

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 8, 2021

Findings Date: January 8, 2021

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: G-11970-20

Facility: Mebane Dialysis

FID #: 170018

County: Alamance

Applicant: Renal Treatment Centers - Mid-Atlantic, Inc.

Project: Add no more than 6 dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 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

Renal Treatment Centers - Mid-Atlantic, Inc. (hereinafter referred to as “RTC” or “the applicant”) proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 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 Alamance 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	12
Number of stations in the facility as of the data cut-off date in the SMFP	10
According to Table 9B in the 2020 SMFP, the facility is designated as new, small, or new and small	New and Small
Number of stations proposed in this application	6
Number of in-center patients per station as of the current reporting date	31
Current Reporting Date	6/30/2020
Previous Reporting Date	12/31/2019

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	31
2	# of In-Center Patients as of the Previous Reporting Date	25
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	6
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.24
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.48
6	Multiply Line 5 by Line 1 (New Patients)	14.88
7	Add Line 6 to Line 1 (Total Patients)	45.88
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	16.3857
9	# of Stations as of the Current Reporting Date ^	10
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	6.3857

^ 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 Mebane 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 six new stations; therefore,

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

Policies

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

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

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

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

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

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 50; and Section O, pages 52-53, and referenced exhibits.

The applicant further discusses the promotion of equitable access in Section C.7, page 23; Section L, pages 45-47; and Section N.2, page 50; and referenced exhibits.

The applicant further discusses maximizing healthcare value for resources expended in Section N.2, page 50.

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 that the application is consistent with Policy GEN-3 based on 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 six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

According to Table 9A on page 118 of the 2020 SMFP, Mebane Dialysis offers only in-center (IC) dialysis services.

In Section A, page 5, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with RTC to refer to itself or its facilities. References to DaVita should be interpreted to mean RTC 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 Alamance County. Facilities may serve residents of counties not included in their service area.

The following table provides current patient origin, as of December 31, 2019 and projected patient origin for the second operating year (OY2), January 1, 2023-December 31, 2023.

**Mebane Dialysis
In-Center Patient Origin**

County	Historical CY2019		Projected OY2 CY2023	
	Patients	% of Total	Patients	% Total
Alamance	18	72.0%	42	80.8%
Orange	4	16.0%	6	11.5%
Guilford	1	4.0%	1	1.9%
Caswell	1	4.0%	1	1.9%
Northampton	1	4.0%	1	1.9%
Durham	0	0.0%	1	1.9%
Total	25	100.0%	52	100.0%

Table may not foot due to rounding
Source: Section C, pages 19-20

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

- The applicant projects patient origin at the facility based on its existing population.
- The applicant increases the number of projected future patients based on a reasonable growth rate considering the facility's two-year growth rate

Analysis of Need

In Section C.4, pages 21-22, 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 Mebane Dialysis, has for the 6-station expansion proposed in this application.”

Application of the facility need methodology on page 11 shows that the facility 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 June 30, 2020, the facility had a patient census of 31 in-center patients dialyzing on 10 stations for a station utilization rate of 77.5%.
- Growing at 22.0%, which is higher than the county's five-year Average Annual Change Rate (AACR) of 3.0% and lower than the facility's two-year annualized growth rate of 38%, the facility will have 45 in-center patients and operate at a utilization rate of 70.3% on the 16 dialysis stations at the end of the project's first operating year, thus showing the need for the proposed additional dialysis stations.

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

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

Projected Utilization

In Section Q Form C Utilization, the applicant provides its projected utilization for in-center patients and treatments. The projected in-center 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	13.00	25.00	33.31	38.44	44.69
# of Patients at the End of the Year	25.00	33.31	38.44	44.69	52.33
Average # of Patients during the Year	19.00	29.16	35.87	41.57	48.51
# of In-center Treatments / Patient / Year	147.42	148.20	148.20	148.20	148.20
Total # of In-center Treatments	2,801.00	4,320.77	5,316.54	6,160.14	7,189.33
Total Patients					
# of Patients at the Beginning of the Year	13.00	25.00	33.31	38.44	44.69
# of Patients at the End of the Year	25.00	33.31	38.44	44.69	52.33
Average # of Patients during the Year	19.00	29.16	35.87	41.57	48.51
# of Treatments / Patient / Year	147.42	148.20	148.20	148.20	148.20
Total # of Treatments	2,801.00	4,320.77	5,316.54	6,160.14	7,189.33

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

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

Assumptions

- The census, as reported in the facility’s December 2019 ESRD Data Collection form, included 25 in-center patients.
- Projections begin with the patient population as of June 30, 2020, which includes 31 in-center patients with 21 living in Alamance County.
- The applicant applies a growth rate of 22.0% to the beginning census of Alamance County residents.
 - Per Table 9C of the 2020 SMFP, the Alamance County Five-year AACR is 3.0%.
 - The applicant provides the facility’s patient census from December 2018 through June 2020, through 2019, resulting in a 92.3% increase during 2019 and a 19.4% increase from December 31, 2019 through June 30, 2020.

- The applicant states that a 22.0% growth rate is therefore reasonable, “so as to be conservative.”
- 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 does not grow the patient population from outside Alamance County.

Methodology

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

	IC Stations	IC Patients
Begin with facility census of Alamance County patients as of June 30, 2020.	10	21
Project this census forward six months to 12/31/2020 at 11.0%, half the proposed annual growth rate of 22.0%.		$21 \times 1.011 = 23.31$
Add the 10 patients from outside of Alamance County		$23.31 + 10 = 33.31$
Project the Alamance County population forward one year to December 31, 2021, using a growth rate of 22.0%.		$23.31 \times 1.22 = 28.44$
Add the 10 patients from outside of Alamance County		$28.44 + 10 = 38.44$
Project Alamance County patients forward one year to December 31, 2022, using a growth rate of 22.0%.	$10 + 6 = 16$	$28.44 \times 1.22 = 34.69$
Add the 10 patients from outside of Alamance County. This is the ending census for OY1, CY2022.		$34.69 + 10 = 44.69$
Project Alamance County patients forward one year to December 31, 2023, using a growth rate of 22.0%.		$34.69 \times 1.22 = 42.33$
Add the 10 patients from outside Alamance County. This is the ending census for OY2, CY2023.		$42.33 + 10 = 52.33$

Source: Table in Section Q

Calculations may not be precise due to rounding

As the table above shows, using conventional rounding, the methodology used by the applicant achieves a projection of 45 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 2.8 patients per station per week or 70.3% ($45 \text{ patients} / 16 \text{ stations} = 2.81 \text{ patients per station} / 4 = 0.703$). The projected utilization of 2.8 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 bases the beginning patient census on existing patients served.
- The applicant projects the growth of the patient census by 22% annually based on its status as a new and small facility which increased by 92% during its first year of operation and another 19% during the following six-month period, which represents an annualized growth rate of 38%.

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 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.

Mebane 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 23, 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	46.2%
People age 65 and older	57.7%
Medicare beneficiaries	92.0%
Medicaid recipients	0.0%
American Indian	0.0%
Asian	3.8%
Black or African-American	61.5%
Native Hawaiian or Pacific Islander	0.0%
White or Caucasian	34.6%
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 six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

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

- Maintain the Status Quo: the applicant states 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 Mebane Dialysis is one of five DaVita facilities in Alamance County. The applicant states that three of the other DaVita Alamance County facilities have high utilization and the fourth, Glen Raven Dialysis is newly certified with only 10 stations; thus, relocating stations from any of those facilities would negatively impact the patients presently served by those facilities.
- Apply for the Six-station Expansion: the applicant states that this alternative meets the growing demand for dialysis services at Mebane 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. Renal Treatment Centers - Mid-Atlantic, Inc. (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 six additional in-center dialysis stations for a total of no more than 16 in-center stations at Mebane Dialysis upon project completion.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.**

4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$102,006 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. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

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

In Section F, pages 31-32, the applicant states there are no projected start-up expenses or initial operating expenses because Mebane 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 shows that as of December 31, 2019, DaVita, Inc. had adequate cash and assets to fund the capital needs of the proposed project.

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

- DaVita is the parent and 100% owner of RTC.
- The Chief Accounting Officer for DaVita confirms DaVita's willingness to commit the funds to the development of the project.

- DaVita’s December 31, 2019 Form 10-K shows adequate cash and assets to fund the capital needs 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	6,160	7,189
Total Gross Revenues (Charges)	\$2,090,505	\$2,439,772
Total Net Revenue	\$1,962,682	\$2,290,593
Average Net Revenue per Treatment	\$319	\$319
Total Operating Expenses (Costs)	\$1,789,438	\$1,960,760
Average Operating Expense per Treatment	\$290	\$273
Net Income/(Loss)	\$173,245	\$329,833

Totals may not sum due to rounding

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

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

According to Table 9B of the 2020 SMFP, there are seven existing or approved dialysis facilities in Alamance County. Information on these dialysis facilities, from Table 9B of the 2020 SMFP, is provided below:

Alamance County Dialysis Facilities

Dialysis Facility	Owner/ Operator	Certified Stations	Percent Utilization	Patients Per Station Per Week
Alamance County Dialysis	DaVita	10	90.00%	3.6
BMA of Burlington	BMA	45	53.89%	2.2
Burlington Dialysis	DaVita	16	101.56%	4.1
Carolina Dialysis of Mebane	BMA	20	80.00%	3.2
Glen Raven Dialysis ^{^/^^}	DaVita	10	60.00%	2.4
Mebane Dialysis ^{^/^^}	DaVita	10	32.50%	1.3
North Burlington Dialysis	DaVita	18	96.88%	3.9

Source: 2020 SMFP, Table 9B, page 151

^{^/^^}New facility / Small facility

Per the 2020 SMFP and the table above, DaVita related entities own and operate five of the seven existing dialysis facilities in Alamance County. Of the five DaVita related facilities in Alamance County, three are operating at 80% capacity or greater and the other two are designated as new and small facilities.

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 Alamance County:

“In Section B, Question 3 and Section C, Question 3 of this application, we demonstrate the need that Mebane Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Alamance 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 Alamance 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 Alamance 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

The applicant proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

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

Mebane 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	1.25	2.00	2.00
Patient Care Technicians	3.75	6.00	6.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Office	0.50	1.00	1.00
Biomed Technician	0.50	0.50	0.50
TOTAL	8.00	11.50	11.50

The assumptions and methodology used to project staffing are provided in Section Q Form F.4 Operating Costs and Form H Staffing. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 37-38, 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 Exhibit H.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant bases future staffing needs at the facility on historical staffing with the number of FTE positions being a function of the number of stations and the patient census to ensure safety and quality of care and maximize cost effectiveness.
- The type of positions include is guided by policy based on the CMS Conditions for Coverage.

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

The applicant proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

Ancillary and Support Services

In Section I, page 39, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The stated ancillary and support services are currently available.
- The applicant provides a letter from the facility administrator in Exhibit I.1 committing to the continuation of the established agreements.
- The applicant provides copies of agreements for ancillary and support services in Exhibit I.1.

Coordination

In Section I, pages 39-40, the applicant describes its existing 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 based on the following:

- The applicant provides a listing of established relationships with the existing health care system in Exhibit I.1.
- The applicant provides a letter from the facility administrator in Exhibit I.1 committing to the continuation of the established relationships.

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 46, 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		HH/PD Services	
	# Patients	% Patients	# Patients	% of Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	2.0	8.0%	0.0	0.0%
Medicare*	23.0	92.0%	0.0	0.0%
Medicaid*	0.0	0.0%	0.0	0.0%
Other (VA)	0.0	0.0%	0.0	0.0%
Total	25.0	100.0%	0.0	0.0%

*Including any managed care plans

In Section L, page 45, the applicant provides the following comparison.

	% of Patients Served During CY 2019	% of the Population of Alamance County*
Female	46.2%	52.6%
Male	53.8%	47.4%
Unknown	0.0%	0.0%
64 and Younger	42.3%	83.1%
65 and Older	57.7%	16.9%
American Indian	0.0%	1.4%
Asian	3.8%	1.8%
Black or African-American	61.5%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	34.6%	73.9%
Other Race	0.0%	2.2%
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 46, that the facility has no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 46, 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 47, 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		HH/PD Services	
	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	0.0	0.0%
Insurance*	4.2	8.0%	0.0	0.0%
Medicare*	48.1	92.0%	0.0	0.0%
Medicaid*	0.0	0.0%	0.0	0.0%
Other (VA)	0.0	0.0%	0.0	0.0%
Total	52.3	100.0%	0.0	0.0%

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 92.0 percent of in-center dialysis services to Medicare patients and 0.0 percent of services to Medicaid patients.

On page 47, 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 47-48, 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

The applicant proposes to add no more than six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

In Section M, page 49, 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. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant offers the facility as a clinical learning site for students from Alamance Community College.
- The applicant provides a copy of the letter offering the facility as a learning site 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 six dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 16 stations upon project completion.

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

According to Table 9B of the 2020 SMFP, there are seven existing or approved dialysis facilities in Alamance County. Information on these dialysis facilities, from Table 9B of the 2020 SMFP, is provided below:

Alamance County Dialysis Facilities

Dialysis Facility	Owner/ Operator	Certified Stations	Percent Utilization	Patients Per Station Per Week
Alamance County Dialysis	DaVita	10	90.00%	3.6
BMA of Burlington	BMA	45	53.89%	2.2
Burlington Dialysis	DaVita	16	101.56%	4.1
Carolina Dialysis of Mebane	BMA	20	80.00%	3.2
Glen Raven Dialysis ^{^/^^}	DaVita	10	60.00%	2.4
Mebane Dialysis ^{^/^^}	DaVita	10	32.50%	1.3
North Burlington Dialysis	DaVita	18	96.88%	3.9

Source: 2020 SMFP, Table 9B, page 151

^{^/^^}New facility / Small facility

Per the 2020 SMFP and the table above, DaVita related entities own and operate five of the seven existing dialysis facilities in Alamance County. Of the five DaVita related facilities in Alamance County, three are operating at 80% capacity or greater and the other two are designated as new facilities.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 50, the applicant states:

“The expansion of Mebane Dialysis will have no effect on competition in Alamance County.”

Regarding the impact of the proposal on quality and cost effectiveness, in Section N, page 50, the applicant states:

“The expansion of Mebane 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 50, the applicant states:

“The expansion of Mebane Dialysis will enhance accessibility to dialysis for our patients, ...”

In Section N, page 51, 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 52-53, 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 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- Mebane 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 Mebane Dialysis will serve 45 patients on 16 stations, or a rate of 2.8 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 used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.