

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 4, 2021

Findings Date: January 4, 2021

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: A-11975-20

Facility: Franklin Township Dialysis

FID #: 120162

County: Macon

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 1 dialysis station pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion

REVIEW CRITERIA

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

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

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “TRC” or “the applicant”) proposes to add no more than one dialysis station pursuant to Condition 1 of the facility need methodology for a total of no more than 12 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 not a county need determination for additional dialysis stations in Macon 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 reports the following:

Facility Need Methodology Condition 1 (New and Small Facilities Only)	Response
Number of months the facility had been certified as of the data cut-off date in the SMFP	71
Number of stations in the facility as of the data cut-off date in the SMFP	11
According to Table 9B in the 2020 SMFP, the facility is designated as new, small, or new and small	Small
Number of stations proposed in this application	1
Number of in-center patients per station as of the current reporting date	37
Current Reporting Date	7/31/2020
Previous Reporting Date	1/31/2020

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

1	# of In-center Patients as of the Current Reporting Date	37
2	# of In-Center Patients as of the Previous Reporting Date	32
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	5
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.15625
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.3125
6	Multiply Line 5 by Line 1 (New Patients)	11.5625
7	Add Line 6 to Line 1 (Total Patients)	48.5625
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	17.34375
9	# of Stations as of the Current Reporting Date ^	11
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	6.34375

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

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at Franklin Township Dialysis is six stations, based on rounding allowed in Condition 1.b.(vii). Condition 1.c of the facility need methodology states, “The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations.” The applicant proposes to add one new station;

therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

Policies

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

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

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

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

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

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

The applicant further discusses the promotion of safety and quality in Section N.2, page 49; and Section O, page 51, and referenced exhibits.

The applicant further discusses the promotion of equitable access in Section C.7, pages 23-24; Section L, pages 44-46; and Section N.2, page 49; and referenced exhibits.

The applicant further discusses maximizing healthcare value for resources expended in Section N.2, page 49.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
 - The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than one dialysis station to Franklin Township Dialysis pursuant to Condition 1 of the facility need methodology for a total of 12 stations following project completion.

According to Table 9A on page 134 of the 2020 SMFP, Franklin Township Dialysis offers in-center (IC) and home peritoneal (PD) dialysis services.

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

Patient Origin

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

The following table illustrates current patient origin, as of December 31, 2019.

**Franklin Township Dialysis
 Current Patient Origin
 As of December 31, 2019**

County	# IC Patients	% of IC Total	# PD Patients	% of PD Total
Macon	27	84.4%	3	37.5%
Clay	1	3.1%	3	37.5%
Georgia	2	6.3%	0	0.0%
South Carolina	1	3.1%	0	0.0%
Virginia	1	3.1%	0	0.0%
Cherokee	0	0.0%	2	25.0%
Total	32	100.0%	8	100.0%

Table may not foot due to rounding.
Source: Section C, page 19.

The following table illustrates the projected patient origin for operating year two (OY2), January 1, 2023-December 31, 2023.

**Franklin Township Dialysis
 Projected Patient Origin
 OY2**

County	# IC Patients	% of IC Total	# PD Patients	% of PD Total
Macon	43	91.5%	7	63.6%
Clay	1	2.1%	3	27.3%
Georgia	0	0.0%	0	0.0%
South Carolina	0	0.0%	0	0.0%
Virginia	0	0.0%	0	0.0%
Cherokee	0	0.0%	1	9.1%
Buncombe	1	2.1%	0	0.0%
Other States	2	4.3%	0	0.0%
Total	47	100.0%	11	100.0%

Table may not foot due to rounding.
Source: Section C, page 20

In Section C, pages 20-22, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 22, the applicant refers to the Facility Need Determination table in Section B.3, page 11, for an explanation of why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Section B, Question 3 clearly outlines the need that the population to [sic] served, the in-center patients of Franklin Township Dialysis, has for the 1-station expansion proposed in this application.”

Application of the facility need methodology on page 11 shows that Franklin Township Dialysis is eligible to apply for up to six dialysis stations. In Section Q Form C Utilization Assumptions and Methodology, the applicant provides information as to why the population projected to utilize the proposed services needs the proposed services, as summarized below:

- As of July 31, 2020, Franklin Township Dialysis had a patient census of 37 in-center patients dialyzing on 11 stations for a station utilization rate of 84.1%.
- Growing at Macon County's five-year Average Annual Change Rate (AACR), Franklin Township Dialysis will have 44 in-center patients and operate at a utilization rate of 92.5% on the 12 dialysis stations at the end of the project's first operating year, thus showing the need for the proposed additional dialysis station.

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

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

Projected Utilization

In Section Q Form C Utilization, the applicant provides its projected utilization for in-center and PD patients and treatments. The projected in-center and PD patient utilization is summarized below.

Form C Utilization*	Last Full OY 01/01/2019- 12/31/2019	Interim Year 01/01/2020- 12/31/2020	Interim Year 01/01/2021- 12/31/2021	First Full OY 01/01/2021- 12/31/2022	Second Full OY 01/01/2022- 12/31/2023
In-Center Patients					
# of Patients at the Beginning of the Year	29.00	32.00	37.95	40.87	44.04
# of Patients at the End of the Year	32.00	37.95	40.87	44.04	47.48
Average # of Patients during the Year	30.50	34.97	39.41	42.45	45.76
# of In-center Treatments / Patient / Year	156.26	148.20	148.20	148.20	148.20
Total # of In-center Treatments	4,766.00	5,183.00	5,839.92	6,291.17	6,781.23
PD Patients					
# of Patients at the Beginning of the Year	7.00	8.00	8.00	9.00	10.00
# of Patients at the End of the Year	8.00	8.00	9.00	10.00	11.00
Average # of Patients during the Year	7.50	8.00	8.50	9.50	10.50
# of Treatments / Patient / Year	163.33	148.20	148.2	148.20	148.20
Total # of Treatments	1,225.00	1,185.60	1,259.70	1,407.90	1,556.10
Total Patients					
# of Patients at the Beginning of the Year	36.00	40.00	45.95	49.87	54.04
# of Patients at the End of the Year	40.00	45.95	49.87	54.04	58.48
Average # of Patients during the Year	38.00	42.97	47.91	51.95	56.26
# of Treatments / Patient / Year	157.66	148.20	148.20	148.20	148.20
Total # of Treatments	5,991.00	6,368.60	7,099.62	7,699.07	8,337.33

*The applicant does not propose to serve home hemodialysis patients.

In-Center Patients

In Section Q, following Form C Utilization, the applicant provides the assumptions and methodology for its projected utilization.

Assumptions

- As of July 31, 2020, 33 of Franklin Township Dialysis' 37 dialysis patients lived in Macon County.
- Operating year one is projected to begin January 1, 2022 and end December 31, 2022.
- Operating year two is projected to begin January 1, 2023 and end December 31, 2023.
- The applicant applies the Macon County Five-Year AACR of 8.6%, per the 2020 SMFP, to project growth for its Macon County patients.
- The applicant does not grow the patient population from outside Macon County.

Methodology

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

	IC Stations	IC Patients per Application Calculation	IC Patients per Agency Calculation
Begin with facility census of Macon County patients as of 7/31/2020	11	33	33
Project this census forward from 8/1/20 to 12/31/2020 at 8.6% annually, increased by one third (4 of 12 months) of the five-year AACR of 8.6%*		$33 \times 1.0287 = 33.947$	$33 \times 1.0358 = 34.181$
Add the 4 patients from outside of Macon County		$33.947 + 4 = 37.947$	$34.181 + 4 = 38.181$
Project the Macon County population forward one year to December 31, 2021, using a growth rate of 8.6%.		$33.947 \times 1.086 = 36.8666$	$34.181 \times 1.086 = 37.121$
Add the 4 patients from outside of Macon County		$36.8666 + 4 = 40.8666$	$37.121 + 4 = 41.121$
Project Macon County patients forward one year to December 31, 2022, using a growth rate of 8.6%.	12	$36.8666 \times 1.086 = 40.036$	$37.121 \times 1.086 = 40.3134$
Add the 4 patients from outside of Macon County. This is the ending census for OY1, CY2022.		$40.036 + 4 = 44.036$	$40.3134 + 4 = 44.3134$
Project Macon County patients forward one year to December 31, 2023, using a growth rate of 8.6%.		$40.036 \times 1.086 = 43.479$	$40.3134 \times 1.086 = 43.780$
Add the 4 patients from outside of Macon County This is the ending census for OY2, CY2023.		$43.479 + 4 = 47.479$	$43.7804 + 4 = 47.780$

Source: Table in Section Q

Calculations may not be precise due to rounding

*The applicant uses one third (four of 12 months) of the facility AACR of 0.086 (0.0287) when the percentage should have been for five of 12 months (0.0358). The difference of the one-month growth at the outset of the projection results in no change for the ending census for OY1; however, it results in an increase of one patient in OY2 according to conventional rounding.

As the table above shows, using conventional rounding, the methodology used by the applicant and the Agency achieves a projection of 44 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 3.7 patients per station per week or 92.5% ($44 \text{ patients} / 12 \text{ stations} = 3.7 \text{ patients per station} / 4 = 0.925$). The projected utilization of 3.7 patients per station per week for CY2022 satisfies the 2.8 in-center patients per station per week threshold for the first full year following project completion as required by 10A NCAC 14C .2203(b).

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

- The applicant begins its projections using the current Macon County patient census as of July 31, 2020.

- The applicant uses the Macon County AACR, as recorded in the 2020 SMFP of 8.6% to grow the Macon County patients.
- The applicant does not grow the patients from outside Macon County.

Peritoneal Patients

In Section Q, following Form C, the applicant provides the following assumptions and methodology for projecting the PD patients in Form C Utilization.

- Begin with the PD patient volume as of July 31, 2020, a total of 7 PD patients.
- Operating year one is projected to begin January 1, 2022 and end December 31, 2022.
- Operating year two is projected to begin January 1, 2023 and end December 31, 2023.
- The applicant states that the home-training program will grow at a rate of at least one patient per year during the period of growth.
- Average number of patients during the year equals the mean of the beginning and ending facility census by year.

The following table summarizes the results of the above assumptions in the same format as the applicant provides for the in-center patient utilization and tying back to the PD patient numbers provided on the applicant’s Form C Utilization table.

PD Patients	Start Date	# of Patients - Beginning of Year	# of Patients - End of Year	Average # of Patients
Interim Period	1/1/2020	8.0	8.0	8.0
Interim Period	1/1/2021	8.0	9.0	8.5
OY1	1/1/2022	9.0	10.0	9.5
OY2	1/1/2023	10.0	11.0	10.5

Totals may not sum due to rounding.

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

- The applicant bases the beginning PD patient census on existing PD patients.
- The applicant projects the growth of the patient census by only one patient per year during the period of growth.

Access

In Section C, pages 23-24, the applicant states:

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

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

Franklin Township 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 24, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table. The applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY2019 and projected patient population in CY2023.

Medically Underserved Groups	% of Total Patients
Women	29.7%
People age 65 and older	48.6%
Medicare beneficiaries	96.9%
Medicaid recipients	0.0%
American Indian	2.7%
Asian	0.0%
Black or African-American	5.4%
Native Hawaiian or Pacific Islander	0.0%
White or Caucasian	91.9%
Other Race	0.0%

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

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

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

NA

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

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

CA

The applicant proposes to add no more than one dialysis station to Franklin Township Dialysis pursuant to Condition 1 of the facility need methodology for a total of 12 stations following project completion.

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

- Maintain the Status Quo: the applicant states maintaining the status quo was not an effective alternative because of the growth rate of the patient population at the facility.
- Relocate Stations from Another DaVita Facility: the applicant states that Franklin Township Dialysis is the only DaVita facility in Macon County. Macon County has a one-station surplus as indicated in Table 9C of the 2020 SMFP, so it is not possible to relocate stations from a continuous county.
- Apply for the One-station Expansion: the applicant states that this alternative meets the growing demand for dialysis services at Franklin Township Dialysis, as documented in responses to Sections B.3 and C.3.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- 1. 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 1 of the facility need determination in the 2020 SMFP, the certificate holder shall add no more than one additional in-center dialysis station for a total of no more than 12 in-center stations at Franklin Township Dialysis upon project completion.**
 - 3. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than one dialysis station to Franklin Township Dialysis pursuant to Condition 1 of the facility need methodology for a total of 12 stations following project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$19,948 to be used for medical equipment, non-medical equipment, and furniture. In Section Q, the applicant provides the assumptions used to project the capital cost. In Section F, pages 31-32, the applicant states there are no projected start-up expenses or initial operating expenses because Franklin Township Dialysis is an existing and operational facility.

Availability of Funds

In Section F, page 30, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the Chief Accounting Officer of DaVita, Inc., authorizing the use of accumulated reserves for the capital needs and any other needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2019, DaVita, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total In-center Treatments	6,291	6,781
Total PD Treatments	1,408	1,556
Total Treatments	7,699	8,337
Total In-center Gross Revenue	\$1,630,397	\$1,757,399
Total PD Gross Revenue	\$542,217	\$599,293
Total Gross Revenues (Charges)	\$2,172,615	\$2,356,692
Total Net Revenue	\$2,065,773	\$2,240,637
Average Net Revenue per Treatment	\$268	\$269
Total Operating Expenses (Costs)	\$1,608,800	\$1,690,388
Average Operating Expense per Treatment	\$209	\$203
Net Income/(Loss)	\$456,644	\$550,248

Totals may not sum due to rounding

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than one dialysis station to Franklin Township Dialysis pursuant to Condition 1 of the facility need methodology for a total of 12 stations following project completion.

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

Franklin Township Dialysis is the only existing and/or approved facility which provides dialysis and/or dialysis home training and support in Macon County, as shown below.

Macon County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Franklin Township Dialysis	DaVita	Franklin	11	65.91%

Source: Table 9B, page 158, Chapter 9, 2020 SMFP

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 Macon County:

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

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

C

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

Franklin Township Dialysis Current and Projected Staffing			
	Current	Projected	
	12/31/19	OY 1 (CY2022)	OY 2 (CY2023)
Administrator	1.00	1.00	1.00
Registered Nurses	1.50	1.50	1.50
Home Training Nurse	0.50	0.50	0.50
Patient Care Technicians	4.25	4.50	4.50
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Office	0.50	1.00	1.00
Biomed Technician	0.50	0.50	0.50
TOTAL	9.25	10.00	10.00

Adequate costs for the health manpower and management personnel proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing support for the proposed project and stating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I, page 38, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

Ancillary and Support Services	
Services	Provider
Self-care training (in-center)	On site
Peritoneal dialysis training & follow-up	On site
Home hemodialysis training & follow-up	Asheville Kidney center
Isolation – hepatitis	On site
Psychological counseling	On site (by registered nurse)
Nutritional counseling	On site (by registered dietician)
Social Work services	On site (by MSW)
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Mission Hospital
Emergency care	Mission Hospital
Blood bank services	Mission Hospital
Diagnostic and evaluation services	Mission Hospital
X-ray services	Mission Hospital
Pediatric nephrology	Mission Hospital
Vascular surgery	Mission Hospital
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Macon County Vocational Rehab Services
Transportation	Macon County Public Transport

The applicant provides supporting documentation in Exhibit I-1.

In Section I, pages 38-39, the applicant describes its existing relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 45, the applicant provides the historical payor mix during CY2019 for the facility's existing services, as shown in the table below.

Historical Payor Mix CY2019

Payment Source	IC Dialysis		PD Services	
	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	0.0	0.0%	1.0	12.5%
Medicare*	31.0	96.9%	7.0	87.5%
Medicaid*	0.0	0.0%	0.0	0.0%
Other (VA)	1.0	3.1%	0.0	0.0%
Total	32.0	100.0%	8.0	100.0%

*Including any managed care plans

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

	% of Patients Served During CY 2019	% of the Population of Macon County*
Female	29.7%	51.5%
Male	70.3%	48.5%
Unknown	0.0%	0.0%
64 and Younger	51.4%	71.1%
65 and Older	48.6%	28.9%
American Indian	2.7%	0.9%
Asian	0.0%	1.0%
Black or African-American	5.4%	1.7%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	91.9%	95.1%
Other Race	0.0%	1.2%
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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 45, that the facility has no obligation to provide uncompensated care or community service under any federal regulations.

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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 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.

Projected Payor Mix CY2023

Payment Source	IC Dialysis		PD Services	
	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	0.0	0.0%	1.4	12.5%
Medicare*	46.0	96.9%	9.6	87.5%
Medicaid*	0.0	0.0%	0.0	0.0%
Other (VA)	1.5	3.1%	0.0	0.0%
Total	47.5	100.0%	11.0	100.0%

Table may not foot due to rounding.

*Including any managed care plans

As shown in the table above, during the applicant's second full fiscal year following project completion, the applicant projects to provide 96.9 percent of IC dialysis services to Medicare patients and 0.0 percent of IC services to Medicaid patients. The applicant projects to provide 87.5 percent of PD services to Medicare patients and 0.0 percent of PD services to Medicaid patients.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 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 no more than one dialysis station to Franklin Township Dialysis pursuant to Condition 1 of the facility need methodology for a total of 12 stations following project completion.

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

Franklin Township Dialysis is the only existing and/or approved facility which provides dialysis and/or dialysis home training and support in Macon County, as shown below.

Macon County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Franklin Township Dialysis	DaVita	Franklin	11	65.91%

Source: Table 9B, page 158, Chapter 9, 2020 SMFP

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

“The expansion of Franklin Township Dialysis will have no effect on competition in Macon County.”

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

The expansion of Franklin Township Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will

make it easier for patients, family members and others involved in the dialysis process to receive services.

...

As discussed in Section B, DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients.”

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

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

“The expansion of Franklin Township Dialysis will enhance accessibility to dialysis for current and projected patients, . . .”

In Section N, page 50, the applicant states:

“The expansion of this facility is not expected to have an unfavorable impact on competition nor cost effectiveness, quality, and access to the proposed services.”

See also Section L of the application and any exhibits.

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, quality, and access because it adequately demonstrates the following:

- the need the population to be served has for the proposal, the proposal would not result in an unnecessary duplication of existing and approved health services, and the reasonableness of projected revenues and operating costs which collectively results in a cost-effective proposal.
- the quality of the care to 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.
- 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 for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.7, page 9, the applicant states that DaVita Inc. and its related entities operate over 100 facilities in North Carolina and provides a listing in Section Q Form A.

In Section O, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident resulting in an Immediate Jeopardy violation occurred in one of its related facilities. The applicant states that all the problems have been corrected and the facility is back in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 100+ facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of*

2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- Franklin Township 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 21, and on Form C in Section Q, the applicant projects that Franklin Township Dialysis will serve 44 patients on 12 stations, or a rate of 3.7 patients per station per week, as of the end of the first operating year following project completion, exceeding the 2.8 patients per station per week requirement. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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