

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 3, 2022

Findings Date: June 3, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: G-12197-22

Facility: Mebane Dialysis

FID #: 170018

County: Alamance

Applicant(s): Renal Treatment Centers-Mid-Atlantic, Inc.

Project: Add no more than two in-center dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 18 in-center 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

The applicant, Renal Treatment Centers-Mid-Atlantic, Inc. (“the applicant”), proposes to add no more than two in-center (IC) dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

Mebane Dialysis does not provide a peritoneal dialysis or home hemodialysis program.

Need Determination (Condition 2)

Chapter 9 of the 2022 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9C, page 139, 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 2 of the facility need methodology in the 2022 SMFP, if the utilization rate for the facility as reported in the 2022 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for the facility is 87.50 percent or 3.5 patients per station per week, based on 35 in-center dialysis patients and 10 certified dialysis stations (35 patients / 10 stations = 3.5; $3.5 / 4 = 0.875$ or 87.50%).

As shown in Table 9D, page 140, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to two additional stations; thus, the applicant is eligible to apply to add up to two stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

Policies

There is one policy in the 2022 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, page 30 of the 2022 SMFP, states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 20-21; Section N, page 77; Section O, pages 80-82; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 21-22; Section C, pages 31-32; Section L, pages 69-73; Section N, page 77; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 22; Section F, pages 44-45; Section N, page 77; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on:
 - DaVita (parent corporation) facilities encourage all staff to provide quality care to every patient at every treatment as part of their quality management program and their goal to create a “culture of safety” by incorporating components that promote safety and quality.
 - DaVita facilities have a history of providing care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category defined as underserved.
 - DaVita facilities incorporate cost-saving strategies such as preventative maintenance and an inventory control plan.

(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.

The applicant proposes to add no more than two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

Mebane Dialysis				
County	Historical Patient Origin		Projected patient Origin	
	Last Full FY		2nd Full FY	
	01/01/2021-12/31/2021 (FY 2021)		01/01/2024-12/31/2024 (FY 2024)	
	IC Patients	% of Total	IC Patients	% of Total
Alamance	22	59.5%	43	74.0%
Caswell	2	5.4%	2	3.5%
Chatham	1	2.7%	1	1.7%
Durham	1	2.7%	1	1.7%
Orange	7	18.9%	7	12.1%
Person	1	2.7%	1	1.7%
Rockingham	1	2.7%	1	1.7%
Vance	1	2.7%	1	1.7%
Other States	1	2.7%	1	1.7%
Total	37	100.0%	58	100.0%

Source: Section C, pages 25-26
 Totals may not foot due to rounding.

In Section C, page 27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin for Alamance residents based on the facility’s historical patient origin. The applicant does not project growth for patients residing outside Alamance County. The applicant’s assumptions are reasonable and adequately supported. The applicant projects patient origin for Alamance County residents using an annual growth rate of 18%, which is significantly lower than the actual average annual growth rate experienced at the facility during the most recent three years.

Analysis of Need

In Section C, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 28-29, the applicant states:

“There is a facility need determination of 2 stations for Mebane Dialysis, which had 16 existing stations, as reported in Tables 9D and 9A of the 2022 SMFP...we demonstrate that an additional 2 stations will be well utilized by the population to be served, the current and projected in-center patients of Mebane Dialysis. The addition

of stations serves to increase capacity and proactively address the issues of growth and access at the facility.”

The information is reasonable and adequately supported based on the following:

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2022 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility’s historical growth in the patient population.

Projected Utilization

In Section C, page 28 and Section Q, page 89, the applicant provides projected utilization, as illustrated in the following table.

Mebane Dialysis Projected Utilization		
	IC stations	IC patients
The applicant begins with the 37 patients dialyzing on 16 stations at the facility as of December 31, 2021.	16	37
The facility's Alamance County patient census is projected forward a year to December 31, 2022 and is increased by 18.0%.		$22 \times 1.180 = 25.960$
The 15 patients from outside Alamance County are added to the facility's census. This is the ending census for the first full interim year.		$25.96 + 15 = 40.96$
The facility's Alamance County patient census is projected forward a year to December 31, 2023 and is increased by 18.0%.		$25.96 \times 1.180 = 30.63280$
The 15 patients from outside Alamance County are added to the facility's census. This is the ending census for the second full interim year.		$30.63 + 15 = 45.63$
The proposed project is projected to be certified on January 1, 2024. This is the station count at the beginning of the project's first full fiscal year (FY1). The facility's Alamance County patient census is projected forward a year to December 31, 2024 and is increased by 18.0%.		$16 + 2 = 18$
The 15 patients from outside Alamance County are added to the facility's census. This is the ending census for FY1.		$36.15 + 15 = 51.15$
The facility's Alamance County patient census is projected forward a year to December 31, 2025 and is increased by 18.0%.		$36.15 \times 1.180 = 42.65311$
The 15 patients from outside Alamance County are added to the facility's census. This is ending census as of the project's second full fiscal year (FY2).		$42.65 + 15 = 57.65$

Totals may not foot due to rounding.

In Section C, pages 27-28 and Section Q, pages 88-89, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins projections of the future patient population to be served with the facility census as of December 31, 2021.
- The applicant projects the growth of the Alamance County patient population using a growth rate of 18%.
- As of December 31, 2021, the facility was serving 15 patients residing outside of Alamance County. The applicant does not project growth for this population and adds these patients to projections of future patient populations at the appropriate time.
- The applicant projects the first fiscal year of the project will be January 1, 2024–December 31, 2024 and the second full fiscal year will be January 1, 2025–December 31, 2025.

At the end of FY1, Mebane Dialysis is projected to serve 51 IC patients and at the end of FY2 the facility is projected to serve 58 IC patients on 18 stations.

The projected utilization rates for the end of first two full fiscal years are as follows:

- FY1: 2.8 patients per station per week or 70.83% ($51 \text{ patients} / 18 \text{ stations} = 2.8333/4 = 0.7083$ or 70.83%)
- FY2: 3.2 patients per station per week or 80.55% ($58 \text{ patients} / 18 \text{ stations} = 3.2222/4 = 0.8055$ or 80.55%)

The projected utilization of 2.8 patients per station per week at the end of FY1 meets the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects utilization using a growth rate that is conservative given the facility's growth the last few years.
- The applicant's proposal to add two dialysis stations will meet the need of the significant growth of the facility's patient population.
- Projected utilization at the end of FY1 meets the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 31, the applicant states:

“By policy, the proposed services will be made available to all residents in the service area without qualifications.”

The applicant provides the estimated percentage during the second full fiscal year for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	78.6%
Racial and ethnic minorities	53.7%
Women	43.9%
Persons with Disabilities	100.0%
Persons 65 and Older	63.4%
Medicare beneficiaries	64.9%
Medicaid recipients	10.8%

Source: Section C, page 32

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 because Mebane Dialysis is an existing dialysis facility in Alamance County currently providing services to underserved groups.

Conclusion

The Agency reviewed the:

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

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

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

NA

The applicant does not propose a reduction, elimination or relocation of 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 two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

In Section E, page 42, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo-The applicant states that this alternative was dismissed because of the facility's historical growth in the patient population.

Relocate Stations from Another DaVita Facility-The applicant states that this alternative would negatively impact operations at the only DaVita facility in Alamance County operating at less than 75% capacity.

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

- The applicant's proposal is in response to a facility need pursuant to condition 2 of the facility need methodology, as reported in the 2022 SMFP.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. 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 2 of the facility need determination in the 2022 SMFP, the certificate holder shall develop no more than two additional in-center dialysis stations for a total of no more than 18 in-center (and home hemodialysis) 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. The first progress report shall be due on December 1, 2022.
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 two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

Capital and Working Capital Costs

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

Mebane Dialysis Capital Costs	
Medical Equipment	\$28,000
Non-Medical Equipment	\$5,693
Furniture	\$3,000
Total	\$36,693

In Section Q, page 93, the applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions. DaVita, Inc., parent corporation to Renal Treatment Centers-Mid-Atlantic, Inc., incorporates a project management team to develop capital cost for their projects and ensure project costs are reasonable.

In Section F, page 45, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because revenues exceed operating costs at this existing facility.

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Renal Treatment Centers-Mid-Atlantic, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$36,693	\$36,693
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$36,693	\$36,693

* OE = Owner's Equity

Exhibit F-2 contains a letter from the Chief Accounting Officer of DaVita, Inc., parent corporation to Renal Treatment Centers-Mid-Atlantic, Inc., stating its commitment to fund the project through its cash reserves. Exhibit F-2 also contains DaVita's 2021 consolidated balance sheets stating there are over \$460 million in cash and cash equivalents and over \$17 billion in assets available to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibit F-2.

Financial Feasibility

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

Mebane Dialysis	1 st Full FY FY2024	2 nd Full FY FY 2025
Total Treatments	7,171	8,062
Total Gross Revenues (Charges)	\$3,098,028	\$3,482,813
Total Net Revenue	\$2,899,229	\$3,259,322
Average Net Revenue per Treatment	\$404	\$404
Total Operating Expenses (Costs)	\$1,834,712	\$1,955,937
Average Operating Expense per Treatment	\$256	\$243
Net Income	\$1,064,517	\$1,303,385

Totals may not foot due to rounding.

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- 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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Alamance County as of December 31, 2020, as reported in the 2022 SMFP. There are seven dialysis facilities providing dialysis services.

Facility Name	Certified Stations as of 12/31/2020	# IC Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020	Patients Per Station Per Week
Alamance County Dialysis	13	42	80.77%	3.23
BMA of Burlington	45	94	52.22%	2.09
Burlington Dialysis	16	71	110.94%	4.44
Carolina Dialysis of Mebane	24	72	75.00%	3.00
Glen Raven Dialysis	14	27	48.21%	1.93
Mebane Dialysis	10	35	87.50%	3.50
North Burlington Dialysis	18	57	79.17%	3.17
Total	140	398		

Source: Table 9A on page 121 of the 2022 SMFP

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Alamance County. The applicant states:

“Based on the facility need methodology in the 2022 SMFP under Condition 2, Mebane Dialysis qualifies to add up to two (2) dialysis stations...It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists.”

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

- The applicant adequately demonstrates that the proposed dialysis stations is needed in addition to the existing or approved dialysis stations.
- There is a facility need determination in the 2022 SMFP for the proposed two dialysis stations.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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 two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

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

	Current Staff	Projected FTE Staff	
	as of 02/28/2022	1 st Full FY FY 2024	2 nd Full FY FY 2025
Administrator	1.00	1.00	1.00
RNs	2.00	2.25	2.25
Technicians (PCT)	6.00	6.75	6.75
Dieticians	0.50	0.50	0.50
Social Work	0.50	0.50	0.50
Administration/Business Office	1.00	1.00	1.00
Other-Biomedical Tech	0.50	0.50	0.50
TOTAL	11.50	12.50	12.50

The assumptions and methodology used to project staffing are provided in Section Q, page 101. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 54-55, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- Facility administrators partner with DaVita’s Teammate Recruiter to assist with staffing needs.
- DaVita’s School of Clinical Education provides clinical and technical training to nurses and patient care technicians.

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 all the reasons described above.

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

C

The applicant proposes to add no more than two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

Ancillary and Support Services

In Section I, page 57, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 57-59, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 60, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- As a provider of dialysis services in Alamance County, the facility has established relationships with several healthcare providers and social service agencies in the county.
- In Exhibit 1.2, the applicant provides letters from the facility's administrator and medical director stating their intention to continue their agreements and working relationship.

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 all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space nor 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 69, the applicant provides the historical payor mix during FY 2021 for the proposed services, as shown in the table below.

Mebane Dialysis Historical Payor Mix FY 2021		
Payor Category	IC Patients	% of Total
Self-Pay	1	2.7%
Insurance*	7	18.9%
Medicare*	24	64.9%
Medicaid*	4	10.8%
Other - VA	1	2.7%
Total	37	100.0%

*Including any managed care plans.

In Section L, page 70, the applicant provides the following comparison.

Mebane Dialysis	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	43.9%	52.5%
Male	56.1%	47.5%
Unknown	N/A	N/A
64 and Younger	36.6%	82.9%
65 and Older	63.4%	17.1%
American Indian	0.0%	1.5%
Asian	0.0%	1.7%
Black or African-American	46.3%	20.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	46.3%	73.6%
Other Race	7.3%	2.3%
Declined / Unavailable	N/A	N/A

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

The Agency reviewed the:

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

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

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

C

In Section L, page 71, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 71, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 72, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Mebane Dialysis Projected Payor Mix FY 2025		
Payor Category	In-Center Patients	% of Total
Self-Pay	1.56	2.7%
Insurance*	10.91	18.9%
Medicare*	37.40	64.9%
Medicaid*	6.23	10.8%
Other - VA	1.56	2.7%
Total	57.65	100.0%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.7% of total services will be provided to self-pay patients, 64.9% to Medicare patients and 10.8% to Medicaid patients.

The applicant does not include charity care in the projected payor mix. However, on page 71, the applicant estimates that the facility will serve three charity care patients per year in the first three years of the project.

On page 72, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on the historical patient census and percentage of treatment by payor category.
- Patients are calculated as partial patients based on multiple payor sources applied to one patient during a fiscal year.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 73, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

In Section M, page 75, 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.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on Mebane Dialysis serving as clinical learning site for nursing students from Alamance Technical Community College.

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 all the reasons described above.

- (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 two IC dialysis stations to Mebane Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 18 IC dialysis stations upon project completion.

On page 115, the 2022 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located.”* Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Alamance County as of December 31, 2020, as reported in the 2022 SMFP. There are dialysis facilities providing dialysis services.

Facility Name	Certified Stations as of 12/31/2020	# IC Patients as of 12/31/2020	Utilization by Percent as of 12/31/2020	Patients Per Station Per Week
Alamance County Dialysis	13	42	80.77%	3.23
BMA of Burlington	45	94	52.22%	2.09
Burlington Dialysis	16	71	110.94%	4.44
Carolina Dialysis of Mebane	24	72	75.00%	3.00
Glen Raven Dialysis	14	27	48.21%	1.93
Mebane Dialysis	10	35	87.50%	3.50
North Burlington Dialysis	18	57	79.17%	3.17
Total	140	398		

Source: Table 9A on page 121 of the 2022 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, the applicant states:

“Although the addition of stations at this facility could serve to provide more patients another option...this project primarily serves to address the needs of a population already served...”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 77, the applicant states:

“...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.”

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

Regarding the impact of the proposal on quality, in Section N, page 77, the applicant states:

“...this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meet their needs...”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 77, the applicant states:

“The expansion of Mebane Dialysis will enhance accessibility and/or convenience to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients...”

See also Sections L, B and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form O, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 106 of this type of facility located in North Carolina.

In Section O, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new dialysis facility for in-center hemodialysis services 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 full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.*

-NA- The applicant is not proposing to establish a new dialysis facility.

- (b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.

- C- In Section C, pages 27-28 and Section Q, pages 89-90, the applicant projects that Mebane Dialysis will serve 51 IC patients on 18 stations, or a rate of 2.8 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- In Section C, pages 27-28 and Section Q, pages 89-90, 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.