

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 20, 2019

Findings Date: May 20, 2019

Project Analyst: Ena Lightbourne

Team Leader: Fatima Wilson

Project ID #: A-11686-19

Facility: Waynesville Dialysis Center

FID #: 10800

County: Haywood

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 21 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Waynesville Dialysis Center (Waynesville Dialysis) proposes to add two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion.

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of three dialysis stations in Haywood County; thus the applicant cannot apply to add any additional stations based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations in its existing facility, based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Waynesville

Dialysis in the January 2019 SDR is 3.36 patients per station per week, or 84.21%, based on 64 in-center dialysis patients and 19 certified dialysis stations [$64 / 19 = 3.3684$; $3.3684 / 4 = 0.8421$ or 84.21%].

The applicant used the October 1 Review Table for facility need methodology instead of the April 1 Review Table. However, the applicant incorporated the correct data, which matches the results below. Application of the facility need methodology indicates up to three additional stations are needed for this facility, as illustrated in the following the table.

April 1 Review Table (January SDR)

		Part A
Required SDR Utilization		80%
Waynesville Dialysis		
January 2019 SDR		
Facility Utilization Rate (as of 6/30 of the previous year)		84.21%
		Part B
# of Certified Stations (6/30/2018) January 2019 SDR		19
# of Pending Stations		0
Total Existing and Pending Stations		19
In-Center Patients as of 6/30/18 - (January 2019 SDR) (SDR2)		64
In-Center Patients as of 12/31/2017 - (July 2018 SDR) (SDR1)		58
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients from SDR1	0.2069
(ii)	Divide the result of Step (i) by 12	0.0172
(iii)	Multiply the result of Step (ii) by 12	0.1034
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	70.6207
(v)	Divide the result of Step (iv) by 3.2 patients per station	22.0690
	and subtract the number of certified and pending stations to determine the number of stations needed	3

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 31 of the 2019 SMFP, is applicable to this review because the facility need methodology is applicable to this review. 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 will promote safety and quality in Section B.4 (a), pages 9-10; Section N.1, page 47; Section O.2, page 47; 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.4 (b), page 10; Section C.3, page 15; Section L, pages 41-45; Section N.1, page 47; 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.4(c), page 11; Section F, pages 21-26; Section K, pages 36-37; Section N.1, page 47; 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 will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application

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

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

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion.

Waynesville Dialysis Center does not currently provide nor proposes to provide Home Hemodialysis (HHD) or Peritoneal Dialysis (PD) in this application. Patients for these services are referred to Asheville Kidney Center.

Patient Origin

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

The following table illustrates current and projected patient origin for the first two years of operation following project completion, as provided in Section C, pages 13 and 16.

County	Current (12/31/18)	OY1 (CY2021)	OY2 (CY2022)	% of Total	
	In-Center	In-Center	In-Center	OY1	OY2
Haywood	49	53	54	77.9%	78.3%
Buncombe	7	7	7	10.3%	10.1%
Jackson	2	2	2	2.9%	2.9%
Madison	1	1	1	1.5%	1.4%
Tennessee	1	1	1	1.5%	1.4%
South Carolina	1	1	1	1.5%	1.4%
Other States	3	3	3	4.4%	4.3%
Total	64	68	69	100.0%	100.0%

In Section C, page 13, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to add two dialysis stations to the Waynesville Dialysis Center facility for a total of 21 dialysis stations upon project completion. On pages 13-14, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility as follows:

- The applicant projects the first two full operating years of the project will be January 1, 2021-December 31, 2021 (CY2021) and January 1, 2022-December 31, 2022 (CY2022).
- The applicant projects annual growth of the Haywood County residents at 2.5% which is the Haywood County Five Year Average Annual Change Rate (AACR) per the January 2019 SDR.
- As of June 30, 2018, Waynesville Dialysis had 49 Haywood County in-center patients and 15 in-center patients from other counties and states.
- The applicant begins utilization projections with the patient census of Haywood County residents at Waynesville Dialysis as of June 30, 2018. No patient growth calculations were performed for patients residing outside of the service area but they are added in at the appropriate time.

Projected Utilization

In Section C, page 14, the applicant provides projected utilization, as illustrated in the following table.

**Waynesville Dialysis
 Projected In-Center Utilization**

Beginning service area census	Start date	# of service area patients	x	Growth Rate	=	Service Area year end census	+	# out of service area patients	=	Total Year-end census	Year-end date
Service Area: Haywood	6/30/18	49									
Interim Period	7/1/18	49	x	1.0125	=	49.6125	+	15	=	64.6125	12/31/18
Current Year	1/1/19	49.6125	x	1.025	=	50.85281	+	15	=	65.85281	12/31/19
Interim Period	1/1/20	50.85281	x	1.025	=	52.12413	+	15	=	67.12413	12/31/20
Census OY 1	1/1/21	52.12413	x	1.025	=	53.42723	+	15	=	68.42723	12/31/21
Census OY 2	1/1/22	53.42723	x	1.025	=	54.76291	+	15	=	69.76291	12/31/22

Source: Table in Section C, page 14

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2021) the facility is projected to serve 68 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 69 in-center patients.

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

- OY1: 3.24 patients per station per week or 81.0% (68 patients / 21 stations = 3.24/4 = 0.8100 or 81.0%)
- OY2: 3.29 patients per station per week or 82.1% (69 patients / 21 stations = 3.29/4 = 0.8214 or 82.14%)

The projected utilization of 3.24 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- Waynesville Dialysis is currently operating at 84.21% capacity.
- The applicant projects future utilization based on historical utilization.
- The applicant assumes a projected annual growth rate of 2.5 percent for Haywood County patients at Waynesville Dialysis, which is equal to the Haywood County Five Year AACR, as published in the January 2019 SDR.
- The applicant does not project growth for its patients who do not reside in Haywood County.

- The applicant demonstrates a need for three additional stations based on the Facility Need Methodology but is only proposing to add two stations.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 15, 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 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.

Payment will not be required upon admission. Therefore services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped, elderly, and other under-served.”

In Section L, page 42, 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.

**Waynesville Dialysis
Projected Payor Mix, Project Year 2 CY 2022**

Payment Source	% Total Patients
Private Pay	1.5%
Medicare	25.0%
Medicaid	5.9%
Commercial Insurance	4.4%
Medicare/Commercial	27.9%
Medicare/Medicaid	29.4%
VA	5.9%
Total	100.0%

Source: Table in Section L, page 42

The applicant states on page 42 that the projected payor mix is based on the sources of patient payment that have been received by the existing facility in the last full operating year. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

NA

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

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

CA

The applicant proposes to add two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion.

In Section E, page 20, the applicant describes the alternatives it considered and explains why the 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 because of growth of the facility.
- Relocate stations from another Davita facility-Waynesville is the only operational DaVita facility in Haywood County.

- Apply for a Two-Station Expansion-The applicant states that this was the most effective alternative because it meets the growing demand for dialysis services at Waynesville Dialysis and avoids creating an inconvenient third shift of patients.

In Section E.2, Page 20, the applicant states that its proposal is the most effective alternative because it is the most efficient alternative to the meet the growing needs of patients choosing to dialyze at Waynesville Dialysis.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the January 2019 SDR, Total Renal Care of North Carolina, LLC shall develop no more than two additional dialysis stations for a total of no more than 21 certified stations upon completion of this project, 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.

The applicant proposes to add two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 21, the applicant projects the total cost of the project as shown in the table below.

Dialysis Machines	\$15,000
Equipment/Furniture	\$7,758
Total	\$22,758

In Section F, page 24, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.2, page 22, 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 *	\$22,758	\$22,758
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$22,758	\$22,758

* OE = Owner's Equity
Source: Table in Section F, page 22

Exhibit F-5 contains a letter from the Chief Accounting Officer for Davita Inc., parent company to Total Renal Care of North Carolina, LLC authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-7 contains a copy of the Consolidated Balance Sheets for DaVita, Inc., for year ending December 31, 2018 and December 31, 2017. DaVita, Inc. had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
Waynesville Dialysis	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	10,004	10,152
Total Gross Revenues (Charges)	\$2,700,079	\$2,739,220
Total Net Revenue	\$2,582,397	\$2,619,797
Average Net Revenue per Treatment	\$258.13	\$258.05
Total Operating Expenses (Costs)	\$2,475,938	\$2,520,185
Average Operating Expense per Treatment	\$247.50	\$248.24
Net Income/Profit	\$106,459	\$99,612

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus,

the service area is Haywood County. Facilities may serve residents of counties not included in their service area.

Waynesville Dialysis is the only dialysis provider in Haywood County.

Facility Name	Provider	Location	# of Stations	Utilization
Waynesville Dialysis	DaVita	Haywood	19	84.21%

Source: January 2019 SDR, Table B

In Section G, page 27, 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:

“The lone operational DaVita facility in Haywood County operated at 80% or greater utilization as reported on the January 2019 SDR. Therefore, Waynesville Dialysis has the potential for adding stations, given that they can show a need.”

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

- Waynesville Dialysis is the only dialysis provider in Haywood County.
- There is a facility need determination, as calculated using the methodology in the January 2019 SDR, for the proposed additional dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 28, the applicant provides current and projected staffing in full time equivalents (FTEs) for Waynesville Dialysis.

Position	Current	Projected	
		Operating Year 1 (CY2021)	Operating Year 2 (CY2022)
RNs	3.0	3.0	3.0
Technician (PCT)	8.0	8.0	8.0
Administrator	1.0	1.0	1.0
Dietician	0.5	0.5	0.5
Social Worker	0.5	0.5	0.5
Admin Assistant	1.0	1.0	1.0
Biomed Tech	0.5	0.5	0.5
TOTAL	14.5	14.5	14.5

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H.3 and H.4, pages 29-30, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.2, page 29, the applicant identifies the current medical director. In Exhibit I-3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit I-1, 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 32, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

Waynesville Dialysis – Ancillary and Support Services		
Services	Provider	Explanation/Supporting Documentation
In-center dialysis/maintenance	DaVita on site	
Self-care training (in-center)	DaVita on site	
Home Training HH PD Accessible follow-up program	Asheville Kidney Center	Exhibit I-1
Psychological counseling	DaVita on site	
Isolation – hepatitis	DaVita on site	
Nutritional counseling	DaVita on site	
Social Work services	DaVita on site	
Acute dialysis in an acute care setting	Mission Hospital	Exhibit I-1
Emergency care	Mission Hospital	Exhibit I-1
Blood bank services	Mission Hospital	Exhibit I-1
Diagnostic and evaluation services	Mission Hospital	Exhibit I-1
X-ray services	Mission Hospital	Exhibit I-1
Laboratory services	Mission Hospital	Exhibit I-1
Pediatric nephrology	Mission Hospital	Exhibit I-1
Vascular surgery	Mission Hospital	Exhibit I-1
Transplantation services	Carolina Medical Center	Exhibit I-1
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services	Exhibit I-1
Transportation	Haywood Public Transport	Exhibit I-1

Source: Table in Section I, page 32

On page 32, 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 33-34, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 45, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

**Waynesville Dialysis
 Historical Payor Mix CY 2018**

Payment Source	% Total Patients
Private Pay	1.5%
Medicare	25.0%
Medicaid	5.9%
Commercial Insurance	4.4%
Medicare/Commercial	27.9%
Medicare/Medicaid	29.4%
VA	5.9%
Total	100.0%

Source: Table in Section L, page 45

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance **
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Haywood	24%	52%	7%	16%	12%	11%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographical levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g. V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not

provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L.3, page 44, the applicant states:

Waynesville Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the rehabilitation Act of 1973 and its subsequent amendment in 1933. The facility has no obligation under the Hill Burton Act.

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

In Section L, page 44, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 42, 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 Projected Payor Mix Projected Year 2, CY 2022	
Payment Source	% Total Patients
Private Pay	1.5%
Medicare	25.0%
Medicaid	5.9%
Commercial Insurance	4.4%
Medicare/Commercial	27.9%
Medicare/Medicaid	29.4%
VA	5.9%
Total	100.0%

Source: Table in Section L, page 42

As shown in the table above, during the second year of operation, the applicant projects that 1.5% of total services will be provided to self-pay patients, 82.3% to Medicare patients and 5.9% to Medicaid patients.

On page 42, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- The projected payor mix is based on the sources of patient payment that have been received by the existing facility in the last full operating year.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.4, page 44, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 46, 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 two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion.

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

Waynesville Dialysis is the only dialysis provider in Haywood County.

Facility Name	Provider	Location	# of Stations	Utilization
Waynesville Dialysis	DaVita	Haywood	19	84.21%

Source: January 2019 SDR, Table B

In Section N, page 47, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 47, the applicant states:

“The expansion of Waynesville Dialysis will have no effect on competition in Haywood 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 TRC of NC LLC.

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

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Exhibit A-11, 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 106 of this type of facility located in North Carolina.

In Section O, page 48, the applicant states that, during the 18 months immediately preceding the submittal of the application, two facilities did not operate in compliance with Medicare

conditions of participation. Supporting documentation is provided in Exhibit O-2. The applicant states that each facility is currently in compliance. Supporting documentation is provided in Exhibit O-3. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 106 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Waynesville Dialysis is an existing facility.

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

-C- In Section C, page 14, the applicant projects that Waynesville Dialysis will serve 68 in-center patients on 21 stations, or a utilization rate of 3.24 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 13-17, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.