

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 4, 2024

Findings Date: October 4, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Mike McKillip

Project ID #: D-12529-24

Facility: Mayland Dialysis Center

FID #: 060380

County: Mitchell

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

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

### REVIEW CRITERIA

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

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

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or “Mayland Dialysis Center”) proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

#### **Need Determination (Condition 1)**

Chapter 9 of the 2024 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, on page 136 of the 2024 SMFP, the county need methodology shows there is not a county need determination for additional dialysis stations anywhere in the state.

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 2024 SMFP, if the facility is a “new,” “small,” or “new and small” facility as defined in the 2024 SMFP, and if the facility’s current reported utilization is at least 75%, 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. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

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 2024 SMFP, if the facility is a “new,” “small,” or “new and small” facility as defined in the 2024 SMFP, and if the facility’s current reported utilization is at least 75%, 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. If applying pursuant to Condition 1, the facility may only apply once during the calendar year.

In Section B, page 19, the applicant reports the following:

<b>Facility Need Methodology Condition 1 (New and Small Facilities Only)</b>	<b>Response</b>
Number of months the facility had been certified as of the data cut-off date in the SMFP	177
Number of stations in the facility as of the data cut-off date in the SMFP	9
According to Table 9A in the 2024 SMFP, the facility is designated as new, small, or new and small	Small
Number of stations proposed in this application	3
Number of in-center patients per station as of the current reporting date	3.0
<b>Current Reporting Date</b> (no more than 90 days before the application is submitted)	4/30/2024
<b>Previous Reporting Date</b> (six months prior to the Current Reporting Date)	10/30/2023

Application of the facility need methodology for Condition 1 indicates that up to a potential maximum of 7 additional stations are needed at this facility, as illustrated in the following table.

<b>1</b>	# of In-center Patients as of the Current Reporting Date *	27
<b>2</b>	# of In-Center Patients as of the Previous Reporting Date **	20
<b>3</b>	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	7
<b>4</b>	Divide Line 3 by Line 2 (6-month Growth Rate)	0.35
<b>5</b>	Multiply Line 4 by 2 (Annual Growth Rate)	0.7
<b>6</b>	Multiply Line 5 by Line 1 (New Patients)	18.9
<b>7</b>	Add Line 6 to Line 1 (Total Patients)	45.9
<b>8</b>	Divide Line 7 by 2.8 (Total # of Stations Needed)	16.4
<b>9</b>	# of Stations as of the Application Deadline^	9
<b>10</b>	Subtract Line 9 from Line 8 (Additional Stations Needed)	7.4

\* Current Reporting date should be no more than 90 days before the date the CON application was submitted.

\*\* Previous Reporting date is six months prior to the Current Reporting date.

^ Includes all stations that were: 1) certified; 2) CON approved but not yet certified; and 3) proposed to be added in applications still under review as of the application deadline.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 7, 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.*” Mayland Dialysis Center proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion; therefore, the application is consistent with Condition 1 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2024 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2024 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, page 20, Section N, page 74, and Section O, pages 77-79. 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 L, pages 68-70, Section N, pages 74-75, 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, and Section N, page 74. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal 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

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 Condition 1 of the facility need methodology as applied from the 2024 SMFP.
  - The applicant adequately demonstrates how Mayland Dialysis Center projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3.
- (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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

In Section C, page 25, the applicant states Mayland provides in-center hemodialysis. There are nine (9) certified dialysis stations, as reported in Table 9A of the Proposed 2025 SMFP. This project proposes the addition of three (3) stations pursuant to Condition 1 of the facility need methodology of the 2024 SMFP for a total of 12 in-center stations upon project completion.

### **Patient Origin**

On page 113, the 2024 SMFP defines the service area for dialysis stations as “...*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Avery, Mitchell, and Yancey Counties. Facilities may serve residents of counties not included in their service area. The following table illustrates current and projected patient origin.

Mayland Dialysis Center				
County	Last Full FY CY2023		Second Full FY Project Completion CY2027	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Mitchell	13	54.2%	22.7598	56.3%
Yancey	10	41.7%	16.691	41.3%
Other States	1	4.2%	1	2.5%
<b>Total</b>	<b>24</b>	<b>100.0%</b>	<b>40.4504</b>	<b>100.0%</b>

Source: Section C, pages 24-25

In Section C, pages 26-28, and Form C in Section Q, 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 bases projected patient origin on the historical patient origin from the facility census as of December 31, 2023.
- The applicant explains the growth projections for Mitchell-Yancey Counties patient population.

**Analysis of Need**

In Section C, page 29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 27-28, the applicant states:

*“The addition of stations serves to increase capacity and proactively address the issues of growth and access at this small facility. Dialysis patients spend a significant amount of time in their facilities preparing for and receiving treatment -- three times a week for in-center patients. And for Mayland’s patients, travel time is often impacted by the terrain and weather conditions in the mountains of western North Carolina. This facility is the only dialysis facility in the Mitchell-Avery-Yancey Planning Area. The additional stations provide opportunities to open appointment times on the more desirable first shift.”*

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 1 of the facility need methodology, as stated in the 2024 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**

On Form C Utilization, in Section Q, page 1, the applicant provides historical and projected utilization, as illustrated in the following table.

Form C Utilization	Last Full FY 1/1/2023 to 12/31/2023	Interim Full FY 1/1/2024 to 12/31/2024	Interim Full FY 1/1/2025 to 12/31/2025	1 <sup>st</sup> Full FY 1/1/2026 to 12/31/2026	2 <sup>nd</sup> Full FY 1/1/2027 to 12/31/2027
<b>In-Center Patients</b>					
# of Patients at the Beginning of the Year	21.00	24.00	29.08	32.45	36.22
# of Patients at the End of the Year	24.00	29.08	32.45	36.22	40.45
Average # of Patients during the Year	22.50	26.54	30.76	34.34	38.34
# of Treatments / Patient / Year	145.33	148.20	148.20	148.20	148.20
<b>Total # of Treatments</b>	<b>3,270.00</b>	<b>3,933.23</b>	<b>4,559.34</b>	<b>5,088.68</b>	<b>5,681.54</b>

In Section C, pages 26-27, and on Form C Utilization, in Section Q, page 85, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- The applicant begins the current reporting date is April 30, 2024. There were 27 in-center patients at Mayland as of this date.
- The applicant projects a growth rate of 12.0%. The facility need methodology, pursuant to Condition 1, indicates that the 6-month growth rate for Mayland 35% was from October 30, 2023, to April 1, 2024.
- The applicant serves all the patients residing in two of the three counties in this multicounty service area: Mitchell and Yancey Counties. The number of patients at Mayland are split between residents of Mitchell (15) and Yancey (11) Counties.
- The period of growth begins May 1, 2024, and is calculated forward to December 31, 2027. The first full FY is projected to begin January 1, 2026, and end December 31, 2026. The second full FY is projected to begin January 1, 2027, and end December 31, 2027.

In Section C, page 27, and in Section Q, page 86, the applicant provides the in-center methodology used to project the patient census for Operating Year 1 and Operating Year 2 as summarized in the table below:

<b>Mayland Dialysis Center Projected Utilization</b>	
Projection begin with patient census at the facility as of 04/30/2024.	Mitchell (M) = 15 Yancey (Y) = 11 Other = 1 15 + 11 + 1 = 27
The facility's Mitchell-Avery-Yancey Planning Area patient census is projected forward eight months, from 05/01/2024 to 12/31/2024.	0.120 x (8/12) = 0.08 M: 15 x 1.080 = 16.20 Y: 11 x 1.080 = 11.88
The patient from outside the multicounty service area is added to the facility's census. This is the ending census for the first interim partial year.	16.20 + 11.88 + 1 = 29.08
The facility's multicounty service area patient census is projected forward a year to 12/31/2025.	M: 16.20 x 1.120 = 18.1440 Y: 11.88 x 1.120 = 13.3056
The patient from outside the multicounty service area is added to the facility's census. This is the ending census for the first interim full year.	18.14 + 13.31 + 1 = 32.45
The proposed project is projected to be certified on 1/1/2026. The facility's multicounty service area patient census is projected forward a year to 12/31/2026 and is increased by 12.0%.	M: 18.14 x 1.120 = 20.321 Y: 13.31 x 1.120 = 14.902
The patient from outside the multicounty service area is added to the facility's census. This is the ending census for FY1.	20.321 + 14.902 + 1 = 36.22
The facility's the multicounty service area patient census is projected forward a year to 12/31/2027 and is increased by 12.0%.	M: 20.321 x 1.120 = 22.7598 Y: 14.902 x 1.120 = 16.691
The patient from outside the multicounty service area is added to the facility's census. This is the ending census as of the project's second full fiscal year (FY2).	22.76 + 16.691 + 1 = 40.45

Based on the calculations above, by the end of FY1, Mayland is projected to serve the following number of patients for the Operating Year 1 and Operating Year 2:

	<b>Operating Year 1</b>	<b>Operating Year 2</b>
In-center Patients	36.22	40.45

- The applicant projects to serve 36 patients on 12 stations, which is 3.0 patients per station per week (36 patients / 12 stations = 3.0), by the end of first full operating year.
- The applicant projects to serve 40 patients on 12 stations, which is 3.33 patients per station per week (40 patients / 12 stations = 3.33) by the end of the second full operating year.
- This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on historical utilization from October 30, 2023, to April 30, 2024.
- While the Average Annual Change Rate for the Past Five Years (5YAACR) is negative for Mitchell County, the facility has experienced significant growth in utilization over the most recent reporting period.

**Access to Medically Underserved Groups**

In Section C, page 30, the applicant states:

*“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis. We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided three days per week with up to three patient shifts per day to accommodate patient need.*

*Mayland 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.”*

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

<b>Groups</b>	<b>Estimated % of Total Patients in FY 2</b>
Low-income persons	91.7%
Racial and ethnic minorities	0.0%
Women	33.3%
Persons with disabilities	100%
Persons 65 and older	50.0%
Medicare beneficiaries	87.5%
Medicaid recipients	4.2%

Source: Section C, page 30

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

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.



- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

### 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.

- (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.

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

In Section E, page 39, 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.** This alternative was dismissed given the growth rate of the facility, as of the current reporting date, at this small facility.
- **Add more than three stations.** Relocating stations from another facility is not possible as there are no other DaVita facilities in Mitchell County and transferring stations from a contiguous county would increase a surplus of stations in the county. Mayland's physical plant can currently support the addition of three stations. Adding more than that would require renovation and a significant capital expenditure. The projections

indicate that the addition of three stations will sufficiently meet the need at Mayland, so this alternative was also dismissed.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC (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 2024 SMFP, the certificate of need holder shall develop no more than three additional in-center dialysis stations for a total of no more than 12 in-center dialysis stations at Mayland Dialysis Center 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 January 1, 2025.**

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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

**Capital and Working Capital Costs**

On Form F.1a, in Section Q, the applicant projects \$3,000 for site preparation, \$40,500 in for medical equipment, \$8,960 for non-medical equipment, and \$4,500 for furniture for a total capital cost of \$56,960. Immediately following Form F.1a in Section Q, the applicant provides the assumptions used to project capital costs. The applicant's projected capital costs are reasonable and adequately supported because they are based on the cost of the necessary furniture and equipment.

<b>Form F.1a Capital Cost</b>	<b>Total</b>
Site Preparation	\$3,000
Medical Equipment	\$40,500
Non-Medical Equipment	\$8,960
Furniture	\$4,500
<b>Total Capital Cost</b>	<b>\$56,960</b>

In Section F, page 43, the applicant states there are no start-up costs or initial operating costs because Mayland Dialysis Center is an operational facility.

**Availability of Funds**

In Section F, page 42, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. The Consolidated Balance Sheets, as published in DaVita's publicly available U.S. Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2023, serve as Exhibit F.2. Page 3 of the exhibit reflects the company's reported \$380,063,000 in Cash and Cash Equivalents.

See Exhibit F.2c for documentation from DaVita's Chief Accounting Officer.

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

- The applicant provided a letter from a company executive authorizing the use of accumulated reserves for the proposed project.
- The letter from the applicant documents that it has adequate cash and assets to fund 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 full fiscal years following completion of the project, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>Mayland Dialysis Center</b>	<b>FY 1 - CY 2026</b>	<b>FY 2 - CY 2027</b>
Total Treatments	5,089	5,682
Total Gross Revenues (Charges)	\$1,514,095	\$1,690,494
Total Net Revenue	\$1,453,126	\$1,622,422
Average Net Revenue per Treatment	\$286	\$286
Total Operating Expenses (Costs)	\$1,328,152	\$1,392,134
Average Operating Expense per Treatment	\$261	\$245
<b>Net Income</b>	<b>\$124,974</b>	<b>\$230,288</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided on Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- 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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

On page 113, the 2024 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 Mitchell-Avery-Yancey Counties. Facilities may serve residents of counties not included in their service area.

As of December 31, 2022, there was one existing or approved facility providing dialysis and/or dialysis home training and support in Avery, Mitchell, and Yancey counties. Information on this one dialysis facility is provided in the table below.

<b>Mitchell-Avery-Yancy Planning Area Certified Stations and Utilization as of December 31, 2022</b>			
<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b># of In-Center Patients</b>	<b>Utilization</b>
Mayland Dialysis Center	9	21	58.33%%

Source: Table 9A, 2024 SMFP

In Section G, page 48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in Mitchell-Avery-Yancey Counties. The applicant states:

*“In Section B, Question 3 and Section C, Question 3 of this application, we demonstrate the need that Mayland has for adding stations. While adding stations at this facility does increase the number of stations in Mitchell-Avery-Yancey Planning Area, 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 proposes to increase the number of dialysis stations in Mitchell-Avery-Yancey Counties based on Condition 1 of the facility need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Mitchell-Avery-Yancey Counties.

### **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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 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.

<b>Mayland Dialysis Center Current and Projected Staffing</b>			
	<b>Current Staff</b>	<b>Projected Staff</b>	
	<b>As of 6/30/2024</b>	<b>1<sup>st</sup> Full FY CY2026</b>	<b>2<sup>nd</sup> Full FY CY2027</b>
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	1.25	1.50	1.50
Licensed Practical Nurse (LPNs)	0.00	0.00	0.00
Home Training Nurse	0.00	0.00	0.00
Technicians (PCT)	3.50	4.50	4.50
Medical Records	0.00	0.00	0.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Housekeeping	0.00	0.00	0.00
Maintenance	0.00	0.00	0.00
Administration/Business Office	0.50	1.00	1.00
Other (Describe)- Biomedical Tech	0.50	0.50	0.50
<b>TOTAL</b>	<b>7.75</b>	<b>9.50</b>	<b>9.50</b>

Source: Section Q, form H

The assumptions and methodology used to project staffing are provided on Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

**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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

**Ancillary and Support Services**

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 54-57, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

**Coordination**

In Section I, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and 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 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.

- (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

- (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 a new space or renovate an 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 66, the applicant provides the historical payor mix during CY 2023 for its existing services, as shown in the table below.

<b>Mayland Dialysis Center CY2023</b>		
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>
Insurance*	1	4.2%
Medicare*	21	87.5%
Medicaid*	1	4.2%
Misc. (including VA)	1	4.2%
<b>Total</b>	<b>24</b>	<b>100.0%</b>

\* Including any managed care

In Section L, page 67, the applicant provides the following comparison.

<b>Mayland Dialysis Center</b>	<b>Percentage of Total Patients Served by Mayland Dialysis Center during CY 2023</b>	<b>Percentage of the Population of the Service Area</b>
Female	33.3%	50.6%
Male	66.7%	49.4%
Unknown	0.0%	0.0%
64 and Younger	50.0%	74.4%
65 and Older	50.0%	25.6%
American Indian	0.0%	1.0%
Asian	0.0%	0.7%
Black or African-American	0.0%	1.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	100.0%	95.4%
Other Race	0.0%	1.8%
Declined / Unavailable	-	-

**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 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, in Section L, page 68, the applicant states it has no such obligation.

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Mayland Dialysis Center.

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 68, 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.

<b>Mayland Dialysis Center Projected Payor Sources</b>		
<b>2<sup>nd</sup> Full FY - CY2027</b>		
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>
Insurance*	1.69	4.2%
Medicare*	35.39	87.5%
Medicaid*	1.69	4.2%
Misc. (including VA)	1.69	4.2%
<b>Total</b>	<b>40.45</b>	<b>100.0%</b>

\* Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects 87.5% of services will be provided to Medicare patients, and 4.2% of services will be provided to Medicaid patients.

On pages 68-69, 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 recent facility history of treatment volumes at Mayland Dialysis Center.

### **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, page 70, the applicant adequately describes the range of means by which patients will have access to the proposed services. The applicant states:

*“DaVita will accept and dialyze patients with renal failure needing a regular course of dialysis, in accordance with the policy found at Exhibit L.5, upon referral by a nephrologist with privileges at Mayland. Patients, families and friends can obtain access by contacting a nephrologist with privileges at the facility. Should a patient contact the facility either directly or indirectly, the patient will be referred to a qualified nephrologist for evaluation and subsequent admission if it were found to be medically necessary. A visiting or transfer patient will be processed in accordance with the facility transfer and transient policies,*

*found at Exhibit L.5. The patient will be referred to a qualified nephrologist for final evaluation and then admission based on the doctor's orders."*

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- (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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

In Section M, page 72, 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 the following:

- The applicant provides a copy of a letter sent to Mayland Community College offering the facility as a clinical learning site for nursing students.
- The applicant states they will offer dialysis specific orientation to the nursing students. This will include observation, hands on opportunities in certain areas of treatment, interaction with the dialysis patients and the ability to prepare or initiate Care Plans under the supervision of a nursing instructor from the community college or a registered nurse at 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 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 three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion.

On page 113, the 2024 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 Mitchell-Avery-Yancey Counties. Facilities may serve residents of counties not included in their service area.

As of December 31, 2022, there was one existing or approved facility providing dialysis and/or dialysis home training and support in Avery, Mitchell, and Yancey counties. Information on this one dialysis facility is provided in the table below.

<b>Mitchell-Avery-Yancy Planning Area Certified Stations and Utilization as of December 31, 2022</b>			
<b>Dialysis Facility</b>	<b># of Certified Stations</b>	<b># of In-Center Patients</b>	<b>Utilization</b>
Mayland Dialysis Center	9	21	58.33%%

Source: Table 9A, 2024 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

*“The expansion of Mayland will have no effect on competition in the Mitchell-Avery-Yancey Planning Area. There are no other dialysis facilities in this multicounty service area. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita..”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

*“The expansion of Mayland will enhance accessibility to dialysis for current and projected patients and, by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”*

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

Regarding the impact of the proposal on quality, in Section N, page 75, the applicant states:

*“DaVita is committed to providing quality care to the ESRD population and, by policy, works to make every reasonable effort to accommodate all of its patients”.*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

*“The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”*

See also Sections C and L of 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 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

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

The applicant proposes to add no more than three dialysis stations pursuant to Condition 1 of the facility need methodology for a total of no more than 12 stations upon project completion. On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 108 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 108 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 Criteria and Standards for End Stage Renal Disease promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

**10 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- Mayland Dialysis Center is an existing facility. Therefore, this Rule is not applicable to this review.
- (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 26-27, and on Form C in Section Q, the applicant projects that Mayland Dialysis Center will serve 36 patients on 12 stations, or a rate of 3.0 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*
- C- In Section C, pages 24-27, and in 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.
- (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 does not propose to increase the number of home hemodialysis stations. Therefore, this Rule does not apply.
- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section C, pages 24-26, 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.