

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 27, 2023

Findings Date: April 27, 2023

Project Analyst: Terris S. Riley

Co-Signer: Gloria C. Hale

Project ID #: A-12312-23

Facility: Cherokee Dialysis Center

FID #: 000047

County: Swain

Applicant: Total Renal Care of North Carolina, LLC

Project: Relocate existing dialysis facility

REVIEW CRITERIA

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

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

NA

Total Renal Care of North Carolina, LLC (hereinafter “TRC” or “the applicant”) proposes to relocate the Cherokee Dialysis Center (hereinafter “CDC”) to a new location in Cherokee in Swain County. CDC currently provides in-center (IC) dialysis. Upon completion of the proposed project, CDC will provide IC dialysis on 20 in-center stations.

Davita is the parent company of TRC. The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP)
- Offer a new institutional health service for which there are any applicable policies in the 2021 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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

C

The applicant proposes to relocate the CDC facility to a new location in Cherokee. Upon completion of this project, CDC will have a new location and continue providing only in-center dialysis on 20 stations.

Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” The proposed new location for CDC is in Cherokee. Thus, the service area for this facility consists of Swain County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin.

Cherokee Dialysis Center Current Patient Origin Last Full FY (01/01/2022 – 12/31/2022)		
County/State	# Patients	% Patients
Swain	33	70.2%
Graham	4	8.5%
Jackson	9	19.1%
Other States	1	2.1%
Total	47	100.00%

Source: Table on page 24 of the application.

Note: Table may not foot due to rounding.

Cherokee Dialysis Center Projected Patient Origin Second Full FY (01/01/2026 – 12/31/2026)		
County/State	# Patients	% Patients
Swain	33.3	70.4%
Graham	4.0	8.5%
Jackson	9.0	19.0%
Other States	1.0	2.1%
Total	47.3	100.00%

Source: Table on page 25 of the application.

Note: Table may not foot due to rounding.

In Section C, pages 25-26, and Section Q, the applicant provides the assumptions and methodology used to project patient origin.

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

- The applicant clearly explains how and why growth was projected in the Swain County patient population.
- The applicant did not project any growth in patients residing outside of Swain County.

Analysis of Need

In Section C, page 26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The applicant proposes to relocate the existing facility approximately three miles away from its current location. The lease for the existing facility is expiring. The community's need for the center will not change with relocation.
- The Eastern Band of Cherokee Indians, the Tribe, has a new site that is being developed to house various community health services and would like the county's only dialysis facility to be included with them.
- Relocating the Cherokee Dialysis Center will allow the facility to offer updates and upgrades that are currently offered at other DaVita facilities.
- By the end of FY1, Cherokee Dialysis is projected to serve 47 patients on 20 stations which is 2.35 patients per station per week ($47 \text{ patients} / 20 \text{ stations} = 2.35$ by the end of OY1) and 47 patients on 20 stations by the end of OY2 which is also 2.35 patients per week.

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

- The facility's lease is ending and the new location will allow for updates and upgrades.
- The applicant demonstrates that the patient census will continue to grow.

Projected Utilization

In Section C, pages 25-26, and Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized as follows:

- The applicant states that it begins its utilization projections with the in-center patient census at CDC on December 31, 2022.
- The applicant states that on December 31, 2022, it was serving 47 IC patients; 33 Swain County patients, four Graham County patients, nine Jackson County patients, and one patient residing out of state. See Section C, page 24, of the application.
- The applicant projects the Swain County IC patients will grow at a rate of 0.20 percent per year, which is the 5-year Average Annual Change Rate (AACR) for Swain County as published in the 2023 SMFP (page 133).
- The applicant states that the first full FY is projected to begin January 1, 2025, and end on December 31, 2025. The second full FY is projected to be January 1, 2026, through December 31, 2026.
- The applicant assumes no population growth for the patients residing in Graham and Jackson counties but assumes the patients will continue to dialyze at Cherokee Dialysis and adds them to the calculations when appropriate.
- The applicant also assumes that they will continue serving one patient that resides in a state other than North Carolina.

In Section C, page 26, and in Form C of Section Q, the applicant provides the calculations used to project utilization, as summarized as follows:

Cherokee Dialysis In-Center Projected Utilization	
The applicant begins with the 47 patients dialyzing on 20 stations at the facility as of 12/31/2022.	47
The facility's Swain County patient census is projected forward a year to 2023 and is increased by the five-year Average Annual Change Rate (AARC) for Swain County of .20%.	$33 \times 1.002 = 33.066$
The 14 patients residing in Graham County, Jackson County, and outside the state are added to the facility's census. This reflects the ending census for the first full interim year ending 12/31/2023.	$33.07 + 14 = 47.07$
The facility's Swain County patient census is projected forward a year to 2024 and is increased by the five-year Average Annual Change Rate (AARC) of .20%.	$33.07 \times 1.002 = 33.13$
The 14 patients residing in Graham County, Jackson County, and outside the state are added to the facility's census. This reflects the ending census for the second full interim year ending 12/31/2024.	$33.13 + 14 = 47.13$
The facility's Swain County patient census is projected forward a year to 2025 and is increased by the five-year Average Annual Change Rate (AARC) of .20%.	$33.13 \times 1.002 = 33.20$
The 14 patients residing in Graham County, Jackson County, and outside the state are added to the facility's census. This reflects the ending census for FY1.	$33.20 + 14 = 47.20$
The facility's Swain County patient census is projected forward a year to 2026 and is increased by the five-year Average Annual Change Rate (AARC) of .20%.	$33.20 \times 1.002 = 33.27$
The 14 patients residing in Graham County, Jackson County, and outside the state are added to the facility's census. This reflects the ending census for FY2.	$33.26 + 14 = 47.26$

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

- The applicant begins the projections with the existing CDC patient census as of December 31, 2021.
- The applicant projects growth in the Swain County patient population using the Swain County 5-year AACR as published in the 2022 SMFP.
- The applicant projects no growth for patients residing outside of Swain County but adds them at appropriate points in time.

Access to Medically Underserved Groups

In Section C, page 29, the applicant states:

“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.”

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

Cherokee Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, disabled persons, elderly and other under-served persons.”

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year following project completion, as shown in the following table.

Medically Underserved Groups	Estimated % of Total Patients
Low-income persons	87.2%
Racial and ethnic minorities	90.7%
Women	41.9%
Persons with disabilities	100.0%
Persons 65 and older	55.8%
Medicare beneficiaries	76.6%
Medicaid recipients	10.6%

Source: Section C, page 29.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant projects the estimates of underserved groups based on the recent facility experience of Cherokee Dialysis Center.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to relocate the Cherokee Dialysis facility to a new location in Swain County. Upon completion of this project the facility will continue to offer in-center dialysis on 20 stations in a new location approximately three miles from the current location, serving the same patient populations.

In Section D, pages 34, 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.

“...the needs of all current and projected patients will continue to be met at the relocated facility.

...all the dialysis patients of the facility will continue to have appropriate access to dialysis care.”

The applicant further states it is proposing to relocate the entire complement of in-center dialysis stations (20 stations) to the new location and do not anticipate any difficulties for patients to obtain the services at the new location.

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

- The applicant still plans to serve all patients it previously served and will be located three miles away from its current location.
- The applicant is relocating for the purpose of facility updates and upgrades that are cost-prohibited at their existing location.

Access to Medically Underserved Groups

In Section D, page 34, the applicant states that the relocation of the facility will have no effect on the ability of medically underserved groups to receive dialysis services. The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project because:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.

- The applicant projects the estimates of underserved groups based on the recent facility experience of Cherokee Dialysis Center.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

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 above-mentioned reasons.

- (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 Cherokee Dialysis Center to a new location in Swain County. Upon completion of this project, Cherokee Dialysis will have a new location and provide only in-center dialysis on 20 stations.

The applicant states in Section E, page 39, that there are no alternatives to meet the need for the proposal because the lease on the current facility is expiring and will not be renewed. In addition, the applicant states that the proposed, relocated facility will be on tribal land and that the Tribe is seeking to co-locate the facility with other community services.

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 reasonable 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 publicly available during the review and used by the Agency

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

- 1. Total Renal Care of North Carolina, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. The certificate holder shall relocate the existing Cherokee Dialysis Center facility in Swain County to a new location in Swain County.**
 - 3. Cherokee Dialysis Center shall be certified for no more than 20 in-center stations upon completion of this project.**
 - 4. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 20 in- center stations.**
 - 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on November 1, 2023.**
 - 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this project, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 88, the applicant projects the total capital cost of the project, as summarized below.

Site Costs	\$72,858
Construction Costs	\$1,163,202
Architect/Engineering Fees	\$115,360
Medical Equipment	\$303,160
Non-Medical Equipment	\$444,712
Furniture	\$134,585
Interest During Construction	\$71,484
Total Capital Cost	\$2,305,360

In Section Q, pages 88-89, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant describes each item that makes up the projected capital cost.
- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.
- The applicant relies on its experienced team of Project Managers and corporate finance to project the capital cost.

In Section F, page 42, the applicant states there will be no working capital costs because the facility’s revenues will exceed its operating costs.

Availability of Funds

In Section F, page 41, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total Renal Care of North Carolina, LLC	Total
Accumulated reserves or OE *	\$2,305,360	\$ 2,305,360
Total Financing	\$2,305,360	\$2,305,360

In Exhibit F.2, the applicant provides DaVita’s Consolidated Balance Sheets for the fiscal year ended December 31, 2021, which reflects \$461,900,000 in Cash and Cash equivalents.

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

- The applicant provides a letter in Exhibit F.2c submitted on behalf of the parent company of Total Renal Care of North Carolina, LLC, DaVita, confirming the applicant's intent to provide the necessary cash reserves for the capital cost of the proposed project.
- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The letter from the applicant demonstrates the availability of adequate cash and assets to fund the proposed project.

Financial Feasibility

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

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	6,990	7,000
Total Gross Revenues (Charges)	\$2,634,297	\$2,638,002
Total Net Revenue	\$2,625,560	\$2,629,252
Average Net Revenue Per Treatment	\$376	\$376
Total Operating Expenses (Costs)	\$1,713,148	\$1,742,671
Average Operating Expense (Costs) Per Treatment	\$245	\$249
Net Income	\$912,412	\$886,581

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 93 and 95. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected revenues for the first two full fiscal years will exceed the applicant's projected operating expenses for the first two full fiscal years.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

On page 113, the 2022 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” The proposed new location for Cherokee Dialysis Center is in Cherokee. Thus, the service area for this facility consists of Swain County. Facilities may serve residents of counties not included in their service area.

Cherokee Dialysis Center is the only dialysis facility in Swain County. Information on this facility is provided in the table that follows.

Swain County Dialysis Facilities					
Certified Stations and Utilization as of December 31, 2021					
Dialysis Facility	Owner	Location	Certified Stations	Utilization	# IC Patients
Cherokee Dialysis Center	TRC	Cherokee	20	61.25%	49

Source: Table 9A, Chapter 9, 2022 SMFP; Dialysis Patient Origin Reports

In Section G, page 48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Swain County. The applicant states:

“Cherokee Dialysis is the only kidney disease treatment center in Swain County.”

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

- The applicant does not propose to increase the number of certified dialysis stations in Swain County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis stations is needed in Swain County

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

On Form H referenced in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

Cherokee Dialysis Current and Projected Staffing			
	Current FTEs	Projected FTEs	
	12/31/2022	1st Full FY	2nd Full FY
Administrator	1.00	1.00	1.00
Registered Nurse	2.50	2.50	2.50
Patient Care Technicians	7.50	7.50	7.50
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Admin/Business Office	1.00	1.00	1.00
Other (Biomedical Tech)	0.50	0.50	0.50
TOTAL	13.50	13.50	13.50

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 54-57, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The facility is an existing facility already providing the necessary ancillary and support services.
- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and 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 for all the reasons described above.

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

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 (page 60). 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

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

In Section K, page 61, the applicant states that the project will consist of constructing 7,448 square feet. The applicant further states that it will either up-fit a shell building that is built to specifications by a developer who has purchased a parcel of property, or they will have a contractor up-fit space in an existing structure which the applicant will lease.

On pages 61-64, 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. Supporting documentation is provided in Exhibit K-4.

On page 62, the applicant identifies the applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 66, the applicant provides the historical payor mix during CY 2022 for its existing services, as shown in the tables below.

Cherokee Dialysis Historical Payor Mix CY 2022						
	IC		HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	0.0	0.00%	0.0	0.00%
Insurance*	6.0	12.8%	0.0	0.00%	0.0	0.00%
Medicare*	36.0	76.6%	0.0	0.00%	0.0	0.00%
Medicaid*	5.0	10.6%	0.0	0.00%	0.0	0.00%
Misc. (including VA)	0.0	0.0%	0.0	0.00%	0.0	0.00%
Total	47.0	100.00%	0.0	0.00%	0.0	0.00%

*Including any managed care plans

Note: Table may not foot due to rounding.

In Section L, page 67, the applicant provides the following comparison.

	% of Total Patients Served by Cherokee Dialysis during FY 2022	% of the Population of the Service Area during FY 2022
Female	41.9%	51.8%
Male	58.1%	48.2%
Unknown	0.0%	0.0%
64 and Younger	44.2%	81.1%
65 and Older	55.8%	18.9%
American Indian	86.0%	31.7%
Asian	0.0%	0.8%
Black or African-American	0.0%	1.4%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	9.3%	61.3%
Other Race	4.7%	6.8%

Sources: Cherokee Dialysis Internal Data, US Census Bureau.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states it has no such obligation.

The applicant further states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against Cherokee Dialysis Center.

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 69, 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.

Cherokee Dialysis Projected Payor Mix CY 2026						
	IC		HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.00	0.0%	0.0	0.00%	0.0	0.00%
Insurance*	6.03	12.8%	0.0	0.00%	0.0	0.00%
Medicare*	36.20	76.6%	0.0	0.00%	0.0	0.00%
Medicaid*	5.03	10.6%	0.0	0.00%	0.0	0.00%
Misc. (including VA)	0.00	0.0%	0.0	0.00%	0.0	0.00%
Total	47.26	100.0%	0.0	0.00%	0.0	0.00%

*Including any managed care plans/ **Note:** Table may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 76.6 percent of services will be provided to Medicare patients and 10.6 percent of services to Medicaid patients.

On page 70, 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 because the projected payor mix for in-center patients is based on the historical payor mix of in-center patients at Cherokee Dialysis Center.

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 70, the applicant describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-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.

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

C

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

In Section M, page 72, 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.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation for their Healthcare Professional Training Agreement/Outreach initiatives as well as a confirmation letter expressing their intent to extend their services as a clinical training site for nursing students of a community college in the area.
- The applicant states it often receives requests to utilize the facility for health professional training programs and discusses the options it offers when it receives such an inquiry.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

On page 113, the 2022 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” The proposed new location for Cherokee Dialysis Center is in Cherokee. Thus, the service area for this facility consists of Swain County. Facilities may serve residents of counties not included in their service area. Cherokee Dialysis Center is the only facility in Swain County and information on this facility is in the table below.

Swain County Dialysis Facilities					
Certified Stations and Utilization as of December 31, 2021					
Dialysis Facility	Owner	Location	Certified Stations	Utilization	# IC Patients
Cherokee Dialysis Center	TRC	Cherokee	20	61.25%	49

Source: Table 9A, Chapter 9, 2022 SMFP; Dialysis Patient Origin Reports

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

“The relocation of Cherokee Dialysis will have no effect on competition in Swain County. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition. The relocation of the facility will not have an adverse effect on competition since the patients already being served by DaVita will be continuing their care at a new site in the County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

“...Cherokee Dialysis’ relocation will enhance accessibility and/or convenience 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

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

Regarding the impact of the proposal on quality, in Section O, page 78, the applicant states:

“DaVita is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality

Management and Director of Integrated Quality Development. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita.”

See also Section B of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

“As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”

See also Sections C, D, and L of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes to relocate the Cherokee Dialysis Center to a new location in Swain County. Upon completion of this, Cherokee Dialysis Center will have a new location and provide only in-center dialysis on 20 stations.

On Form O in Section Q, 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 109 existing or approved kidney disease treatment facilities located in North Carolina.

In Section L, page 68, the applicant confirms that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 109 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.

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

NA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review.