

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 15, 2020

Findings Date: June 15, 2020

Project Analyst: Celia C. Inman

Co-Signer: Gloria C. Hale

Project ID #: G-11883-20

Facility: Glen Raven Dialysis

FID #: 160341

County: Alamance

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

Project: Add no more than 4 dialysis stations pursuant to facility need for a total of no more than 14 dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Renal Treatment Centers - Mid-Atlantic, Inc., the applicant, proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven Dialysis (Glen Raven) upon project completion.

#### **Need Determination**

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Alamance County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 1 of the facility need methodology in the 2020 SMFP if the facility is a “new” facility or a “small” facility (or both) as defined in the 2020 SMFP, and if the facility’s current reported utilization is at least 75 percent, or 3.0 patients per station in a given week. “Current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted. In Section B.3 page 11, the applicant states it was serving 33 in-center patients on 10 certified stations on its current reporting date of December 20, 2019. This is a utilization rate of 82.5%, or 3.3 patients per station per week (33 patients / 10 stations = 3.3 / 4 = 0.825). According to Table 9B, page 151 of the 2020 SMFP, Glen Raven Dialysis is defined as both a new and a small facility.

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

Facility Need Methodology Condition 1 (New and Small Facilities)		Response
SMFP in effect on the day the review begins		2020 SMFP
County		Alamance
FID # / Facility Name		FID#160341 / Glen Raven
# of stations in the facility as of the data cut-off date in the SMFP in effect on the day the review begins *		10
# of months the facility had been certified as of the data cut-off date in the SMFP in effect on the day the review begins *		18
Number of stations proposed in this application		4
Current Reporting Date *		12/20/2019
Previous Reporting Date *		6/20/2019
1	# of In-center Patients as of the Current Reporting Date *	33
2	# of In-Center Patients as of the Previous Reporting Date *	30
3	Subtract Line 2 from Line 1 (Net In-center Change for 6 Months)	3
4	Divide Line 3 by Line 2 (6-month Growth Rate)	0.10
5	Multiply Line 4 by 2 (Annual Growth Rate)	0.20
6	Multiply Line 5 by Line 1 (New Patients)	6.60
7	Add Line 6 to Line 1 (Total Patients)	39.60
8	Divide Line 7 by 2.8 (Total # of Stations Needed)	14.14
9	# of Stations as of the Current Reporting Date ^ / *	10
10	Subtract Line 9 from Line 8 (Additional Stations Needed)	4.14

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

### **Policies**

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3: Basic Principles, pages 30-31 of the 2020 SMFP, states:

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

In Sections B, C, L, N and O, the applicant explains why it believes its application is conforming to Policy GEN-3, as discussed below:

**Promote Safety and Quality** – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5(a and d), pages 13-14 and 15-16, respectively; Section N, page 49; Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

**Promote Equitable Access** - The applicant describes how it believes the proposed project would promote equitable access in Section B. 5 (b and d), pages 14-15 and 15-16, respectively; Section C.7, page 23; Section L, pages 44-47; Section N, page 49; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

**Maximize Healthcare Value** - The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c and d), pages 15-16; and in Section N, page 49. The information provided by the applicant is reasonable and

adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how Glen Raven's projected volumes incorporate the concepts of safety and quality, equitable access and maximum healthcare value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates how Glen Raven's projected volumes incorporate the concepts of safety and quality, equitable access and maximum healthcare value for resources expended in meeting the facility need.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

### C

The applicant proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven upon project completion.

The following table, summarized from data on page 7 of the application and page 151 of the 2020 SMFP, shows the projected number of stations at Glen Raven upon project completion.

<b>Glen Raven Dialysis</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
10	Total # of existing certified stations in the SMFP in effect on the day the review will begin	
+4	# of stations to be added as part of this project (add four stations pursuant to facility need)	G-11883-20
14	Total stations upon completion of proposed project and previously approved projects	

**Patient Origin**

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

In Section C, pages 19-20, the applicant provides Glen Raven’s current patient origin and projected patient origin for the second full operating year following project completion, January 1, 2023 – December 31, 2023 (CY2023), as summarized in the following table:

<b>County</b>	<b>CY2019</b>		<b>CY2023</b>	
	<b>IC Patients</b>	<b>% of Total</b>	<b>IC Patients</b>	<b>% of Total</b>
Alamance	29.0	90.6%	39.0	92.9%
Guilford	3.0	9.4%	3.0	7.1%
<b>Total</b>	<b>32.0</b>	<b>100.0%</b>	<b>42.0</b>	<b>100.0%</b>

Totals may not sum due to rounding

In the applicant’s tables on pages 19-20 and 38, the applicant shows that it does not offer home hemodialysis or peritoneal dialysis training and support services at the Glen Raven facility.

In Section C, pages 20-21, the applicant provides the assumptions, methodology, and support documentation used to project Glen Raven’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, page 21, the applicant refers to the Facility Need Determination table in Section B.3, page 11, for an explanation of why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

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

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

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

### *Projected Utilization*

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

#### *Assumptions*

- As of December 31, 2019, 29 of Glen Raven’s 32 dialysis patients lived in Alamance County.
- Operating year one is projected to begin January 1, 2022 and end December 31, 2022.
- Operating year two is projected to begin January 1, 2023 and end December 31, 2023.
- The applicant uses a projected growth rate of 8% per year for its Alamance County patients.
  - Alamance County’s Five Year Average Annual Change Rate (AACR) is 3%, per the 2020 SMFP;
  - The applicant states that Glen Raven’s one-year change rate for CY2019 was 33.3%, far greater than the Alamance County Five Year AACR of 3%.
  - Based on Glen Raven’s CY2019 growth rate, the applicant states that the assumption of an 8% growth rate for the next three years is a reasonable growth rate.

#### *Methodology*

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

Begin with facility census of Alamance County patients as of December 31, 2019.	29
Project this population forward one year to December 31, 2020, using a growth rate of 8.0%.	$29 \times 1.08 = 31.32$
Project Alamance County patients forward one year to December 31, 2021, using a growth rate of 8.0%.	$31.32 \times 1.08 = 33.8256$
Project Alamance County patients forward one year to December 31, 2022, using a growth rate of 8.0%.	$33.8256 \times 1.08 = 36.5317$
Add the three patients from Guilford County. This is the ending census for OY1, CY2022.	$36.5317 + 3 = 39.5317$
Project Alamance County patients forward one year to December 31, 2023, using a growth rate of 8.0%.	$36.5317 \times 1.08 = 39.4542$
Add the three patients from Guilford County. This is the ending census for OY2, CY2023.	$39.4542 + 3 = 42.4542$

Source: Table in Section Q

As the table above shows, using conventional rounding, the methodology used by the applicant achieves a projection of 40 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 2.9 patients per station per week or 71.4% (40 patients / 14 stations = 2.86 patients per station / 4 = 0.7143). The projected utilization of 2.9 patients per station per week for CY2022 satisfies the 2.8 in-center patients per station per week threshold for the first full year following project completion as required by 10A NCAC 14C .2203(b).

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

- The applicant begins its projections using the historical Alamance County patient census as of December 31, 2019.
- The applicant uses an 8% growth rate for the Alamance County patients, a rate somewhat above the county 3% growth rate and considerably below Glen Raven’s CY2019 growth rate of more than 30%.
- The applicant does not grow its patients from outside Alamance County.

**Access**

In Section C.7, pages 22-23, the applicant states:

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

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as those with disabilities, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.*

*Glen Raven Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, disabled persons, elderly, and other under-served persons.”*

The applicant projects payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.3(b), page 46.

**Projected Payor Mix  
CY2023**

<b>Payor Source</b>	<b>% of IC Patients</b>	<b>% of HH Patients</b>	<b>% of PD Patients</b>
Self-Pay	0.0%	0.0%	0.0%
Insurance*	15.6%	0.0%	0.0%
Medicare*	78.1%	0.0%	0.0%
Medicaid*	0.0%	0.0%	0.0%
Other: Misc. including VA	6.3%	0.0%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>0.0%</b>	<b>0.0%</b>

\*Including any managed care

In Section L, page 46, the applicant provides the assumptions for projecting payor mix, stating that the projected payor mix is based upon sources of patient payment that were received by Glen Raven in the last full operating year. The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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



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

- (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 four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven upon project completion.

In Section E, page 28, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- Maintain status quo – the applicant states that not applying to expand the facility was deemed unacceptable due to the growth experienced by Glen Raven. Thus, this alternative was not considered an effective alternative.
- Relocate stations from another DaVita facility – of the DaVita's four other Alamance County facilities, three are operating at greater than 75% capacity: Alamance County Dialysis, Burlington Dialysis, and North Burlington Dialysis. The applicant states that relocating stations from these centers would negatively impact the patients presently served. Mebane Dialysis, the fourth DaVita facility, is a newly certified 10-station facility and therefore not eligible to have any stations relocated from it. Thus, this alternative was not considered an effective alternative.
- Apply for the four stations pursuant to the Facility Need Methodology – the applicant demonstrates the need for the addition of four stations in Section Q Form C Utilization, pursuant to facility need in Section B.3, page 11.

On page 28, the applicant states that it chose to apply for four stations pursuant to facility need, as proposed in this application, because it meets the growing demand for dialysis services at Glen Raven.

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

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

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application.

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. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the 2020 SMFP, Renal Treatment Centers – Mid-Atlantic, Inc. shall develop no more than four additional in-center dialysis stations at Glen Raven Dialysis for a total of no more than 14 in-center dialysis stations.**
  - 3. Renal Treatment Centers – Mid-Atlantic, Inc. 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 four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven upon project completion.

### **Capital and Working Capital Costs**

In Section Q Form F.1a Capital Cost, the applicant projects the total capital cost for the project as summarized below.

**Projected Capital Costs**

	<b>Total Costs</b>
Medical Equipment	\$59,400
Non-Medical Equipment	\$3,004
Furniture	\$5,600
<b>Total Capital Costs</b>	<b>\$68,004</b>

The applicant provides the assumptions used to project the capital cost in Section Q, following Form F.1a Capital Cost.

In Section F, pages 30-31, the applicant states that there will be no start-up or initial operating costs because Glen Raven is an operational facility.

**Availability of Funds**

In Section F, page 29, the applicant states that the capital cost will be funded by the parent company, DaVita, Inc., as shown in the table below.

**Sources of Capital Financing**

<b>Type</b>	<b>DaVita, Inc.</b>
Loans	
Accumulated reserves or OE *	\$68,004
Bonds	
Other (Specify)	
<b>Total Financing</b>	<b>\$68,004</b>

\* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated March 15, 2020, from DaVita's Chief Accounting Officer, authorizing and committing accumulated reserves of DaVita, Inc. for the capital costs of the project. Exhibit F also contains DaVita, Inc.'s 2019 Form 10-K Consolidated Balance Sheets which reflects more than \$1.1 billion in cash and cash equivalents, total assets exceeding \$17.3 billion, and equity exceeding \$2.3 billion.

The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

**Financial Feasibility**

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

<b>Glen Raven Revenue and Expenses</b>		
	<b>CY2022</b>	<b>CY2023</b>
In-Center Patients*	38.18	40.99
In-Center Treatments	5,658	6,075
Gross Patient Revenue	\$2,371,970	\$2,546,817
Adjustment from Gross	\$112,143	\$120,409
Net Patient Revenue	\$2,259,827	\$2,426,407
Average Net Revenue per Treatment	\$399	\$399
Total Operating Expenses	\$2,118,959	\$2,221,095
Average Operating Expense per Treatment	\$375	\$366
Net Income	\$140,868	\$205,312

Totals may not sum due to rounding

\*Average number of patients during the year ((beginning patients + ending patients) / 2)

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

**Conclusion**

The Agency reviewed the:

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

**C**

The applicant proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven upon project completion.

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

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

**Alamance County Dialysis Facilities**

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

Source: 2020 SMFP, Table 9B, page 151

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

In Section G, page 34, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Alamance County. The applicant states:

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

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

- The proposal is consistent with the facility need methodology.

- The applicant adequately demonstrates that the proposed addition of stations at the existing facility is needed in addition to the operational facilities in Alamance County.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

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

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

C

In Section Q Form H Staffing, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions, as summarized in the following table.

<b>POSITION</b>	<b>FTE Positions as of 12/31/19</b>	<b>FTE POSITIONS CY2022</b>	<b>FTE POSITIONS CY2023</b>
Administrator	1.00	1.00	1.00
Registered Nurses	2.00	2.00	2.00
Patient Care Technicians	4.00	6.00	6.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Administration/Office	0.50	1.00	1.00
Biomed Technician	0.50	0.50	0.50
<b>Total</b>	<b>9.00</b>	<b>11.50</b>	<b>11.50</b>

Source: Section Q Form H of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 37, the applicant identifies the current medical director for the facility as Dr. Sarath Kolluru. In Exhibit H-4, the

applicant provides a letter from Sarath Kolluru, MD indicating his intent in continuing to serve as medical director for the proposed services.

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

### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

### C

In Section I.1, pages 38-39, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 38, as summarized below.

**Glen Raven  
 Ancillary and Support Services**

SERVICES	PROVIDER
Self-care training	On site
HH training and follow-up	Durham West Dialysis
PD training and follow-up	Alamance County Dialysis
Isolation – Hepatitis B	On site
Psychological counseling	On site by RN
Nutritional counseling	On site by RD
Social Work services	On site by MSW
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Alamance Regional Medical Center
Emergency care	Alamance Regional Medical Center
Blood bank services	Alamance Regional Medical Center
Diagnostic and evaluation services	Alamance Regional Medical Center
X-ray services	Alamance Regional Medical Center
Pediatric nephrology	Alamance Regional Medical Center
Vascular surgery	Alamance Regional Medical Center
Transplantation services	UNC Health Care
Vocational rehabilitation & counseling	North Carolina Vocational Rehabilitation
Transportation	Alamance County Transportation Authority

Source: Table in Section I, page 38

In Section I, pages 38-39, the applicant describes Glen Raven’s relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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



NA

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

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

NA

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

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

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services,

particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The applicant proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven upon project completion.

In Section L.1(b), page 45, the applicant provides the historical payor mix during CY2019 for its existing services, as summarized in the table below.

**Glen Raven Dialysis  
Historical Payor Mix CY2019**

<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>
Self-pay	0.0	0.0%
Insurance*	5.0	15.6%
Medicare*	25.0	78.1%
Medicaid*	0.0	0.0%
Other (Incl. VA)	2.0	6.3%
<b>Total</b>	<b>32.0</b>	<b>100.00%</b>

Totals may not sum due to rounding

\*Including any managed care plans

In Section L.1(a), page 44, the applicant provides a comparison of the demographical information on Glen Raven patients and the service area residents during CY2019, as summarized below.

	Percentage of Total Glen Raven Patients Served during the Last Full OY	Percentage of the Population of the Service Area
Female	43.8%	52.6%
Male	56.3%	47.4%
Unknown	0.0%	0.0%
64 and Younger	65.6%	83.1%
65 and Older	34.4%	16.9%
American Indian	0.0%	1.4%
Asian	3.1%	1.8%
Black or African-American	78.1%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	15.6%	73.9%
Other Race	3.1%	2.2%
Declined / Unavailable	0.0%	0.0%

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

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L.2, page 45, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons under any federal regulations.

In Section L, page 45, the applicant states that no patient civil rights access complaints have been filed against Glen Raven Dialysis during the last five years.

**Conclusion**

The Agency reviewed the:

- application, and
- 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.3(b), page 46, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**Glen Raven  
Projected Payor Mix CY 2023**

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	0.0	0.0%
Insurance*	6.6	15.6%
Medicare*	33.2	78.1%
Medicaid*	0.0	0.0%
Miscellaneous (Incl. VA)	2.7	6.3%
<b>Total</b>	<b>42.5</b>	<b>100.0%</b>

Totals may not sum due to rounding

\*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 0% of total in-center services will be provided to self-pay patients, 78% to Medicare patients, and 0% to Medicaid patients.

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

### **Conclusion**

The Agency reviewed the:

- application, and
- 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.5, pages 46-47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

The applicant proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 14 stations at Glen Raven upon project completion.

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

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

**Alamance County Dialysis Facilities**

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

Source: 2020 SMFP, Table 9B, page 151

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

In Section N, page 49, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

*“The expansion of Glen Raven Dialysis will have no effect on competition in Alamance County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.*

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, N and Q of the application and any exhibits).
- Quality services will be provided (see Sections B, C, N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B, L and N of the application and any exhibits).

## **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

## C

In Section Q Form A, the applicant identifies the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies more than 100 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, pages 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred at one of DaVita’s facilities: Waynesville Dialysis Center. The applicant provides documentation regarding the deficiency and subsequent measures taken by the facility to ensure compliance with CMS Conditions for Coverage in Exhibit O. The applicant states that all of the problems have been corrected and that Waynesville Dialysis Center is back in compliance. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Therefore, the application is conforming to this criterion.

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



teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

**10A NCAC 14C .2203 PERFORMANCE STANDARDS**

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

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

- (b) An applicant proposing to increase the number of dialysis stations in:
- (1) an existing dialysis facility; or
  - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section Q, Form C Utilization, the methodology proposed by the applicant achieves a projection of 40 in-center patients by the end of the first operating year, OY1 (CY2022), for a utilization rate of 2.9 patients per station per week or 71.4% (40 patients / 14 stations = 2.86 patients per station / 4 = 0.7143). The projected utilization of 2.9 patients per station per week for CY2022 satisfies the 2.8 in-center patients per station per week threshold for the first full year following project completion as required by 10A NCAC 14C .2203(b).

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

-C- In Section Q, following Form C Utilization, the applicant provides the assumptions and methodology used to project utilization of the facility.