

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 22, 2020

Findings Date: June 22, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: B-11884-20

Facility: Asheville Kidney Center

FID #: 955773

County: Buncombe

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

Project: Add no more than 4 dialysis stations pursuant to facility need for a total of no more than 52 stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis)

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 four dialysis stations to the existing facility (Asheville Kidney Center) pursuant to facility need for a total of no more than 52 dialysis stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis).

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Buncombe 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 Asheville Kidney Center on page 151 of the 2020 SMFP is 79.81 percent or 3.19 patients per station per week, based on 166 in-center dialysis patients and 52 certified dialysis stations (166 patients / 52 stations = 3.19; $3.19 / 4 = 0.7981$ or 79.81%).

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 Asheville Kidney Center is up to eight additional stations; thus, the applicant is eligible to apply to add up to eight additional stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than four new stations to Asheville Kidney Center, which is consistent with the 2020 SMFP calculated facility need determination for up to eight additional 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 52; Section O, pages 54-55, 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 25-26; Section L, pages 47-50; Sections N.2. page

52, 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 32-36; Section K, pages 44-45; Section N.2, page 52; 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.

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 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 four dialysis stations to the existing facility (Asheville Kidney Center) pursuant to facility need for a total of no more than 52 dialysis

stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis).

Patient Origin

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 Buncombe 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 home hemodialysis (HH) patients at Asheville Kidney Center.

Asheville Kidney Center Current Patient Origin				
County	Last Full Operating Year CY 2019			
	# of IC Patients	% of Total	# of HH Patients	% of Total
Buncombe	162	85.7%	14	31.82%
Henderson	5	2.6%	7	15.91%
Alleghany	1	0.5%	0	0.00%
Brunswick	1	0.5%	0	0.00%
Caldwell	1	0.5%	1	2.27%
Forsyth	1	0.5%	0	0.00%
Transylvania	1	0.5%	4	9.09%
Georgia	2	1.1%	0	0.00%
South Carolina	3	1.6%	0	0.00%
Virginia	3	1.6%	0	0.00%
Other States	9	4.8%	0	0.00%
Cherokee	0	0.0%	1	2.27%
Graham	0	0.0%	1	2.27%
Haywood	0	0.0%	6	13.64%
McDowell	0	0.0%	3	6.82%
Macon	0	0.0%	1	2.27%
Mitchell	0	0.0%	1	2.27%
Swain	0	0.0%	2	4.55%
Yancey	0	0.0%	3	6.82%
Total	189	100.0%	44	100.00%

Source: Section C, page 20

Asheville Kidney Center Projected Patient Origin				
County	2nd Full Operating Year CY 2023			
	# of IC Patients	% of Total	# of HH Patients	% of Total
Buncombe	125	83.9%	18	37.50%
Henderson	2	1.3%	7	14.58%
Alleghany	1	0.7%	0	0.00%
Brunswick	1	0.7%	0	0.00%
Caldwell	1	0.7%	1	2.08%
Forsyth	1	0.7%	0	0.00%
Transylvania	1	0.7%	4	8.33%
Georgia	2	1.3%	0	0.00%
South Carolina	3	2.0%	0	0.00%
Virginia	3	2.0%	0	0.00%
Other States	9	6.0%	0	0.00%
Cherokee	0	0.0%	1	2.08%
Graham	0	0.0%	1	2.08%
Haywood	0	0.0%	6	12.50%
McDowell	0	0.0%	3	6.25%
Macon	0	0.0%	1	2.08%
Mitchell	0	0.0%	1	2.08%
Swain	0	0.0%	2	4.17%
Yancey	0	0.0%	3	6.25%
Total	149	100.0%	48	100.00%

Source: Section C, page 21

In Section C, pages 19-24 and Section Q, Form C, the applicant provides the assumptions and methodology used to project IC and HH patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 24, the applicant explains why it believes the population projected to utilize the proposed services needs the proposes services. On page 24, the applicant references Section B, Question 2 of its application wherein it demonstrates that up to eight additional dialysis stations are needed at Asheville Kidney Center based on application of the facility need methodology. On pages 21-24, the applicant states:

- Projections begin with the 189 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 189 IC patients, 162 lived in Buncombe County and 27 lived outside of the service area (Henderson, Alleghany, Brunswick, Caldwell, Forsyth, Transylvania Counties, Georgia, South Carolina, and Other States). The applicant does not project growth for the 27 IC patients living outside the service area.

- The applicant projects that 45 patients will transfer from Asheville Kidney Center to Arden Dialysis when Arden Dialysis is certified, based on the following:
 - The previously approved application, B-11037-15 was approved to relocate the 10-station Swannanoa Dialysis to Arden Dialysis. The application included 32 letters of support from IC patients, including 30 patients living in Buncombe County and two living in Henderson County.
 - The previously approved application, B-11831-19 was approved to relocate four stations from Asheville Kidney Center to Arden Dialysis. The application included 13 letters of support from IC patients, including 12 patients living in Buncombe County and one living in Henderson County.
- The Five-Year Average Annual Change Rate (AACR) for Buncombe County is 0.3%, as published in the 2020 SMFP. However, on page 22, the applicant states that it experienced a 13.9% growth rate of IC patients between December 2018 and December 2019. This growth rate is evidenced by ESRD data collection forms for December 2018 and 2019. Thus, the applicant uses a conservative growth rate of 1.0% which is less than the historical growth rate of 13.9% for IC patients at the facility between December 2018 and December 2019 but slightly higher than the 0.3% AACR for the county.
- 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 Asheville Kidney 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 23 and Section Q, Form C, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table.

	In-Center Stations	In-Center Patients
The applicant begins with the 189 patients at Asheville Kidney Center dialyzing on 52 stations as of 12/31/2019.	52	189
The facility's Buncombe County patient census is projected forward a year to 12/31/2020 and is increased by 1.0%.		$162 \times 1.010 = 163.620$
The 27 patients from outside Buncombe County are added to the facility's census. This is the ending census as of 12/31/2020.		$163.620 + 27 = 190.620$
Four stations are projected to transfer to Arden Dialysis from Asheville Kidney Center by 1/1/2021 leaving the facility with 48 stations.	$52 - 4 = 48$	
Forty-two Buncombe County patients are projected to transfer to Arden Dialysis from Asheville Kidney Center by 1/1/2021.		$163.620 - 42 = 121.620$
Three Henderson County patients are projected to transfer to Arden Dialysis to Asheville Kidney Center by 1/1/2021.		$27 - 3 = 24$
The facility's Buncombe County patient census is projected forward a year to 12/31/2021 and is increased by 1.0%.		$121.620 \times 1.010 = 122.836$
The 24 patients from outside Buncombe County are added to the facility's census. This is the ending census as of 12/31/2021.		$122.836 + 24 = 146.836$
The proposed project is projected to be certified on 01/1/2022. The facility's station count increases to 52.	$48 + 4 = 52$	
The facility's Buncombe County patient census is projected forward a year to 12/31/2022 and is increased by 1.0%.		$122.836 \times 1.010 = 124.065$
The 24 patients from outside Buncombe County are added to the facility's census. This is the ending census as of 12/31/2022.		$124.065 + 24 = 148.065$
The facility's Buncombe County patient census is projected forward a year to 12/31/2023 and is increased by 1.0%.		$124.065 \times 1.010 = 125.305$
The 24 patients from outside Buncombe County are added to the facility's census. This is the ending census as of 12/31/2023.		$125.305 + 24 = 149.305$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 148 in-center patients and at the end of OY2 (CY2023) the facility is projected to serve 149 in-center patients.

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

- OY1: 2.84 patients per station per week or 71.15% ($148 \text{ patients} / 52 \text{ stations} = 2.8461/4 = 0.7115$ or 71.15%)
- OY2: 2.86 patients per station per week or 71.63% ($149 \text{ patients} / 52 \text{ stations} = 2.8653/4 = 0.7163$ or 71.63%)

The projected utilization of 2.84 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).

Home Hemodialysis Projected Utilization

In Section C, pages 23-24 and Section Q, Form C, the applicant describes its methodology and assumptions for projecting HH 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 44 HH patients receiving dialysis services at Asheville Kidney Center.
- The applicant assumes that the Asheville Kidney 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 24 and Section Q, Form C, the applicant provided the methodology used to project home hemodialysis utilization, as illustrated in the following table.

HH Patient Projections	Start Date	# of patients beginning of the year	# of patients ending of the year	Average # of patients in the year
Interim Period	1/1/2020	44	45	44.5
Interim Period	1/1/2021	45	46	45.5
OY 1	1/1/2022	46	47	46.5
OY 2	1/1/2023	47	48	47.5

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

- The applicant projects future utilization based on historical utilization at Asheville Kidney Center.
- The applicant applies a conservative growth rate of 1.0 percent based on the significant growth in its IC patients experienced during the last year of operation at Asheville Kidney Center (13.9%), which is higher than the Five-Year AACR for Buncombe County (0.3%), as published in the 2020 SMFP. The applicant does not project growth for its patients who do not reside in Buncombe County.
- The applicant assumes a growth rate of at least one patient per year for HH 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 25-26, 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.

Asheville Kidney 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 49, 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.

Asheville Kidney Center Projected Payor Mix CY 2023				
Payor Source	In-Center Dialysis		Home Hemodialysis	
	# of Patients	% of Total Patients	# of Patients	% of Total Patients
Self-Pay	5.5	3.7%	0.0	0.0%
Insurance*	11.1	7.4%	3.3	6.8%
Medicare*	105.1	70.4%	42.5	88.6%
Medicaid*	12.6	8.5%	1.1	2.3%
Other: VA	15.0	10.1%	1.1	2.3%
Total	149.3	100.0%	48	100.0%

*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 Asheville Kidney 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
- 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
- (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 no more than four dialysis stations to the existing facility (Asheville Kidney Center) pursuant to facility need for a total of no more than 52 dialysis stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis).

In Section E, page 31, 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 current and future census of the facility.

Relocate Stations from Another DaVita Facility-According to Table B of the 2020 SMFP, there are two DaVita-owned facilities operating in Buncombe County. Asheville Kidney Center is currently operating at 79.81% capacity and Weaverville Dialysis is operating at 67.50% capacity. The applicant states that relocating four stations from Weaverville Dialysis will increase the station utilization to 81.25% and would negatively impact the patients served by the facility.

Apply for the Four-Station Expansion-The applicant states that this alternative was selected because it represents the maximum number of stations the facility can physically accommodate. Additionally, 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
- 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. 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 4 additional in-center dialysis stations for a total of no more than 52 in-center stations at Asheville Kidney Center upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis) which shall include any home hemodialysis training or isolation stations.**
 - 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 four dialysis stations to the existing facility (Asheville Kidney Center) pursuant to facility need for a total of no more than 52 dialysis stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis).

Capital and Working Capital Costs

In Section F page 33, the applicant states that the proposed project does not require financing. On page 34, the applicant states that there are no start-up or initial expenses projected since this is an existing facility that is already operational. Therefore, there are no capital or working capitals costs for the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
Asheville Kidney Center	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	28,743.45	29,074.60
Total Gross Revenues (Charges)	\$9,187,368	\$9,293,753
Total Net Revenue	\$8,639,230	\$8,739,300
Average Net Revenue per Treatment	\$300.56	\$300.58
Total Operating Expenses (Costs)	\$6,233,499	\$6,327,264
Average Operating Expense per Treatment	\$216.86	\$217.62
Net Income	\$2,405,731	\$2,412,036

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 sufficient funds for the operating needs of the proposal.
- The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than four dialysis stations to the existing facility (Asheville Kidney Center) pursuant to facility need for a total of no more than 52 dialysis stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis).

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 Buncombe 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 four dialysis facilities in Buncombe County. Two of the facilities are not yet operational. The applicant is the only provider of dialysis services in Buncombe County.

Buncombe 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
Asheville Kidney Center	52	0	166	79.81%	3.19
South Buncombe County Dialysis (Arden Dialysis)	0	10	0	00.00%	0.00
Swannanoa Dialysis Center	10	0	0	00.00%	0.00
Weaverville Dialysis	20	0	54	67.50%	2.70
Total	82	10	220		

Source: 2020 SMFP, Table 9B

In Section G, page 37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Buncombe. The applicant states:

“While adding stations at this facility does increase the number of stations in Buncombe 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 Nurses (RNs)	7.00	7.00
Home Training Nurse	1.00	1.00
Technicians (PCT)	20.00	20.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Administration/Business Office	1.00	1.00
Other: Biomedical Tech	1.00	0.50
TOTAL	33.00	32.50

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.3, which is found in Section Q. In Section H.2 and H.3, pages 39 and 40, 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 40, 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 41, the applicant states that the following ancillary and support services are necessary for the proposed services:

Asheville Kidney Center – Ancillary and Support Services		
Services	Provider	Explanation/Supporting Documentation
Self-care training (performed in-center)	On site	
Hemodialysis training and follow-up program	On site	
Peritoneal dialysis training and follow-up program	Biltmore at Home	
Isolation – hepatitis B	On site	
Psychological counseling	On site by RN	
Nutritional counseling	On site by RD	
Social work services	On site by MSW	
Laboratory services	DaVita Laboratory Services, Inc.	Exhibit I-1
Acute dialysis in an acute care setting	Memorial Mission Hospital	Exhibit I-1
Emergency care	Memorial Mission Hospital	Exhibit I-1
Blood bank services	Memorial Mission Hospital	Exhibit I-1
Diagnostic and evaluation services	Memorial Mission Hospital	Exhibit I-1
X-ray services	Memorial Mission Hospital	Exhibit I-1
Pediatric nephrology	Memorial Mission Hospital	Exhibit I-1
Vascular surgery	Memorial Mission Hospital	Exhibit I-1
Transplantation services	Wake Forest Baptist Medical Center	Exhibit I-1
Vocational rehabilitation counseling and services	Care Partners	Long-term, established relationship
Transportation	Mountain Mobility	Long-term, established relationship

On page 41, 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 41-42, the applicant describes its existing and proposed 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 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 48, the applicant provides the historical payor mix during last full operating year (CY 2019) for the proposed services, as shown in the table below.

Asheville Kidney Center Historical Payor Mix, CY 2019				
Payor Source	In-Center Dialysis		Home Hemodialysis	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	7.0	3.7%	0.0	0.0%
Insurance*	14.0	7.4%	3.0	6.8%
Medicare*	133.0	70.4%	39.0	88.6%
Medicaid*	16.0	8.5%	1.0	2.3%
Other (VA)	19.0	10.1%	1.0	2.3%
Total	189	100.0%	44	100.0%

*Including any managed care plans.

In Section L, page 47, the applicant provides the following comparison.

Asheville Kidney 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	35.0%	52.1%
Male	65.0%	47.9%
Unknown	0.0%	0.0%
64 and Younger	57.5%	80.0%
65 and Older	42.5%	20.0%
American Indian	1.3%	0.5%
Asian	1.3%	1.4%
Black or African-American	38.8%	6.3%
Native Hawaiian or Pacific Islander	3.8%	0.2%
White or Caucasian	46.3%	83.5%
Other Race	8.8%	2.2%
Declined / Unavailable	0.0%	0.0%

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

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 49, the applicant states

“DaVita may provide patient assistance related to patient obligations based on an individualized determination of a patient’s financial need. After counseling with a DaVita Social Worker or other appropriate teammate, patients may be eligible to submit a request for financial assistance via the Patient Financial Evaluation Policy, the policy for the American Kidney Fund Health Insurance Premium Program and other assistance programs as are made available to patients.

...

Patients with End Stage Renal Disease have access to dialysis services upon referral by a nephrologist with privileges at Asheville Kidney Center. Patients, families and friends can obtain access by contacting a nephrologist with privileges at the facility.”

In Section L, page 48, 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 49, 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.

Asheville Kidney Center Projected Payor Mix, CY 2023				
Payor Source	In-Center Dialysis		Home Hemodialysis	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	5.5	3.7%	0.0	0.0%
Insurance*	11.1	7.4%	3.0	6.8%
Medicare*	105.1	70.4%	39.0	88.6%
Medicaid*	12.6	8.5%	1.0	2.3%
Other (VA)	15.0	10.1%	1.0	2.3%
Total	149.3	100.0%	44	100.0%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 70.4% of total IC services will be provided to Medicare patients and 8.5% to Medicaid patients.

On page 49, 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 Asheville Kidney 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 49-50, 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 51, 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 four dialysis stations to the existing facility (Asheville Kidney Center) pursuant to facility need for a total of no more than 52 dialysis stations upon completion of this project and Project ID# B-11831-19 (relocate 4 stations to Arden Dialysis).

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 Buncombe 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 four dialysis facilities in Buncombe County. Two of the facilities are not yet operational. The applicant is the only provider of dialysis services in Buncombe County.

Buncombe 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
Asheville Kidney Center	52	0	166	79.81%	3.19
South Buncombe County Dialysis (Arden Dialysis)	0	10	0	00.00%	0.00
Swannanoa Dialysis Center	10	0	0	00.00%	0.00
Weaverville Dialysis	20	0	54	67.50%	2.70
Total	82	10	220		

Source: 2020 SMFP, Table 9B

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 52, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 52, the applicant states:

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

Regarding the impact of the proposal on quality, in Section N, page 52, the applicant states:

“...DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Asheville Kidney Center will enhance accessibility to dialysis for current and projected patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 52, the applicant states:

“...DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Asheville Kidney Center will enhance accessibility to dialysis for current and projected patients...”

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

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 54-55, 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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 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 23, and Section Q, Form C, the applicant projects Asheville Kidney Center will serve 148 patients on 52 stations, or a rate of 2.84 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 20-24, 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.