

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2019

Findings Date: September 27, 2019

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: C-11741-19

Facility: McDowell Dialysis Center

FID #: 040266

County: McDowell

Applicant: Total Renal Care of North Carolina, LLC

Project: Relocate the entire facility to a new location for a total of no more than 17 stations upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Total Renal Care of North Carolina, LLC (TRC) proposes to relocate the entire dialysis facility McDowell Dialysis Center from 100 Spaulding Drive in Marion to new space to be constructed by a subsidiary of DaVita, Inc., parent company of the applicant, to 1549 Sugar Hill Road in Marion. Upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations), the facility will be certified for a total of no more than 17 stations.

Need Determination

The applicant proposes to relocate the entire facility; therefore, neither the county need methodology nor the facility need methodology in the 2019 State Medical Facilities Plan (SMFP) are applicable to this review.

Policies

There are two policies in the 2019 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy ESRD-2: Relocation of Dialysis Stations (page 25 of the 2019 SMFP) states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate existing dialysis stations within McDowell County; thus, there will be no change to the dialysis inventory of McDowell County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards

incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, pages 14-15, the applicant describes the project's plan to improve energy efficiency and conserve water, including energy efficient lighting, water optimization protocols, sustainable design and building materials, high-performance HVAC systems, and high-efficient equipment and appliances. In Exhibit B-4, the applicant includes a statement from DaVita's development department describing the project's plans to assure energy efficiency and water conservation. Therefore, the application is consistent with Policy Gen-4.

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 the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 and Policy GEN-4.

- (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 relocate an existing dialysis facility, McDowell Dialysis Center, from 100 Spaulding Road in Marion to new space to be constructed at 1549 Sugar Hill Road in Marion, which according to Google Maps is 0.3 miles and a one-minute drive time from the

current site. According the July 2019 Semiannual Dialysis Report (SDR), McDowell Dialysis Center was certified for 13 stations as of December 31, 2018. There are two projects previously approved but not yet developed, which will affect the number of dialysis stations at McDowell Dialysis Center. Project ID# C-11594-18 will add two stations to McDowell Dialysis Center and Project ID# C-11685-19 will also add two stations to McDowell Dialysis Center. Both projects are pursuant to the facility need methodology. In Section A, page 7, the applicant states the relocated facility will have no more than 17 certified dialysis stations upon completion of all three projects.

McDowell Dialysis Center currently does not offer home hemodialysis training (HH) or home peritoneal dialysis training (PD) and does not plan to offer HH and PD following completion of the proposed project.

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

The following table shows historical and projected patient origin.

McDowell Dialysis Center Historical (CY 2018) and Projected (CY 2022) Patient Origin				
County	Last Full Operating Year CY 2018		Operating Year 2 CY 2022	
	IC	% of Total	IC	% of Total
McDowell	52	92.8%	66	94.3%
Burke	2	3.6%	2	2.9%
Onslow	1	1.8%	1	1.4%
Other States	1	1.8%	1	1.4%
Total	56	100.0%	70	100.0%

Source: Section C, pages 17-18

In Section C, page 18, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 19-20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- Relocating the McDowell Dialysis Center to a new location will meet the current and future patient need. As of the July 2019 SDR, utilization at the facility was 107.69%.

- Although the facility is approved to add more stations, there is limited space to expand the existing facility to accommodate the projected patient growth in McDowell County.
- The proposed site, which is approximately a quarter mile from the current site, was selected to maximize patient access to care and other health care services in the area.

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

- The applicant bases the need to relocate the facility on factors such as patient population growth and proximity to current patients.
- The applicant has considered options other than relocation and provides reasonable and adequately supported information to justify the choice to relocate the facility.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization, as shown in the table below.

McDowell Dialysis Center					
Historical and Projected Utilization – CY 2018-2022					
	Historical	Interim		Projected	
	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
In-Center Patients	56	59	62	66	70
Total Patients	56	59	62	66	70

Note: Consistent with the applicant’s assumptions, the table shows the number of patients at the end of each year, rounded down to the nearest whole patient.

In Section C, the applicant provides the assumptions and methodology it used to project in-center utilization, which are summarized below.

- The applicant begins its utilization projections by using its in-center patient facility census as of December 31, 2018.
- The applicant assumes the in-center patient population currently receiving treatment at McDowell Dialysis Center and who currently reside in McDowell County will increase annually at a rate of 6.8 [6.4] percent, which is the Five Year Average Annual Change Rate (AACR) for McDowell County, as published in the July 2019 SDR.
- The applicant assumes no population growth for the in-center patients who utilize the facility and live in Burke and Onslow Counties and other states but assumes the patients will continue to dialyze at McDowell Dialysis Center and adds them to the calculations when appropriate.

- The applicant includes the addition of the four stations from projects C-11595-18 and C-11685-19. Therefore, utilization is based on 17 stations.
- Operating Year 1 is projected to begin January 1, 2021 and End December 31, 2021
 Operating Year 2 is projected to begin January 1, 2022 and End December 31, 2022

The applicant's calculations are summarized in the table below.

McDowell Dialysis Center In-Center Projections		
	IC Stations	IC Patients
The applicant begins with the 56 patients at Central Greensboro Dialysis [McDowell Dialysis Center] dialyzing on 13 stations at the facility as of 12/31/2018.	13	56
The facility's McDowell County patient census is projected forward one year to 12/31/2019 and increased by the Five-Year AACR (6.4%).		$52 \times 1.064 = 55.32800$
The 4 patients from outside McDowell County are added to the facility's census.		$55.33 + 4 = 59.33$
The facility's McDowell County patient census is projected forward a year to the end of the second interim year and is increased by 6.4%		$55.33 \times 1.064 = 58.86899$
The 4 patients from outside McDowell County are added to the facility's census. This is the ending census as of 12/31/2020.		$58.87 + 4 = 62.87$
Upon certification of the proposed relocation, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations) will also be certified leaving McDowell Dialysis Center with 17 stations.	$13 + 2 + 2 = 17$	
The facility's McDowell County patient census is projected forward a year to the end of OY1 and is increased by 6.4%		$58.87 \times 1.064 = 62.63661$
The 4 patients from outside McDowell County are added to the facility's census. This is the ending census as of 12/31/2021.		$62.64 + 4 = 66.64$
The facility's McDowell County patient census is projected forward a year to the end of OY2 and is increased by 6.4%		$62.64 \times 1.064 = 66.64535$
The 4 patients from outside McDowell County are added to the facility's census. This is the ending census as of 12/31/2022.		$66.65 + 4 = 70.65$

Source: Section C, page 19

The applicant rounds down and projects to serve 66 in-center patients on 17 stations, which is 3.88 patients per station per week ($66 \text{ patients} / 17 \text{ stations} = 3.882 / 4 = .9705$ or 97.1% utilization rate), by the end of OY1 and 70 in-center patients on 17 stations, which is 4.12 patients per station per week ($70 \text{ patients} / 17 \text{ stations} = 4.117 / 4 = 1.029$ or 102.9% utilization rate), by the end of OY2. In Section C, page, 19, the applicant states the facility is eligible to apply for additional stations in October 2019 based on the facility need methodology.

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

- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for McDowell County as published in the July 2019 SDR to project growth of McDowell County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development.
- The applicant does not project growth for its patients who do not reside in McDowell County.
- While the Criteria and Standards for End Stage Renal Disease Services are not applicable to this review, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as promulgated in 10A NCAC 14C .2203(b).

Access

In Section C, page 21, 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, 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 persons, elderly and other under-served persons.”

In Section L, page 43, the applicant projects the following payor mix during the second full year of operation following completion of the project, as illustrated in the following table.

McDowell Dialysis Center Projected Payor Mix CY 2022	
Payment Source	% In-Center Patients
Self-Pay	0.0%
Insurance*	4.3%
Medicare*	80.0%
Medicaid*	8.6%
Other (VA)	7.1%
Total	100.0%

*Including any managed care plans

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.

The applicant proposes to relocate the entire dialysis facility to a new location in Marion for a total of no more than 17 stations upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations).

According to the July 2019 SDR, McDowell Dialysis Center was certified for 13 stations as of December 31, 2018. There are two projects, previously approved but not yet developed, which will affect the number of dialysis stations at McDowell Dialysis Center. Project ID #C-11594-17 will add two stations and Project ID #C-11685-19 will also add two stations pursuant to the facility need methodology. In Section A, page 7, the applicant states the relocated facility will have 17 certified dialysis stations.

In Section D, page 24, the applicant states it will relocate the entire dialysis facility to a new site, which includes all existing and approved stations.

In Section D, page 24, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 30, the applicant states:

“All of the patients presently served at the current site are expected to continue receiving their dialysis services at the new location which is close proximity to the present site.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate the entire dialysis facility to a new location in Marion for a total of no more than 17 stations upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations).

In Section E, page 26, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: The applicant states that this option was dismissed due to the projected growth at the facility.
- Renovate the Current Facility: The applicant states that renovations would not accommodate any additional growth. Although the facility is eligible to apply for more stations in the October 1 review, pursuant to the July 2019 SDR, it would be more costly because an additional capital expense would be necessary almost immediately after completing renovations to accommodate the projected growth in the patient population.

On page 26, the applicant states relocating the facility is the most cost-effective approach to account for patient population 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 provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

- 1. Total Renal Care of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, Inc. shall relocate 13 stations from the existing location of McDowell Dialysis Center to the proposed new site for a total of no more than 17 stations at McDowell Dialysis Center upon**

completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations).

- 3. Total Renal Care of North Carolina, Inc. shall install plumbing and electrical wiring through the walls of McDowell Dialysis Center for no more than 17 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Total Renal Care of North Carolina, Inc. 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 relocate the entire dialysis facility to a new location in Marion for a total of no more than 17 stations upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (add 2 stations).

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects \$2,100,339 in capital costs to develop the proposed project as summarized below:

Site Preparation	\$82,739
Construction/Renovation Contract	\$1,175,330
Architect/Engineering Fees	\$106,400
Medical Equipment	\$261,820
Non-Medical Equipment	\$302,794
Furniture	\$140,217
Interest during Construction	\$31,039
Total	\$2,100,339

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

In Section F, page 28, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility which is already operational.

Availability of Funds

In Section F, page 27, the applicant states funding for the capital expenses of the proposed project will be funded through accumulated reserves.

Type	DaVita	Total
Accumulated reserves or OE *	\$2,100,339	\$2,100,339
Total Financing	\$2,100,339	\$2,100,339

Exhibit F-2 contains a letter dated July 11, 2019 from the Chief Accounting Office of DaVita, the parent company to Total Renal Care of North Carolina, LLC, authorizing and committing accumulated reserves of DaVita for the capital costs of the project. The letter further states:

“This letter confirms that DaVita has committed cash reserves in the total of \$2,100,339 for the capital expenditure.”

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, 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	9,485	10,125
Total Gross Revenues (Charges)	\$2,650,155	\$2,828,970
Total Net Revenue	\$2,503,235	\$2,672,137
Average Net Revenue per Treatment	\$264	\$264
Total Operating Expenses (Costs)	\$1,744,824	\$1,907,991
Average Operating Expense per Treatment	\$184	\$188
Net Income/Profit	\$758,411	*\$764,146

*The applicant stated \$764,147 in the application.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 relocate the entire dialysis facility to a new location in Marion for a total of no more than 17 stations upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (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 is McDowell County. Facilities may serve residents of counties not included in their service area.

There is only one dialysis facility in McDowell County. TRC has also been approved to add four additional stations in McDowell County at McDowell Dialysis Center. There are no other providers of dialysis services in McDowell County. The existing dialysis facility is shown below:

McDowell Dialysis Center Historical Utilization as of December 31, 2018				
Dialysis Facility	Certified Stations 12/31/2018	# of in-center patients as of 12/31/2018	% Utilization	Patients Per Station
McDowell Dialysis Center	13	56	107.69%	4.3077
Total	13	56	107.69%	4.3077

Source: Section G, page 32; July 2019 SDR, Table B

As shown in the table above, McDowell Dialysis Center was operating above 80 percent utilization (3.2 patients per station) as of December 31, 2018.

In Section G, page 42, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in McDowell County. The applicant states the stations to be relocated already exist and there will be no increase or decrease in the number of dialysis stations or facilities in McDowell County.

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

- The proposal would not result in an increase in the number of dialysis stations in McDowell County.
- The applicant adequately demonstrates that the proposed relocation of existing dialysis stations is needed in addition to the existing or approved dialysis stations in McDowell County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits in 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.

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

C

In Section Q, Form H, the applicant provides its current and projected staffing in full-time equivalent positions (FTEs), as shown in the table below.

McDowell Dialysis Current and Projected Staffing (FTEs)			
Position	Current (as of 12/31/18)	OY 1 (CY 2021)	OY 2 (CY 2022)
Administrator	1.00	1.00	1.00
Registered Nurses (RNs)	2.00	3.00	3.00
Technicians (PCT)	5.00	7.00	7.00
Dietician	0.50	0.50	1.00
Social Worker	0.50	0.50	1.00
Administration/Business Office	1.00	1.00	1.00
Other-Biomedical Tech	0.50	0.50	0.50
*Total FTEs	11.00 [10.5]	14.00 [13.50]	15.00 [14.50]

*In the application, the applicant rounds up the total FTEs.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 33-34, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1, H-2 and H-3. In Section H, page 34, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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

McDowell Dialysis Center Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	McDowell Dialysis Center
Self-care training (in-center)	McDowell Dialysis Center
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	Mission Hospital McDowell
Psychological counseling	McDowell Dialysis Center
Isolation – hepatitis	McDowell Dialysis Center
Nutritional counseling	McDowell Dialysis Center
Social Work services	McDowell Dialysis Center
Acute dialysis in an acute care setting	Mission Hospital McDowell
Emergency care	Mission Hospital McDowell
Blood bank services	Mission Hospital McDowell
Diagnostic and evaluation services	Mission Hospital McDowell
X-ray services	Mission Hospital McDowell
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Mission Hospital McDowell
Vascular surgery	Mission Hospital McDowell
Transplantation services	UNC Healthcare
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services
Transportation	McDowell County Department of Social Services

On pages 35-36, 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 35-36, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
 - (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

In Section K, page 38, the applicant states that the project involves constructing 8,800 square feet of new space. Line drawings are provided in Exhibit K-1.

On page 38, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

On page 39, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 39, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 39-40, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The applicant provides supporting documentation in Exhibit K-4.

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.

(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 42, the applicant provides the historical payor mix for CY 2018 at McDowell Dialysis Center, as shown in the table below.

McDowell Dialysis Center Historical Payor Mix CY 2018	
Payment Source	% of Total
Self-Pay	0.0%
Insurance*	3.6%
Medicare*	80.4%
Medicaid*	8.9%
Other (VA)	7.1%
Total	100.0%

*Including any managed care plans

In Section L, page 41, the applicant provides the following comparison.

Last Full Operating Year (CY 2018)		
McDowell Dialysis Center	% of Total Patients Served	% of the Population of McDowell County
Female	42.9%	43.8%
Male	57.1%	56.2%
Unknown	0.0%	0.0%
64 and Younger	50.0%	83.9%
65 and Older	50.0%	16.1%
American Indian	0.0%	1.5%
Asian	1.8%	0.6%
Black or African-American	14.3%	8.5%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	75.0%	77.0%
Other Race	8.9%	12.2%
Declined / Unavailable	0.0%	0.0%

Source: US Census Bureau's QuickFacts

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

In Section L, page 42, the applicant states they are not obligated to provide uncompensated care, community service or access by minorities and handicapped persons.

In Section L, page 42, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility.

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 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 OY 2 CY 2022	
Payment Source	% of Total
Self-Pay	0.0%
Insurance*	4.3%
Medicare*	80.0%
Medicaid*	8.6%
Other (VA)	7.1%
Total	100.0%

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 80 percent to patients having some or all their services paid for by Medicare, and 8.6 percent to Medicaid patients.

On page 43, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for McDowell Dialysis Center.

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, pages 43-44, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

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 relocate the entire dialysis facility to a new location in Marion for a total of no more than 17 stations upon completion of this project, Project ID# C-11594-18 (add 2 stations) and Project ID# C-11685-19 (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 is McDowell County. Facilities may serve residents of counties not included in their service area.

There is only one dialysis facility in McDowell County. TRC has also been approved to add four additional stations in McDowell County at McDowell Dialysis Center. There are no other providers of dialysis services in McDowell County. The existing dialysis facility is shown below:

McDowell Dialysis Center Facility and Utilization as of December 31, 2018				
Dialysis Facility	Certified Stations 12/31/2018	# of in-center patients as of 12/31/2018	% Utilization	Patients Per Station
McDowell Dialysis Center	13	56	107.69%	4.3077
Total	13	56	107.69%	4.3077

Source: Section G, page 32; July 2019 SDR, Table B

In Section N, page 46, 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 46, the applicant states:

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

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 Q of the application and any exhibits).
- Quality services will be provided (see Section B, K, N, and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B, C, D, N, and L of the application and any exhibits).

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.

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

C

In Section Q, Form A, the applicant provides a list of the DaVita-related dialysis facilities located in North Carolina. In Section A, page 9, the applicant states there are over 100 DaVita-related dialysis facilities 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-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 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.

NA

The applicant proposes to relocate its existing facility to new space approximately 0.3 miles from its current location. The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review because the applicant does not propose to establish a new end stage renal disease facility or to add stations to an existing facility.