Catawba County patient census is projected forward a year to 12/31/2021 and is increased by 10.0%.		$24.20 \times 1.10 = 26.62000$
The 16 patients from outside Catawba County are added to the facility's census. This is the ending census as of 12/31/2021.		$26.62 + 16 = 42.62$
The proposed project is projected to be certified on 01/1/2022. This is the station count at the beginning of OY1. The facility's Catawba County patient census is projected forward a year to 12/31/2022 and is increased by 10.0%.	$10 + 6 = 16$	$26.62 \times 1.10 = 29.28200$
The 16 patients from outside Catawba County are added to the facility's census. This is the ending census as of the end of OY1.		$29.28 + 16 = 45.28$
The facility's Catawba County patient census is projected forward a year to 12/31/2023 and is increased by 10.0%.		$29.28 \times 1.10 = 32.21020$
The 16 patients from outside Catawba County are added to the facility's census. This is the ending census as of the end of OY2.		$31.21 + 16 = 48.21$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 45 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 48 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 2.81 patients per station per week or 70.31% ($45 \text{ patients} / 16 \text{ stations} = 2.8125/4 = 0.7031$ or 70.31%)
- OY2: 3.40 patients per station per week or 75.00% ($48 \text{ patients} / 16 \text{ stations} = 3.0000/4 = 0.7500$ or 75.00%)

The projected utilization of 2.81 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Peritoneal Dialysis Projected Utilization

In Section C, pages 21-22 and Section Q, Form C, the applicant describes its methodology and assumptions for projecting PD utilization, summarized as follows:

- The applicant begins its projections with the beginning census as of December 31, 2019. This information is reported in the ESRD Data Collection forms submitted to

the Agency. The facility reported 17 PD patients receiving dialysis services at Catawba County Dialysis.

- The applicant assumes that the Catawba County Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.
- The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

In Section C, page 21 and Section Q, Form C, the applicant provided the methodology used to project peritoneal dialysis utilization, as illustrated in the following table.

PD Patient Projections	Start Date	# of patients beginning of the year	# of patients ending of the year	Average # of patients in the year
Interim Period	1/1/2020	17	18	17.5
Interim Period	1/1/2021	18	19	18.5
OY 1	1/1/2022	19	20	19.5
OY 2	1/1/2024	20	21	20.5

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

- The applicant projects future utilization based on historical utilization at Catawba County Dialysis.
- The applicant applies a conservative growth rate of 10 percent based on the significant growth in its IC patients experienced during the first year of operation at Catawba County Dialysis (52%), which is higher than the Five-Year AACR for Catawba County (7.8%), as published in the 2020 SMFP. The applicant does not project growth for its patients who do not reside in Catawba County.
- The applicant assumes a growth rate of at least one patient per year for PD patients.
- Projected utilization for IC patients at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 23, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. 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 the handicapped, patients attending school or patients who

work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

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

In Section L, page 43, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Catawba County Dialysis Projected Payor Mix CY 2023				
Payor Source	In-Center Dialysis		Peritoneal Dialysis	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	2.5	5.3%	1.2	5.9%
Medicare*	39.3	81.6%	18.5	88.2%
Medicaid*	2.5	5.3%	0.0	0.0%
Other: Misc. Incl. VA	3.8	7.9%	1.2	5.9%
Total	48.21	100.0%	21	100.0%

The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the sources of payment that have been received in the last full operating year at Catawba County Dialysis.
- Projections are based on the assumption that there will be no changes to the payor mix as a result of this project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E, page 29, the applicant states that there are no alternative methods of meeting the needs of the project. On page 29, the applicant states that stations cannot be added to Catawba County Dialysis pursuant to ESRD-2 because the facility is the only DaVita-owned facility in Catawba County and there are no DaVita-owned facilities in any of the contiguous counties. On page 29, the applicant states that Condition 1 of the facility need methodology is the only way that the proposed stations can be added to address the need demonstrated in Section C at this “new” facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- 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 shall materially comply with all representations made in the certificate of need application.**
 2. **Pursuant to the facility need determination in the 2020 SMFP, Total Renal Care of North Carolina, LLC shall develop no more than 6 additional in-center dialysis stations at Catawba County Dialysis for a total of no more than 16 in-center stations upon completion of this project.**
 3. **Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add six dialysis stations to the existing facility for a total of no more than 16 dialysis stations upon project completion.

Capital and Working Capital Costs

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

	Total Costs
Medical Equipment	\$89,100
Non-Medical Equipment	\$4,506
Furniture	\$8,400
Total	\$102,006

In Section Q, the applicant provides the assumptions used to project the capital cost.

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

In Section F.2, 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, Inc.	Total
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$102,006	\$102,006
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$102,006	\$102,006

* OE = Owner's Equity

Financial Feasibility

Exhibit F-2 contains a letter, dated March 15, 2020, from the Chief Accounting Office for DaVita, Inc., parent company to Total Renal Care of North Carolina LLC, authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-8 contains Consolidated Balance Sheets from DaVita, Inc., for year ending December 31, 2019, showing that DaVita, Inc. had \$1.1 billion in cash equivalents and over \$17 billion in assets to fund the capital cost of the proposed project.

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

Projected Revenues and Operating Expenses		
Catawba County Dialysis	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	9,403	9,966
Total Gross Revenues (Charges)	\$2,938,637	\$3,114,114
Total Net Revenue	\$2,753,137	\$2,917,519
Average Net Revenue per Treatment	\$292.79	\$292.74
Total Operating Expenses (Costs)	\$2,360,224	\$2,453,135
Average Operating Expenses per Treatment	\$251.00	\$246.15
Net Income/Profit	\$392,913	\$464,384

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add six dialysis stations to the existing facility for a total of no more than 16 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area is Catawba County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Catawba County as of December 31, 2018. The facility in this review is the only one owned and operated by the applicant in Catawba County. There is only one other provider (BMA) of dialysis services in Catawba County.

Catawba County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
Catawba County Dialysis	10	25	62.50%	2.50
FMC Dialysis of Hickory	35	122	87.14%	3.49
FMC of Catawba Valley	25	97	97.00%	3.88
Fresenius Kidney Care Newton	0	0	00.00%	0.00
Total	70	244	87.14%	3.49

Source: 2020 SMFP, Table 9B

In Section G, page 35, 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:

“While adding stations at the facility does increase the number of stations in Catawba County, it is based on the facility need methodology. It untimely serves to meet the need of the facility’s growing population of patients referred by the facility’s admitting nephrologists.”

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

- The applicant’s proposal to add dialysis stations is based on the facility need methodology.
- 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 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.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current (As of 12/31/2019)	Projected	
		Operating Year 1 (CY2022)	Operating Year 2 (CY2023)
Administrator	1.00	1.00	1.00
Registered Nurse (RNs)	2.00	2.00	2.00
Home Training Nurse	0.50	0.50	0.50
Technicians (PCT)	4.00	6.00	6.00
Dieticians	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Business Office	1.00	1.00	1.00
Other: Biomedical Tech	0.50	0.50	0.50
TOTAL	10.00	12.00	12.00

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 36 and 37, respectively, 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. In Exhibit H-3, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services:

Catawba County Dialysis – Ancillary and Support Services		
Services	Provider	Explanation/Supporting Documentation
Self-care training (performed in-center)	On site	
Home Hemodialysis training and follow-up program	On site	
Peritoneal dialysis training and follow-up program	On site	
Isolation – hepatitis B	On site	
Psychological counseling	On site by RN	
Nutritional counseling	On site by RD	
Social work services	On site by MSW	
Laboratory services	DaVita Laboratory Services, Inc.	Exhibit I-1
Acute dialysis in an acute care setting	Frye Regional Medical Center Catawba Valley Medical Center	Exhibit I-1
Emergency care	Frye Regional Medical Center	Exhibit I-1
Blood bank services	Catawba Valley Medical Center	Exhibit I-1
Diagnostic and evaluation services	Frye Regional Medical Center	Exhibit I-1
X-ray services	Catawba Valley Medical Center	Exhibit I-1
Pediatric nephrology	Frye Regional Medical Center	Exhibit I-1
Vascular surgery	Catawba Valley Medical Center	Exhibit I-1
Transplantation services	Frye Regional Medical Center	Exhibit I-1
Vocational rehabilitation counseling and services	NC DHHS Division of Vocational Rehab Services	Exhibit I-1
Transportation	Premier Care/DSS	Exhibit I-1

On page 38, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 1-1.

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

NA

The applicant does not propose to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 45, the applicant provides the historical payor mix during the last full operating year, for the proposed services, as shown in the table below.

Catawba County Dialysis Historical Payor Mix CY 2019				
Payor Source	In-Center Dialysis		Peritoneal Dialysis	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	2.0	5.3%	1.0	5.9%
Medicare*	31.0	81.6%	15.0	88.2%
Medicaid*	2.0	5.3%	0.0	0.0%
Other: Misc. Incl. VA	3.0	7.9%	1.0	5.9%
Total	38	100.0%	17	100.0%

*Including managed care plans

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

Catawba County Dialysis	Percentage of Total Patients Served (all modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	36.2%	51.2%
Male	63.8%	48.8%
Unknown	0.0%	0.0%
64 and Younger	39.7%	82.1%
65 and Older	60.3%	17.9%
American Indian	0.0%	0.6%
Asian	6.9%	4.4%
Black or African-American	17.2%	9.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	75.9%	84.0%
Other Race	0.0%	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>.

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 46, the applicant states:

“DaVita may provide patient assistance related to patient obligation based on an individualized determination of a patient’s financial need.”

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

Catawba County Dialysis Projected Payor Mix CY 2023				
Payor Source	In-Center Dialysis		Peritoneal Dialysis	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	2.5	5.3%	1.2	5.9%
Medicare*	39.3	81.6%	18.5	88.2%
Medicaid*	2.5	5.3%	0.0	0.0%
Other: Misc. Incl. VA	3.8	7.9%	1.2	5.9%
Total	48.21	100.0%	21	100.0%

*Including managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 39.3% of total in-center services and 88.2% of total PD services will be provided to Medicare patients and a total of 5.3% in-center services to Medicaid patients.

On page 46, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the sources of payment that have been received in the last full operating year at Catawba County Dialysis.

- Projections are based on the assumption that there will be no changes to the payor mix as a result of this project.

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 reasons stated above.

- (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, page 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 have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to add six dialysis stations to the existing facility for a total of no more than 16 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.”* Thus, the service area is Catawba County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Catawba County as of December 31, 2018. The facility in this review is the only one owned and operated by the applicant in Catawba County. There is only one other provider (BMA) of dialysis services in Catawba County.

Catawba County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
Catawba County Dialysis	10	25	62.50%	2.50
FMC Dialysis of Hickory	35	122	87.14%	3.49
FMC of Catawba Valley	25	97	97.00%	3.88
Fresenius Kidney Care Newton	0	0	00.00%	0.00
Total	70	244	87.14%	3.49

Source: 2020 SMFP, Table 9B

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 49, 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, in Section N, page 49, 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.”

Regarding the impact of the proposal on quality, in Section N, page 49, the applicant states:

“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.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 49, the applicant states:

“...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.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 110 of this type of facility located in North Carolina.

In Section O, page 51, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy occurred in one of these facilities. The applicant states that the facility is currently in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 110 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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 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, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

- NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard 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 Section Q, Form C, the applicant projects Catawba County Dialysis will serve 45 patients on 16 stations, or a rate of 2.81 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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