

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 8, 2019

Findings Date: November 8, 2019

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: G-11786-19

Facility: Alamance County Dialysis

FID #: 140092

County: Alamance

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

Project: Add no more than 3 stations for a total of no more than 13 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. (RTC-MA) d/b/a Alamance County Dialysis (ACD) proposes to add three dialysis stations to the existing facility for a total of 13 dialysis stations upon project completion.

#### Need Determination

The 2019 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 the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 36 dialysis stations in Alamance County. Therefore, the July 2019 SDR does not indicate a need for additional stations in Alamance County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most

recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for ACD in the July 2019 SDR is 3.6 patients per station per week, or 90 percent, based on 36 in-center dialysis patients and 10 certified dialysis stations [ $36 / 10 = 3.6$ ;  $3.6 / 4 = 0.90$  or 90%].

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

<b>OCTOBER 1 REVIEW – JULY 2019 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		90.00%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		36
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		32
Step	Description	Result
	Difference (SDR2 - SDR1)	4
(i)	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.2500
(ii)	Divide the result of Step (i) by 12	0.0208
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.2500
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	45.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	14.0625
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>4</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add three new stations and is therefore consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 31 of the 2019 SMFP, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall*

*document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

#### *Promote Safety and Quality*

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 12-13; Section N, page 49; Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

#### *Promote Equitable Access*

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 13-14; Section C, page 23; Section L, pages 44-46; Section N, page 49; 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 14; Section C, pages 19-21; Section F, pages 29-32; Section K, pages 41-42; Section N, page 49; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

#### Conclusion

The Agency reviewed the:

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

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

- (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 three dialysis stations to ACD for a total of 13 dialysis stations upon project completion.

ACD currently offers home peritoneal dialysis training (PD) but not home hemodialysis training (HH). In Section C, page 22, the applicant states it projects no changes to the types of dialysis services offered at ACD – it will continue to offer both in-center dialysis and PD training and support.

In Section A, page 9, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with RTC-MA to refer to itself or its facilities. References to DaVita should be interpreted to mean RTC-MA unless otherwise specified.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Alamance County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

ACD – Current and Projected Patient Origin						
County	Current (12/31/2018)			Projected (Operating Year 2 – CY 2022)		
	# of IC* Patients	# of PD Patients	% of Total	# of IC* Patients	# of PD Patients	% of Total
Alamance	33	22	88.7%	43	28	83.5%
Brunswick	0	0	0.0%	1	0	1.2%
Chatham	1	0	1.6%	1	1	2.4%
Durham	1	0	1.6%	0	0	0.0%
Pitt	1	0	1.6%	1	0	1.2%
Caswell	0	0	0.0%	0	1	1.2%
Guilford	0	4	6.5%	0	7	8.2%
Orange	0	0	0.0%	0	2	2.4%
<b>Total</b>	<b>36</b>	<b>26</b>	<b>100.0%</b>	<b>46</b>	<b>39</b>	<b>100.0%</b>

Table may not foot due to rounding.

Source: Section C, pages 18-19

\*IC = In-Center

In Section C, pages 19-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 21, the applicant states the facility need methodology shows a need for up to four additional stations based on the population growth at ACD. Additionally, the applicant projects the 13-station facility will have a utilization rate of 3.38 patients per station per week, or 84.6 percent, by the end of the first operating year. The projected utilization exceeds the minimum operating standard of 3.2 patients per station per week as promulgated in 10A NCAC 14C. 2203(b).

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

- ACD is currently operating at a rate of 3.6 patients per station per day, or 90 percent of capacity.
- The applicant demonstrates eligibility to add three dialysis stations to its facility via the facility need methodology. The discussion regarding the facility need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, pages 18-19, the applicant provides historical and projected utilization as illustrated in the following table.

<b>ACD – Historical and Projected Patient Utilization</b>						
	<b>Historical (12/31/2018)</b>			<b>Projected (Operating Year 2 – CY 2022)</b>		
<b>County</b>	<b># of IC* Patients</b>	<b># of PD Patients</b>	<b>% of Total</b>	<b># of IC* Patients</b>	<b># of PD Patients</b>	<b>% of Total</b>
Alamance	33	22	88.7%	43	28	83.5%
Brunswick	0	0	0.0%	1	0	1.2%
Chatham	1	0	1.6%	1	1	2.4%
Durham	1	0	1.6%	0	0	0.0%
Pitt	1	0	1.6%	1	0	1.2%
Caswell	0	0	0.0%	0	1	1.2%
Guilford	0	4	6.5%	0	7	8.2%
Orange	0	0	0.0%	0	2	2.4%
<b>Total</b>	<b>36</b>	<b>26</b>	<b>100.0%</b>	<b>46</b>	<b>39</b>	<b>100.0%</b>

Table may not foot due to rounding.

\*IC = In-Center

In Section C, pages 19-21, the applicant provides the assumptions and methodology used to project in-center and PD patient utilization, which are summarized below.

*In-Center*

- The applicant begins its utilization projections with the in-center patient facility census as of June 30, 2019. On page 19, the applicant states that, as of June 30, 2019, it was serving 37 Alamance County patients and three patients residing outside of Alamance County.
- The applicant states the Average Annual Change Rate (AACR) for Alamance County as published in the July 2019 SDR is three percent; however, it states ACD has an average growth rate of 21.1 percent since its opening in 2016, and so uses a five percent AACR for Alamance County patients.
- The applicant assumes no population growth for ACD patients living outside of Alamance County but assumes the patients will continue to dialyze at ACD and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 20, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

<b>ACD IC Projected Utilization</b>	
Starting point of calculations is Alamance County patients dialyzing in-center at ACD on July 1, 2019.	37
Alamance County patient population is projected forward by six months to December 31, 2019, using one-half of the 5% projected AACR.	$37 \times 1.025 = 37.925$
Alamance County patient population is projected forward by one year to December 31, 2020, using the 5% projected AACR.	$37.925 \times 1.05 = 39.821$
The patients from outside Alamance County are added. This is the projected census on December 31, 2020 and the starting census for this project.	$39.821 + 3 = 42.821$
Alamance County patient population is projected forward by one year to December 31, 2021, using the 5% projected AACR.	$39.821 \times 1.05 = 41.812$
The patients from outside Alamance County are added. This is the projected census on December 31, 2021 (OY1).	$41.812 + 3 = 44.812$
Alamance County patient population is projected forward by one year to December 31, 2022, using the 5% projected AACR.	$41.812 \times 1.05 = 43.903$
The patients from outside Alamance County are added. This is the projected census on December 31, 2022 (OY2).	$43.903 + 3 = 46.903$

The applicant rounds down and projects to serve 44 in-center patients on 13 stations, which is 3.38 patients per station per week ( $44 \text{ patients} / 13 \text{ stations} = 3.38$ ), by the end of OY1 and 46 in-center patients on 13 stations, which is 3.54 patients per station per week ( $46 \text{ patients} / 13 \text{ stations} = 3.54$ ), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

There is no explanation in the application as submitted to explain how the applicant calculated an AACR of 21.1 percent since the facility opened. Information in the SDRs where data was reported for ACD shows a growth rate higher than the five percent AACR used by the applicant in its utilization projections. Moreover, even if the applicant uses the three percent AACR for Alamance County as published in the July 2019 SDR, the applicant will still exceed the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

*Home Peritoneal Dialysis Patients*

- The applicant begins its utilization projections with the PD patient facility census as of June 30, 2019. On page 21, the applicant states that, as of June 30, 2019, it was providing training and support to 35 PD patients from Alamance and other counties.
- The applicant assumes the ACD PD patient population will increase by one patient between July 1, 2019 and December 31, 2019.
- After the period of partial growth described in the previous bullet, the applicant assumes the ACD PD patient population will increase by at least one patient per year.
- The project is scheduled to begin offering services on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

The applicant’s utilization projections for the PD patient census at ACD through OY1 and OY2 are summarized in the table below.

<b>ACD PD Projected Utilization</b>	
Starting point of calculations is ACD PD patients on June 30, 2019.	35
One PD patient is projected to start receiving services at ACD by December 31, 2019.	$35 + 1 = 36$
ACD PD patient population is projected forward by one year to December 31, 2020. This is the starting census for the project.	$36 + 1 = 37$
ACD PD patient population is projected forward by one year to December 31, 2021. This is the projected census at the end of OY1.	$37 + 1 = 38$
ACD PD patient population is projected forward by one year to December 31, 2022. This is the projected census at the end of OY2.	$38 + 1 = 39$

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

- The July 2019 SDR states ACD’s utilization was 3.6 patients per station per week (a utilization rate of 90 percent) as of December 31, 2018.
- The applicant projects future utilization based on historical utilization.
- The applicant uses an AACR supported by historical data to project growth.

- The applicant does not project growth for its patients who do not reside in Alamance County.
- The applicant’s in-center projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).
- The applicant’s in-center projected utilization would still exceed the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b) if it used the Five Year AACR for Alamance County as published in the July 2019 SDR.

Access

In Section C, page 23, the applicant states:

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

*We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work.*  
 ...

*Alamance County 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, handicapped persons, elderly and other under-served persons.”*

In Section L, page 46, and in supplemental information, 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>ACD Projected Payor Mix CY 2022</b>				
<b>Type of Dialysis</b>	<b>In-Center</b>		<b>Home Peritoneal Dialysis</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	0	0.0%	0	0.0%
Insurance*	0	0.0%	10.491	26.9%
Medicare*	40.894	88.9%	28.509	73.1%
Medicaid*	1.288	2.8%	0	0.0%
Other	3.818	8.3%	0	0.0%
<b>Total</b>	<b>46</b>	<b>100.0%</b>	<b>39</b>	<b>100.0%</b>

\*Including any managed care plans

The projected payor mix is reasonable and adequately supported.



## Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant 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 to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add three stations to ACD for a total of 13 stations upon project completion.

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

- Maintain the Status Quo: the applicant states maintaining the status quo would lead to higher utilization and potentially restrict patient admissions; therefore, this is not an effective alternative.
- Relocate Stations from Another DaVita Facility: the applicant states three of the five DaVita facilities in Alamance County are operating above 80 percent so relocating stations from those facilities is not feasible. The applicant states the other two DaVita facilities in Alamance County are operating below 80 percent utilization, but both of those facilities are 10-station facilities that began offering services in 2018 and have growing patient populations; therefore, this is not an effective alternative.

On page 28, the applicant states its proposal is the most effective alternative because it meets the growing demand for services at ACD.

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

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

### Conclusion

The Agency reviewed the:

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

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

- 1. Renal Treatment Centers – Mid-Atlantic, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Renal Treatment Centers – Mid-Atlantic, Inc. shall materially comply with the last made representation.**
- 2. Pursuant to the facility need determination in the July 2019 Semiannual Dialysis Report, Renal Treatment Centers – Mid-Atlantic, Inc. shall develop no more than three additional dialysis stations at Alamance County Dialysis for a total of no more than 13 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation 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 three stations to ACD for a total of 13 stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$54,850, to be used entirely for medical equipment. In Section Q, the applicant provides the assumptions used to project the capital cost. In Section F, pages 30-31, the applicant states there are no projected start-up expenses or initial operating expenses because ACD is an existing and operational facility.

Availability of Funds

In Section F, page 29, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., ACD's parent company, authorizing the use of accumulated reserves for the capital needs and any other needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2018, DaVita, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility

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

<b>Projected Revenues and Operating Expenses</b>		
<b>ACD</b>	<b>Operating Year 1 CY 2021</b>	<b>Operating Year 2 CY 2022</b>
Total Treatments	11,930	12,435
Total Gross Revenues (Charges)	\$4,544,777	\$4,712,521
Total Net Revenue	\$4,364,513	\$4,524,630
Average Net Revenue per Treatment	\$366	\$364
Total Operating Expenses (Costs)	\$2,352,624	\$2,428,434
Average Operating Expense per Treatment	\$197	\$195
<b>Net Income/Profit</b>	<b>\$2,011,889</b>	<b>\$2,096,196</b>

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add three stations to ACD for a total of 13 stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning

*Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Alamance County. Facilities may serve residents of counties not included in their service area.*

There are seven facilities which provide dialysis and/or dialysis home training and support in Alamance County. Information on these facilities is provided below.

<b>Alamance County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018</b>						
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># Patients</b>	<b>Patients/Station</b>	<b>Utilization</b>
Alamance County Dialysis	DaVita	Graham	10	36	3.6000	90.00%
BMA of Burlington	BMA	Burlington	45	97	2.1556	53.89%
Burlington Dialysis	DaVita	Burlington	16	65	4.0625	101.56%
Carolina Dialysis of Mebane	BMA	Mebane	20	64	3.2000	80.00%
Glen Raven Dialysis	DaVita	Burlington	10	24	2.4000	60.00%
Mebane Dialysis	DaVita	Mebane	10	13	1.3000	32.50%
North Burlington Dialysis	DaVita	Burlington	16	62	3.8750	96.88%

Sources: Section G, page 34; Table B, July 2019 SDR

In Section G, pages 34-35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Alamance County. The applicant states:

*“Of the five DaVita facilities in Alamance County, three are operating at greater than 80% capacity. Relocating stations from Burlington Dialysis or North Burlington Dialysis would negatively impact the patients presently served and could lead to future third shifts or situations where patients cannot choose to dialysis [sic] at those centers. The two other centers, Glen Raven Dialysis and Mebane Dialysis, are both ten-station centers opened in 2018. Both of the centers are growing and filling needs in their respective areas of Alamance County.*

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

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

- There is a facility need determination, as calculated using the methodology in the July 2019 SDR, for the proposed dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

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

<b>ACD Current and Projected Staffing</b>			
	<b>Current</b>	<b>To Be Added</b>	<b>Total</b>
Administrator	1.0	0.0	1.0
Registered Nurses	2.0	0.0	2.0
Home Training Nurse	1.0	0.0	1.0
Patient Care Technicians	4.0	1.0	5.0
Dietician	0.5	0.0	0.5
Social Worker	0.5	0.0	0.5
Administration/Office	1.0	0.0	1.0
Biomed Technician	0.5	0.0	0.5
<b>TOTAL</b>	<b>10.5</b>	<b>1.0</b>	<b>11.5</b>

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1 through H-3. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing support for the proposed project and stating his interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

<b>ACD – Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training	Durham West Dialysis
HH	
PD	
Accessible follow-up program	
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Cone Health Alamance Regional Medical Center
Emergency care	Cone Health Alamance Regional Medical Center
Blood bank services	Cone Health Alamance Regional Medical Center
Diagnostic and evaluation services	Cone Health Alamance Regional Medical Center
X-ray services	Cone Health Alamance Regional Medical Center
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Cone Health Alamance Regional Medical Center
Vascular surgery	Cone Health Alamance Regional Medical Center
Transplantation services	UNC Healthcare
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Alamance County Transport Authority

The applicant provides supporting documentation in Exhibit I-1.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

In Section L, page 45, and in supplemental information, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

<b>ACD Historical Payor Mix CY 2018</b>				
<b>Type of Dialysis</b>	<b>In-Center</b>		<b>Home Peritoneal Dialysis</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	0	0.0%	0	0.0%
Insurance*	0	0.0%	6.994	26.9%
Medicare*	32.004	88.9%	19.006	73.1%
Medicaid*	1.008	2.8%	0	0.0%
Other	2.988	8.3%	0	0.0%
<b>Total</b>	<b>36</b>	<b>100.0%</b>	<b>26</b>	<b>100.0%</b>

\*Including any managed care plans

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

	Percentage of Total Patients Served by ACD during the Last Full OY	Percentage of the Population of Alamance County
Female	45.5%	52.6%
Male	54.4%	47.4%
Unknown	0.0%	0.0%
64 and Younger	51.0%	83.1%
65 and Older	49.0%	16.9%
American Indian	0.0%	1.4%
Asian	5.5%	1.8%
Black or African-American	40.0%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	54.5%	73.9%
Other Race	0.0%	2.2%
Declined / Unavailable	0.0%	0.0%

Sources: RTC-MA Internal Data, US Census Bureau

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 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, page 45, that ACD has no obligation to provide uncompensated care or community service under any federal regulations.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 46, and in supplemental information, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>ACD Projected Payor Mix CY 2022</b>				
<b>Type of Dialysis</b>	<b>In-Center</b>		<b>Home Peritoneal Dialysis</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	0	0.0%	0	0.0%
Insurance*	0	0.0%	10.491	26.9%
Medicare*	40.894	88.9%	28.509	73.1%
Medicaid*	1.288	2.8%	0	0.0%
Other	3.818	8.3%	0	0.0%
<b>Total</b>	<b>46</b>	<b>100.0%</b>	<b>39</b>	<b>100.0%</b>

\*Including any managed care plans

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

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

- (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 46, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.

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

C

The applicant proposes to add three stations to ACD for a total of 13 stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Alamance County. Facilities may serve residents of counties not included in their service area.

There are seven facilities which provide dialysis and/or dialysis home training and support in Alamance County. Information on these facilities is provided below.

<b>Alamance County Dialysis Facilities</b>						
<b>Certified Stations and Utilization as of December 31, 2018</b>						
<b>Dialysis Facility</b>	<b>Owner</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># Patients</b>	<b>Patients/Station</b>	<b>Utilization</b>
Alamance County Dialysis	DaVita	Graham	10	36	3.6000	90.00%
BMA of Burlington	BMA	Burlington	45	97	2.1556	53.89%
Burlington Dialysis	DaVita	Burlington	16	65	4.0625	101.56%
Carolina Dialysis of Mebane	BMA	Mebane	20	64	3.2000	80.00%
Glen Raven Dialysis	DaVita	Burlington	10	24	2.4000	60.00%
Mebane Dialysis	DaVita	Mebane	10	13	1.3000	32.50%
North Burlington Dialysis	DaVita	Burlington	16	62	3.8750	96.88%

**Sources:** Section G, page 34; Table B, July 2019 SDR

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 Alamance County Dialysis will have no effect on competition in Alamance County. ..., 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 Alamance County 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 F and Q of the application and any exhibits).
- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C and L of the application and any exhibits).

#### Conclusion

The Agency reviewed the:

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

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

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

#### C

On Form A 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 107 existing or approved kidney disease treatment facilities 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, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care

provided at all 107 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.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

### C

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

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- ACD is an existing facility. Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, page 20, the applicant projects that ACD will serve 44 patients on 13 stations, or a rate of 3.38 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 shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C, pages 19-21, 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.