

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 24, 2020

Findings Date: July 24, 2020

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: F-11887-20

Facility: Harrisburg Dialysis Center

FID #: 70392

County: Cabarrus

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

Project: Add no more than 2 dialysis stations pursuant to facility need for a total of no more than 28 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

Total Renal Care of North Carolina, LLC (the applicant) proposes to add no more than two dialysis stations to the existing facility (Harrisburg Dialysis Center) pursuant to facility need for a total of no more than 28 dialysis stations upon project completion.

#### **Need Determination**

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not county need determination for additional dialysis stations in Cabarrus County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Harrisburg Dialysis Center on page 152 of the 2020 SMFP is 91 percent or 3.64 patients per station per week, based on 91 in-center dialysis patients and 25 certified dialysis stations (91 patients / 25 stations = 3.64;  $3.64 / 4 = 91\%$ ).

As shown in Table 9E on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Harrisburg Dialysis Center is up to eight additional stations; thus, the applicant is eligible to apply to add up to eight stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new stations to Harrisburg Dialysis Center, which is consistent with the 2020 SMFP calculated facility need determination for up to eight dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2020 SMFP, Policy GEN-3 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 would promote safety and quality in Section B, pages 13-14; Section N.2, page 50; Section O, pages 52-53, and referenced exhibits. The information provided by the applicant is reasonable and 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, page 15; Section C.7, pages 23-24; Section L, pages 45-48; Sections N.2, page 50, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 15; Section F, pages 30-32; Section K, page 42-43; Section N.2, page 50; Section Q; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal would maximize healthcare value.

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

*“DaVita’s goal is to create a “Culture of Safety” in all of its facilities and to make this a core part of how we function. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients, communication of clear expectations of staff, and complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients.*

...

*Harrisburg Dialysis Center will help uninsured/underinsured patients with identifying and applying 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 parent corporation, DaVita, operates over 2,700 dialysis facilities nationwide and has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. All of the products utilized in the facility purchased as a result of the proposed project, from office supplies to drugs to clinical supplies, will be purchased under these contracts.”*

## **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.

- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the proposal promotes safety and quality, equitable access and maximizes healthcare value.

(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 two dialysis stations to the existing facility (Harrisburg Dialysis Center) pursuant to facility need for a total of no more than 28 dialysis stations upon project completion.

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

The following tables illustrate current and projected patient origin for in-center (IC) and peritoneal dialysis (PD) patients at Harrisburg Dialysis Center.

<b>Harrisburg Dialysis Center Current Patient Origin</b>				
<b>County</b>	<b>Last Full Operating Year CY 2019</b>			
	<b># of IC Patients</b>	<b>% of Total</b>	<b># of PD Patients</b>	<b>% of Total</b>
Cabarrus	67	85.2%	16	67.14% [57.14%]
Mecklenburg	10	12.3%	9	32.14%
Rowan	2	2.5%	0	0.00%
Stanly	0	0.0%	2	7.14%
Other States	0	0.0%	1	3.57%
<b>Total</b>	<b>79</b>	<b>100.0%</b>	<b>28</b>	<b>100.00%</b> <b>[109.99%] *</b>

Source: Section C, page 19  
 \*Project Analyst calculation in brackets

<b>Harrisburg Dialysis Center Projected Patient Origin</b>				
<b>County</b>	<b>2<sup>nd</sup> Full Operating Year CY 2023</b>			
	<b># of IC Patients</b>	<b>% of Total</b>	<b># of PD Patients</b>	<b>% of Total</b>
Cabarrus	76	86.4%	20	62.50%
Mecklenburg	10	11.4%	9	28.13%
Rowan	2	2.3%	0	0.00%
Stanly	0	0.0%	2	6.25%
Other States	0	0.0%	1	3.13%
<b>Total</b>	<b>88</b>	<b>100.0%</b>	<b>32</b>	<b>100.00%</b>

Source: Section C, page 20

In Section C, pages 20-22 and Section Q, Form C, the applicant provides the assumptions and methodology used to project IC and PD patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, page 22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposes services. On page 22, the applicant references Section B, Question 2 of its application wherein it demonstrates that up to eight additional dialysis stations are needed at Harrisburg Dialysis Center based on application of the facility need methodology. The applicant discusses the need for additional dialysis stations based on Harrisburg Dialysis Center patient growth rate over the last year. On pages 20-22 the applicant states:

- Projections begin with the 79 IC patients at the facility as of December 31, 2019. This information was reported on the December 2019 ESRD Data Collection forms submitted to the Agency. Of the 79 IC patients, 67 lived in the Cabarrus County and 12 lived outside of the service area (Mecklenburg and Rowan County).
- To project the growth of the 67 in-center patients residing in Cabarrus County, the applicant uses the Five-Year Average Annual Change Rate (AACR) of 3.3% for Cabarrus County, as published in the 2020.
- The applicant does not project growth for the 12 IC patients living outside the service area.
- The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

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

- The applicant demonstrates the need for additional stations at Harrisburg Dialysis Center based on its existing and future patient population.

- The applicant provides supporting documentation in its projected utilization in Section Q, Form C.

*In-Center Projected Utilization*

In Section C, page 21 and Section Q, Form C, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table.

	<b>In-Center Stations</b>	<b>In-Center Patients</b>
The applicant begins with the 79 patients dialyzing at Harrisburg Dialysis Center dialyzing on 26 stations as of 12/31/2019.	26	79
The facility's Cabarrus County patient census is projected forward a year to 12/31/2020 and is increased by the Five-Year AACR of 3.3% for Cabarrus County.		$67 \times 1.033 = 69.211$
The 12 patients from outside Cabarrus County are added to the facility's census. This is the ending census as of 12/31/2020.		$69.211 + 12 = 81.211$
The facility's Cabarrus County patient census is projected forward a year to 12/31/2021 and is increased by the Five-Year AACR of 3.3% for Cabarrus County.		$69.211 \times 1.033 = 71.495$
The 12 patients from outside Cabarrus County are added to the facility's census. This is the ending census as of 12/31/2021.		$71.495 + 12 = 83.495$
The proposed project is projected to be certified on 01/1/2022. The facility's station count increases to 28.	$26 + 2 = 28$	
The facility's Cabarrus County patient census is projected forward a year to 12/31/2022 and is increased by the Five-Year AACR of 3.3% for Cabarrus County.		$71.495 \times 1.033 = 73.854$
The 12 patients from outside Cabarrus County are added to the facility's census. This is the ending census as of 12/31/2022.		$73.854 + 12 = 85.854$
The facility's Cabarrus County patient census is projected forward a year to 12/31/2023 and is increased by the Five-Year AACR of 3.3% for Cabarrus County.		$73.854 \times 1.033 = 76.291$
The 12 patients from outside Cabarrus County are added to the facility's census. This is the ending census as of 12/31/2023.		$76.291 + 12 = 88.291$

Projected patients for OY1 and OY2 are rounded to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 86 in-center patients and at the end of OY2 (CY2023) the facility is projected to serve 88 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.07 patients per station per week or 76.78% ( $86 \text{ patients} / 28 \text{ stations} = 3.0714/4 = 0.7678$  or 76.78%)
- OY2: 3.14 patients per station per week or 78.57% ( $88 \text{ patients} / 28 \text{ stations} = 3.1428/4 = 0.7857$  or 78.57%)

The projected utilization of 3.07 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Peritoneal Dialysis Projected Utilization

In Section C, pages 21-22 and Section Q, Form C, the applicant describes its methodology and assumptions for projecting PD utilization, summarized as follows:

- The applicant begins its projections with the beginning census as of December 31, 2019. This information is reported in the ESRD Data Collection forms submitted to the Agency. The facility reported 28 PD patients receiving dialysis services at Harrisburg Dialysis Center.
- The applicant assumes that the Harrisburg Dialysis Center home-training program will grow at a rate of at least one patient per year during the period of growth.
- The applicant projects the first two full operating years of the project will be January 1, 2022–December 31, 2022 (CY2022) and January 1, 2023–December 31, 2023 (CY2023).

In Section C, page 22 and Section Q, Form C, the applicant provides the methodology used to project peritoneal dialysis utilization, as illustrated in the following table.

<b>PD Patient Projections</b>	<b>Start Date</b>	<b># of patients beginning of the year</b>	<b># of patients ending of the year</b>	<b>Average # of patients in the year</b>
Interim Period	1/1/2020	28	29	28.5
Interim Period	1/1/2021	29	30	29.5
OY 1	1/1/2022	30	31	30.5
OY 2	1/1/2024	31	32	31.5

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

- The applicant projects future utilization based on historical utilization at Harrisburg Dialysis Center.
- The applicant applies the Five-Year AACR for Cabarrus County (3.3%), as published in the 2020 SMFP. The applicant does not project growth for its patients who do not reside in Cabarrus County.
- The applicant assumes a growth rate of at least one patient per year for PD patients.
- Projected utilization for IC patients at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, pages 23-24, 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. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.*

*Harrisburg Dialysis Center 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 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Harrisburg Dialysis Center Projected Payor Mix CY 2023</b>				
<b>Payor Source</b>	<b>In-Center Dialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total Patients</b>	<b># of Patients</b>	<b>% of Total Patients</b>
Self-Pay	1.1	1.3%	0.0	0.0%
Insurance*	8.9	10.1%	6.9	21.4%
Medicare*	65.9	74.7%	24.0	75.0%
Medicaid*	6.7	7.6%	0.0	0.0%
Other: VA	5.6	6.3%	1.1	3.6%
<b>Total</b>	<b>88.2</b>	<b>100.0%</b>	<b>32.0</b>	<b>100.0%</b>

\*Including any managed care plans

The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the sources of payment that have been received in the last full operating year at Harrisburg Dialysis Center.
- Projections are based on the assumption that there will be no changes to the payor mix as a result of this project.

**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 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 (payer 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.

C

The applicant proposes to add no more than two dialysis stations to the existing facility (Harrisburg Dialysis Center) pursuant to facility need for a total of no more than 28 dialysis stations upon project completion.

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

Maintain the Status Quo-The applicant states that this alternative was dismissed due to the growth rate at the facility.

Relocate Stations from Another DaVita Facility- According to Table B of the 2020 SMFP, there are three DaVita facilities currently operating in Cabarrus County. Harrisburg Dialysis Center is currently operating at 76% capacity and Copperfield Dialysis is operating at 77% capacity as of 12/31/2019. Hickory Ridge Dialysis is a newly certified clinic opened in 2019 with 10 stations. The applicant states that relocating stations from either Copperfield Dialysis and Hickory Ridge Dialysis would negatively impact the patients served by these facilities.

Apply for the Two-Station Expansion-The applicant states that this alternative was selected because this alternative provides the most station/shift availability for the current and projected future census at the facility.

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

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the 2020 SMFP, Total Renal Care of North Carolina, LLC shall develop no more than two additional in-center dialysis stations for a total of no more than 28 in-center dialysis stations at Harrisburg Dialysis Center upon project completion.**
  - 3. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than two dialysis stations to the existing facility (Harrisburg Dialysis Center) pursuant to facility need for a total of no more than 28 dialysis stations upon project completion.

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

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

<b>Harrisburg Dialysis Center Capital Costs</b>		
Medical Equipment		\$7,500
Non-Medical Equipment		\$2,198
Furniture		\$2,800
<b>Total</b>		<b>\$12,498</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 32, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility that is already operational.

**Availability of Funds**

In Section F.2, page 30, the applicant states that the capital cost will be funded as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
<b>Type</b>	<b>DaVita, Inc.</b>	<b>Total</b>
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$12,498	\$12,498
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$12,498</b>	<b>\$12,498</b>

\* OE = Owner's Equity

Exhibit F-2 contains a letter, dated March 15, 2020, from the Chief Accounting Office for DaVita, Inc., parent company to Total Renal Care of North Carolina LLC, authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-8 contains Consolidated Balance Sheets from DaVita, Inc., for year ending December 31, 2019, showing that DaVita, Inc. had \$1.1 billion in cash equivalents and over \$17 billion in assets to fund the capital cost of the proposed project.

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

<b>Projected Revenues and Operating Expenses</b>		
<b>Harrisburg Dialysis Center</b>	<b>Operating Year 1 CY 2022</b>	<b>Operating Year 2 CY 2023</b>
Total Treatments	17,069	17,573
Total Gross Revenues (Charges)	\$6,565,970	\$6,761,568
Total Net Revenue	\$6,143,515	\$6,326,649
Average Net Revenue per Treatment	\$359.92	\$360.02
Total Operating Expenses (Costs)	\$3,855,313	\$3,951,735
Average Operating Expenses per Treatment	\$225.86	\$224.87
<b>Net Income/Profit</b>	<b>\$2,288,202</b>	<b>\$2,374,914</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 based on the following:

- 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 two dialysis stations to the existing facility (Harrisburg Dialysis Center) pursuant to facility need for a total of no more than 28 dialysis stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and

*Yancey counties.*” Thus, the service area is Cabarrus County. Facilities may serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Buncombe County as of December 31, 2018. The applicant owns and operates four dialysis facilities in Cabarrus County. The applicant is the only provider of dialysis services in Cabarrus County.

**Cabarrus County Dialysis Facilities**

Facility Name	Certified Stations as of 12/31/2018	Approved not yet certified stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
Cannon Dialysis	0	11	0	0%	0
Copperfield Dialysis	27	0	67	62.04%	2.48
Harrisburg Dialysis Center	25	0	91	91.00%	3.64
Hickory Ridge Dialysis	0	0	0	0%	0
<b>Total</b>	<b>52</b>	<b>11</b>	<b>158</b>		

Source: 2020 SMFP, Table 9B

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

*“While adding stations at this facility does increase the number of stations in Cabarrus 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 would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant’s proposal to add dialysis stations is based on the facility need methodology.
- 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 based on 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, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 12/31/2019	2nd Full Operating Year CY 2023
Administrator	1.00	1.00
Registered Nurse (RNs)	4.00	4.00
Home Training Nurse	1.00	1.00
Technicians (PCT)	10.00	11.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Administration/Business Office	1.00	1.00
Other: Biomedical Tech	0.50	0.50
<b>TOTAL</b>	<b>19.50</b>	<b>20.50</b>

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, which is found in Section Q. In Section H.2 and H.3, pages 37 and 38, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-1, H-2, and H-3, the applicant provides supporting documentation.

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 39, the applicant states that the following ancillary and support services are necessary for the proposed services:

<b>Harrisburg Dialysis Center – Ancillary and Support Services</b>		
<b>Services</b>	<b>Provider</b>	<b>Explanation/Supporting Documentation</b>
Self-care training (performed in-center)	On site	
Home Hemodialysis training and follow-up program	Dialysis Care of Kannapolis	Exhibit I-1
Peritoneal dialysis training and follow-up program	On site	
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	Atrium Health Carolinas Medical Center	Exhibit I-1
Acute dialysis in an acute care setting	Atrium Health Carolinas Medical Center	Exhibit I-1
Emergency care	Atrium Health Carolinas Medical Center	Exhibit I-1
Blood bank services	Atrium Health Carolinas Medical Center	Exhibit I-1
Diagnostic and evaluation services	Atrium Health Carolinas Medical Center	Exhibit I-1
X-ray services	Atrium Health Carolinas Medical Center	Exhibit I-1
Pediatric nephrology	Atrium Health Carolinas Medical Center	Exhibit I-1
Vascular surgery	Atrium Health Carolinas Medical Center	Exhibit I-1
Transplantation services	Atrium Health Carolinas Medical Center	Exhibit I-1
Vocational rehabilitation counseling and services	Vocational Rehab of Cabarrus County	Long-term, established relationship
Transportation	Cabarrus County Transportation	Long-term, established relationship

On page 39, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

- (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 make more than minor renovations to 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 46, the applicant provides the historical payor mix during last full operating year the proposed services, as shown in the table below.

<b>Harrisburg Dialysis Center Historical Payor Mix CY 2019</b>				
<b>Payor Source</b>	<b>In-Center Dialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total Patients</b>	<b># of Patients</b>	<b>% of Total Patients</b>
Self-Pay	1.0	1.3%	0.0	0.0%
Insurance*	8.0	10.1%	6.0	21.4%
Medicare*	59.0	74.7%	21.0	75.0%
Medicaid*	6.0	7.6%	0.0	0.0%
Other: Misc. Incl. VA	5.0	6.3%	1.0	3.6%
<b>Total</b>	<b>79</b>	<b>100.0%</b>	<b>28</b>	<b>100.0%</b>

\*Including managed care plans

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

Harrisburg Dialysis Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	48.2%	51.3%
Male	51.8%	48.7%
Unknown	0.0%	0.0%
64 and Younger	55.3%	86.8%
65 and Older	44.7%	13.2%
American Indian	0.0%	0.7%
Asian	2.6%	4.4%
Black or African-American	57.9%	19.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	36.0%	73.4%
Other Race	3.5%	2.4%
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>.

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, in Section L, page 46, the applicant states that the facility is not obligated under any applicable federal obligations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 47, 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>Harrisburg Dialysis Center Projected Payor Mix CY 2023</b>				
<b>Payor Source</b>	<b>In-Center Dialysis</b>		<b>Peritoneal Dialysis</b>	
	<b># of Patients</b>	<b>% of Total Patients</b>	<b># of Patients</b>	<b>% of Total Patients</b>
Self-Pay	1.1	1.3%	0.0	0.0%
Insurance*	8.9	10.1%	6.9	21.4%
Medicare*	65.9	74.7%	24.0	75.0%
Medicaid*	6.7	7.6%	0.0	0.0%
Other: Misc. Incl. VA	5.6	6.3%	1.1	3.6%
<b>Total</b>	<b>88.2</b>	<b>100.0%</b>	<b>32.0</b>	<b>100.0%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.3% of total in-center services will be provided to self-pay patients, 74.7% to Medicare patients and 7.6% to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the sources of payment that have been received in the last full operating year at Harrisburg Dialysis Center.
- Projections are based on the assumption that there will be no changes to the payor mix as a result of this project.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 47-48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 49, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than two dialysis stations to the existing facility (Harrisburg Dialysis Center) pursuant to facility need for a total of no more than 28 dialysis stations upon project completion.

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

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Buncombe County as of December 31, 2018. The applicant owns and operates four dialysis facilities in Cabarrus County. The applicant is the only provider of dialysis services in Cabarrus County.

**Cabarrus County Dialysis Facilities**

Facility Name	Certified Stations as of 12/31/2018	Approved not yet certified stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station
Cannon Dialysis	0	11	0	0%	0
Copperfield Dialysis	27	0	67	62.04%	2.48
Harrisburg Dialysis Center	25	0	91	91.00%	3.64
Hickory Ridge Dialysis	0	0	0	0%	0
<b>Total</b>	<b>52</b>	<b>11</b>	<b>158</b>		

Source: 2020 SMFP, Table 9B

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

*“The expansion of Harrisburg Dialysis Center will have no effect on competition in Cabarrus 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 services and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”*

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

*“The expansion of Harrisburg Dialysis Center 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.”*

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

*“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 services and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 50, the applicant states:

*“The expansion of Harrisburg Dialysis Center 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.”*

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N 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 based on 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 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 110 of this type of facility located in North Carolina.

In Section O, pages 52-53, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy occurred in one of these facilities. The applicant states that the facility is currently in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 110 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.

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 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, 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- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*  
(1) *an existing dialysis facility; or*  
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*  
*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*
- C- In Section C, page 21, and Section Q, Form C, the applicant projects that Cabarrus County Dialysis will serve 86 patients on 28 stations, or a rate of 3.07 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 20-21, and Section Q, Form C, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.