

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 17, 2019

Findings Date: June 17, 2019

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: C-11685-19

Facility: McDowell Dialysis Center

FID #: 040266

County: McDowell

Applicant: Total Renal Care of North Carolina, LLC d/b/a McDowell Dialysis Center

Project: Add no more than two dialysis stations for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations)

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 McDowell Dialysis Center proposes to add no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations).

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 deficit of two dialysis stations in McDowell 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 McDowell Dialysis Center in the January 2019 SDR is 4.0000 patients per station per week, or 100.00%, based on 52 in-center dialysis patients and 13 certified dialysis stations [$52 / 13 = 4.0000$; $4.0000 / 4 = 1.0000$ or 100.00%].

Application of the facility need methodology indicates up to three additional stations are needed for this facility, as illustrated in the following table.

April 1 Review Table (January SDR)

		Part A
Required SDR Utilization		80%
McDowell Dialysis Center		
January 2019 SDR		
Facility Utilization Rate (as of 6/30 of the previous year)		100.00%
		Part B
# of Certified Stations		13
# of Pending Stations		2
Total Existing and Pending Stations		15
In-Center Patients as of 6/30/2018 - (January 2019 SDR) (SDR2)		52
In-Center Patients as of 12/31/2017 - (July 2018 SDR) (SDR1)		47
Step	Description	Result
	Difference (SDR2 - SDR1)	5
(i)	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients from SDR1	0.2128
(ii)	Divide the result of Step (i) by 12	0.0177
(iii)	Multiply the result of Step (ii) by 12	0.1064
(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	57.5319
(v)	Divide the result of Step (iv) by 3.2 patients per station	17.9787
	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 K, page 38; Section N.1, page 48; Section O, page 49 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), pages 10-11; Section C.3, page 15; Section L, pages 42-45; Section N.1, page 48; 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 22-27; Section K, pages 37-38; Section N.1, page 48; 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 no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations).

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 McDowell County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	Current (6/30/18)	OY1 (CY2021)	OY2 (CY2022)	% of Total	
	In-Center	In-Center	In-Center	OY1	OY2
McDowell	49	53	55	94.6%	94.8%
Burke	3	3	3	5.4%	5.2%
Total	52	56	68	100.0%	100.0%

Source: Section C, pages 13 and 18

In Section C, pages 13-17, 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

In Section C, page 14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 14, the applicant states:

“Section B-2 clearly outlines the need that the population to [be] served, the in-center patients of McDowell Dialysis Center, has for the [two]-station expansion proposed in this application.”

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

- The applicant demonstrates a facility need of three additional stations based on the facility need methodology, as published in the January 2019 SDR.
- McDowell Dialysis Center is currently operating at 100.00% capacity with 13 stations. The applicant reasonably projects that with the growing demand for dialysis services at McDowell Dialysis Center, a third shift would be needed to address the projected growth.

Projected Utilization

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

**McDowell Dialysis Center
 Projected In-Center Utilization**

	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
Interim Period	7/1/18	49	x	1.016	=	49.784	+	3	=	52.784	12/31/18
Current Year	1/1/19	49	x	1.032	=	50.568	+	3	=	53.568	12/31/19
Interim Period	1/1/20	50.568	x	1.032	=	52.18618	+	3	=	55.18618	12/31/20
Census OY1	1/1/21	52.18618	x	1.032	=	53.85612	+	3	=	56.85613	12/31/21
Census OY1	1/1/22	53.85613	x	1.032	=	55.57953	+	3	=	58.57953	12/31/22

Source: Table in Section C, page 14

The applicant proposes to add two dialysis stations to the existing McDowell Dialysis Center, for a total of 15 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations). In Section C, pages 13-17, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- 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 McDowell County residents at 3.2% which is the McDowell County Five Year Average Annual Change Rate (AACR) per the January 2019 SDR.
- The applicant begins projections using half the McDowell County Five-Year AACR from July 1, 2018 moving forward.
- As of June 30, 2018, the current patient census of McDowell county residents at McDowell Dialysis center was 49 in-center patients.
- As of June 30, 2018, the patient census of non-McDowell county residents at McDowell Dialysis Center was a total of 3 in-center patients from another NC county. No patient growth calculations were performed for this patient population.
- In Project ID# C-11594-18, McDowell Dialysis Center is approved to add two stations for a total of 15 stations. These stations were included in the projections.

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 56 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 58 in-center patients.

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

- OY1: 3.29 patients per station per week or 82.40% ($56 \text{ patients} / 17 \text{ stations} = 3.29/4 = 0.8235$ or 82.40%)
- OY2: 3.4117 patients per station per week or 85.52% ($58 \text{ patients} / 17 \text{ stations} = 3.4117/4 = 0.8529$ or 85.30%)

The projected utilization of 3.29 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:

- McDowell Dialysis Center is currently operating at 100.00% capacity.
- The applicant projects future utilization based on historical utilization.
- The applicant assumes a projected annual growth rate of 3.2 percent for McDowell County patient census at McDowell Dialysis Center, which is equal to the McDowell 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 McDowell County.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- 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.3, 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 the handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

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 43, 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.

**McDowell Dialysis Center
Projected Payor Mix CY 2022**

Payment Source	% Total Patients	% In-Center Patients
Medicare	33.3%	33.3%
Medicaid	10.0%	10.0%
Commercial Insurance	6.7%	6.7%
Medicare/Commercial	11.7%	11.7%
Medicare/Medicaid	30.0%	30.0%
VA	8.3%	8.3%
Total	100.0%	100.0%

The applicant states on page 43 that the future 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

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 no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations).

In Section E, page 21, the applicant describes the alternatives it considered and explains why the alternative not chosen 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 rate of the facility.
- Apply for a Two-Station Expansion-The applicant states that this was the most effective alternative because it ensures that the issue of growth and access at the facility is addressed.

In Section E.2, Page 21, 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 McDowell Dialysis Center. The applicant states if the facility continues to operate at the current capacity, a third shift would be needed to address the projected growth.

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 17 certified stations upon completion of this project and Project ID #C-11594-18 (add 2 stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations).

Capital and Working Capital Costs

In Section F.1, page 22, the applicant projects the total cost of the project as shown in the table below.

Water Treatment Equipment	\$15,000
Equipment	\$7,758
Total	\$22,758

In Section F, pages 24-25, 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 23, 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

Exhibit F-5 contains a letter from the Chief Accounting Officer for DaVita Inc., parent company to Total Renal Care, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-6 contains a copy of the Consolidated Balance Sheets from DaVita, Inc., for year ending December 31, 2017 and December 31, 2018. 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		
McDowell Dialysis Center	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	8,225	8,447
Total Gross Revenues (Charges)	\$2,401,678	\$2,466,713
Total Net Revenue	\$2,272,656	\$2,334,209
Average Net Revenue per Treatment	\$276	\$276
Total Operating Expenses (Costs)	\$2,163,152	\$2,221,748
Average Operating Expense per Treatment	\$263	\$263
Net Income/Profit	\$109,504	\$112,461

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 no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations).

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 McDowell County. Facilities may serve residents of counties not included in their service area.

McDowell Dialysis Center is the only existing and approved facility in McDowell County. Therefore, DaVita is the only provider in McDowell County. The McDowell County facility is shown below.

Facility Name	Provider	Location	# of Stations	Utilization
McDowell Dialysis Center	DaVita	Marion	13	100.00%

Source: January 2019 SDR, Table B

In Section G, page 28, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in McDowell County. The applicant states:

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

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

- There is a facility need determination, based 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 additional 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.

In Section H, pages 29 and 32, the applicant provides current and projected staffing in full time equivalents (FTEs) for McDowell Dialysis Center as demonstrated in the chart below. The applicant projects an increase in direct staffing in Operating Year 2. The applicant states the Medical Director is not directly employed by the facility but has a sign agreement with the facility.

McDowell Dialysis Center Facility Staffing		
Position	Current # FTEs	Projected
	CY 2019	OY1 (CY2022)
Registered Nurse	2.0	3.0
Patient Care Technician	5.0	6.0
Administrator	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Administrative Asst.	1.0	1.0
Biomed Tech	0.5	0.5
Total	10.5	12.5

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 30-31, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 30, the applicant identifies the current medical director. In Exhibit I-3, the applicant provides a letter from medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-2 through H-4, 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 33, 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:

McDowell Dialysis Center – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	DaVita on site
Self-care training (in-center)	DaVita on site
Home training HH PD Accessible follow-up program	DaVita, Inc.-Referral to Asheville Kidney Center
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 Health System-Referral
Emergency care	Mission Health System-Referral
Blood bank services	Mission Health System-Referral
Diagnostic and evaluation services	Mission Health System-Referral
X-ray services	Mission Health System-Referral
Laboratory services	DaVita Laboratory Services, Inc.-Referral
Pediatric nephrology	Mission Health System-Referral
Vascular surgery	Mission Health System-Referral
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab Services
Transportation	McDowell County DSS

On page 33, the applicant adequately explains each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

In Section I, pages 33-35, 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 construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 46, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

**McDowell Dialysis Center
 Historical Payor Mix CY 2018**

Payment Source	% Total Patients
Medicare	33.3%
Medicaid	10.0%
Commercial Insurance	6.7%
Medicare/Commercial	11.7%
Medicare/Medicaid	30.0%
VA	8.3%
Total	100.0%

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
McDowell	20%	50%	12%	18%	16%	14%
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, page 45, the applicant states:

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

“McDowell Dialysis Center 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 1993. The facility has no obligation under the Hill Burton Act.”

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.

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 43, 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.

McDowell Dialysis Center Projected Payor Mix Project Year 2, CY 2022		
Payment Source	% Total Patients	% In-Center Patients
Medicare	33.3%	33.3%
Medicaid	10.0%	10.0%
Commercial Insurance	6.7%	6.7%
Medicare/Commercial	11.7%	11.7%
Medicare/Medicaid	30.0%	30.0%
VA	8.3%	8.3%
Total	100.0%	100.0%

As shown in the table above, during the second year of operation, the applicant projects that 75% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 10% to Medicaid patients.

On page 43, 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 applicant's proposed patient origin is based on historical patient origin of the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 45, 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 47, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to add no more than two dialysis stations to the existing facility for a total of no more than 17 dialysis stations upon completion of this project and Project ID #C-11594-18 (add 2 stations).

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 McDowell County. Facilities may also serve residents of counties not included in their service area.

McDowell Dialysis Center is the only existing and approved facility in McDowell County. Therefore, DaVita is the only provider in McDowell County. The McDowell County facility is shown below.

Facility Name	Provider	Location	# of Stations	Utilization
McDowell Dialysis Center	DaVita	Marion	13	100.00%

Source: January 2019 SDR, Table B

In Section N, page 48, 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 48, 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 Total Renal Care of North Carolina, LLC.

The expansion of McDowell County Dialysis will, enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our service 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, K, 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 105 of this type of facility located in North Carolina.

In Section O, page 49, 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 105 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- McDowell Dialysis Center 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 13, the applicant projects that McDowell Dialysis Center will serve 56 in-center patients on 17 stations, or a rate of 3.29 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.