

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 27, 2021

Findings Date: January 27, 2021

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: A-11973-20

Facility: Waynesville Dialysis Center

FID #: 10800

County: Haywood

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

Project: Add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations)

REVIEW CRITERIA

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

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

Need Determination (Condition 2)

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, the county need methodology shows there is not a county need determination for additional dialysis stations in Haywood 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 facility 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 the facility is 89.47 percent or 3.6 patients per station per week, based on 68 in-center dialysis patients and 19 certified dialysis stations (68 patients / 19 stations = 3.5789; $3.5789 / 4 = 89.47\%$).

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

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on pages 30-31 of the 2020 SMFP, states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 13-14; Section N, page 49; Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 15; Section C, page 23; Section L, pages 44-47; Section N, page 49; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, page 15; Section F, pages 30-33; Section N, page 49; and referenced exhibits.

The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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 based on:
 - DaVita facilities incorporate a "Culture of Safety" which includes components such as risk identification and staff/patient engagement.
 - DaVita facilities incorporate a quality management program as part of their quality improvement, assessment and educational goals.

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

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 for this facility consists of Haywood County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Historical 01/01/2019-12/31/2019 (CY 2019)		Second Full FY of Operation following Project Completion 01/01/2023-12/31/2023 (CY 2023)	
	Patients	% of Total	Patients	% of Total
Haywood	46	62.2%	60	68.2%
Buncombe	10	13.5%	10	11.4%
Cherokee	1	1.4%	1	1.1%
Henderson	1	1.4%	1	1.1%
Jackson	3	4.1%	3	3.4%
Madison	1	1.4%	1	1.1%
Swain	2	2.7%	2	2.3%
Georgia	1	1.4%	1	1.1%
South Carolina	4	5.4%	4	4.5%
Tennessee	1	1.4%	1	1.1%
Other States	4	5.4%	4	4.5%
Total	74	100.0%	88	100.0%

Source: Section C, pages 19-20

In Section C, page 20, the applicant provides the assumptions and methodology used to project its patient origin. On page 20, the applicant states:

“Waynesville Dialysis Center had 74 in-center dialysis patients as of December 31, 2019 ... Of these 74 patients, 46 lived in the service area, Haywood County, and 28 lived outside of the service area...”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on the facility census as of December 31, 2019. Forty-six of the in-center patients reside in Haywood County and 28 reside out of the service area.
- To project the patient census forward, the applicant applies the Haywood County Five-Year Average Annual Change Rate (AACR) of 6.8%, as published in the 2020 SMFP, to the Haywood County patient census.
- The applicant assumes that the 28 in-center patients residing outside of the Haywood County will continue to dialyze at the facility and does not project any growth for this group.

Analysis of Need

In Section C, page 22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 22, the applicant states that the proposed services are needed based on Condition 2 of the facility need methodology; demonstrating a need for a three-station expansion.

The information is reasonable and adequately supported based on the following:

- According to the 2020 SMFP, as of December 31, 2018, Waynesville Dialysis Center was operating at a rate of 3.6 in-center patients per station per week, or

89.47 percent of capacity.

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, page 21, and Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

	In-Center Stations	In-Center Patients
The applicant begins with 74 patients at Waynesville Dialysis Center dialyzing on 21 stations as of 01/01/2020.	21	74
Project ID# A-11793-19 was certified on March 23, 2020. The station count increased from 21 to 24 stations.	$21 + 3 = 24$	
The facility's Haywood County patient census is projected forward a year to 12/31/2020 and is increased by the Five-Year AACR of 6.8% for Haywood County.		$46 \times 1.068 = 49.128$
The 28 patients from outside Haywood County are added to the facility's census. This is the ending census as of 12/31/2020.		$49.128 + 28 = 77.128$
The facility's Haywood County patient census is projected forward a year to 12/31/2021 and is increased by 6.8%.		$49.128 \times 1.068 = 52.469$
The 28 patients from outside Haywood County are added to the facility's census. This is the ending census as of 12/31/2021.		$52.469 + 28 = 80.469$
The proposed project is projected to be certified on 01/1/2022. The facility's station count increases to 27.	$24 + 3 = 27$	
The facility's Haywood County patient census is projected forward a year to 12/31/2022 and is increased by 6.8%.		$52.469 \times 1.068 = 56.037$
The 28 patients from outside Haywood County are added to the facility's census. This is the ending census as of 12/31/2022.		$56.037 + 28 = 84.037$
The facility's Haywood County patient census is projected forward a year to 12/31/2023 and is increased by 6.8%.		$56.037 \times 1.068 = 59.847$
The 28 patients from outside Haywood County are added to the facility's census. This is the ending census as of 12/31/2023.		$59.847 + 28 = 87.847$

Projected patients for Operating Year (OY)1 and OY2 are rounded to the nearest whole number. Therefore, at the end of OY1 (CY2022) the facility is projected to serve 84 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: 3.1 patients per station per week or 76.78% ($84 \text{ patients} / 27 \text{ stations} = 3.1111/4 = 0.7778$ or 77.78%)

- OY2: 3.3 patients per station per week or 81.48% (88 patients / 27 stations = $3.2592/4 = 0.8148$ or 81.48%)

The projected utilization of 3.1 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).

In Section C, pages 20-21 and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant was previously approved to add three stations to Waynesville Dialysis Center (Project ID# A-11793-19). The applicant states that the facility was certified effective March 23, 2020.
- The applicant begins its projections with the facility census as of December 31, 2019. This information is reported in the ESRD Data Collection forms submitted to the Agency. The facility reported 74 in-center patients receiving dialysis services at Waynesville Dialysis Center. Of the 74 patients, 46 reside in Haywood County and 28 reside outside of the service area.
- To project the growth of the 46 in-center patients residing in Haywood County, the applicant applies the Five-Year AACR of 6.8% for Haywood County, as published in the 2020 SMFP.
- The applicant does not project growth for the 28 patients living outside of 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).

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant applied a projected annual growth rate of 6.8 percent for Haywood County patients which reflects the Haywood County Five-Year AACR, as published in the 2020 SMFP.
- The applicant does not project growth for its patients who do not reside in Haywood County.
- Projected utilization for the in-center 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 to Medically Underserved Groups

In Section C, page 23, the applicant states:

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

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

Waynesville 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, disabled persons, elderly and other under-served persons.”

The applicant states that it is reasonable to assume than an estimate percentage of total patients for each group during the second operating year would be similar to the historical and projected payor mix. The applicant provides the estimated percentage for each medically underserved group it intends to serve in OY2, as shown in the following table.

Female	47.3%
Male	52.7%
Unknown	0.0%
64 and Younger	40.5%
65 and Older	59.5%
American Indian	0.0%
Asian	1.4%
Black or African-American	10.8%
Native Hawaiian or Pacific Islander	0.0%
White or Caucasian	83.8%
Other Race	4.1%
Medicare	78.4%
Medicaid	9.5%
Handicapped (data not captured)	0.0%

Source: Section C, Page 23

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based the assumption that there will be no change from the percentage of total patients in each group that currently have access to dialysis services at Waynesville Dialysis Center.

Conclusion

The Agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

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 Waynesville Dialysis Center.

Relocate Stations from Another DaVita Facility-The applicant states that this alternative was not an option since the 2020 SMFP indicates that there is a surplus of stations in Haywood County which precludes the relocation of stations into Waynesville Dialysis Center.

On page 29, the applicant states that its proposal to apply for the three-station expansion is the most effective alternative because it will meet the growing demand for dialysis services 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 proposed project will address the projected growth of the facility.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 3 additional in-center dialysis stations for a total of no more than 27 in-center stations at Waynesville Dialysis Center upon completion of this project and Project ID# A-11793-19 (add 3 stations).**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on February 1, 2022 and so forth.**

4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

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.

Medical Equipment	\$44,550
Non-Medical Equipment	\$4,821
Furniture	\$4,200
Total	\$53,571

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is reasonable and adequately supported.

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

Sources of Capital Cost Financing

Type	DaVita, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$53,571	\$53,571
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$53,571	\$53,571

* OE = Owner's Equity

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

- In Exhibit F-2, the applicant provides a letter dated October 5, 2020 from the Chief Accounting Officer, confirming that DaVita, parent company of Total Renal Care of North Carolina, Inc., is willing to commit cash reserves for the capital cost of the proposed project.
- In Exhibit F-8, the applicant provides DaVita's consolidated balanced sheets for December 2019, reflecting more than one billion in cash and cash equivalents and over \$17 billion in assets to fund the capital cost of 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 two full fiscal years following completion of the project, as shown in the table below.

	1st Full OY CY 2022	2nd Full OY CY 2023
Total Treatments	12,190	12,737
Total Gross Revenues (Charges)	\$3,664,365	\$3,828,719
Total Net Revenue	\$3,455,431	\$3,610,414
Average Net Revenue per Treatment	\$283.46	\$283.45
Total Operating Expenses (Costs)	\$2,577,143	\$2,656,400
Average Operating Expense per Treatment	\$211.41	\$208.55
Net Income	\$878,288	\$954,014

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

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant's assumptions of charges per treatment by source are based on historical revenue of DaVita's North Carolina facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

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 for this facility consists of Haywood County. Facilities may also 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 Haywood County as of December 31, 2018. The applicant owns and operates one dialysis facility in Haywood County. The applicant is the only provider of dialysis services in Haywood County.

Haywood County Dialysis Facilities				
Facility Name	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
Waynesville Dialysis Center	19	68	89.47%	3.5789
Total	19	68		

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 Haywood County. The applicant states:

“While adding stations at the facility does increase the number of stations in Haywood 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 for all the reasons described above.

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

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 OY CY 2023
Administrator	1.00	1.00
Registered Nurses (RNs)	2.75	3.50
Technicians (PCT)	8.00	10.25
Dietician	1.00	1.00
Social Worker	1.00	1.00
Administrator/Business Office	1.00	1.00
Other-Biomedical Tech	0.50	0.50
TOTAL	15.25	18.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by

the applicant are budgeted in F.4. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant utilizes three different resources to fill positions. They include DaVita's Teammate Recruiter, a referral program for current employees, and vocational training through student internship.
- The applicant provides training and continued education through DaVita's School of Clinical Education.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

Ancillary and Support Services

In Section I, page 38, the applicant identifies the necessary ancillary and support services for the proposed services. On page 38, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Waynesville Dialysis Center is a well-established facility in Haywood County and has long-standing relationships with local healthcare providers and social service agencies in Haywood County.

- In Exhibit I-1, the applicant provides a letter of support from the facility administrator ensuring its continuation of established agreements and working relationships in Haywood County.

Coordination

In Section I, pages 38-39, 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 due to facility's existing agreements and working relationships with healthcare providers and social service agencies in Haywood County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

NA

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 45, the applicant provides the historical payor mix during CY 2019 for the proposed services, as shown in the table below.

Waynesville Dialysis Center Historical Payor Mix Last Full OY, CY 2019	
Payor Category	In-Center Dialysis Services as Percent of Total
Self-Pay	1.4%
Insurance*	5.4%
Medicare*	78.4%
Medicaid*	9.5%
Other (VA)	5.4%
Total	100.0%

*Including any managed care plans.

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

Waynesville Dialysis Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full Operating Year	Percentage of the Population of the Service Area where the Stations will be located or Services Offered*
Female	47.3%	51.7%
Male	52.7%	48.3%
Unknown	0.0%	0.0%
64 and Younger	40.5%	75.0%
65 and Older	59.5%	25.0%
American Indian	0.0%	0.7%
Asian	1.4%	0.6%
Black or African-American	10.8%	1.4%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	83.8%	95.8%
Other Race	4.1%	1.4%
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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 45, the applicant states that the facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 45, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility 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 46, 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.

Waynesville Dialysis Center Projected Payor Mix 2nd Full OY, CY 2023	
Payor Category	In-Center Dialysis Services as Percent of Total
Self-Pay	1.4%
Insurance*	5.4%
Medicare*	78.4%
Medicaid*	9.5%
Other (VA)	5.4%
Total	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 1.4% of total services will be provided to self-pay patients, 78.4% to Medicare patients and 9.5% to Medicaid patients.

On page 46, 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 applicant's projected payor mix is based upon the sources of patient payment that have been received in the last full operating year by the facility.
- The applicant did not apply any adjustment rate when projecting payor mix, therefore, it is expected to be the same as the historical payor mix.

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

The Agency reviewed the:

- Application
- 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

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Waynesville Dialysis Center is used as a clinical learning site for students from Haywood Community College.
- In Exhibit M-2, the applicant provides a letter from DaVita to Haywood Community College, establishing Waynesville Dialysis Center as the site for clinical training and dialysis-specific orientation to nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID #A-11793-19 (add 3 stations).

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 for this facility consists of Haywood County. Facilities may also 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 Haywood County as of December 31, 2018. The applicant owns and operates one dialysis facility in Haywood County. The applicant is the only provider of dialysis services in Haywood County.

Haywood County Dialysis Facilities

Facility Name	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
Waynesville Dialysis Center	19	68	89.47%	3.5789
Total	19	68		

Source: 2020 SMFP, Table 9B

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 49, 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 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 49, the applicant states:

“The expansion of Waynesville 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.”

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

Regarding the impact of the proposal on quality, in Section N, page 49, the applicant states:

“Patient selection is the determining factor, as the patient will select the provider that gives the highest quality service and best meets their needs.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 49, the applicant states:

“The expansion of Waynesville Dialysis Center will enhance accessibility to dialysis for our patients...”

See also Section B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

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

C

In Section Q, Form A, the applicant identifies the kidney treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 98 of this type of facility located in North Carolina.

In Section O, page 51, 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 all the problems have been corrected. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 98 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 The specific criteria are 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 21, and Section Q, Form C, the applicant projects that Waynesville Dialysis Center will serve 84 in-center patients on 27 stations, or a rate of 3.1 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.