

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 26, 2020

Findings Date: June 26, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: H-11880-20

Facility: Sandhills Dialysis

FID #: 090624

County: Richmond

Applicant: Total Renal Care of North Carolina, LLC

Project: Relocate Sandhills Dialysis and add no more than 3 dialysis stations pursuant to facility need for a total of no more than 25 dialysis stations upon completion of this project and Project ID #H-11251-16 (add 6 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC (hereinafter referred to as “the applicant” or TRC) was awarded a certificate of need on July 7, 2018 to develop a new 10-station dialysis facility, Pee Dee Dialysis, at 1300 East Broad Street in Rockingham, Richmond County by relocating four dialysis stations from Dialysis Care of Richmond County and six dialysis stations from Sandhills Dialysis (Project ID #H-11494-18). In November 2019 TRC was approved pursuant to a material compliance determination to relocate the proposed facility to a new site one mile from the originally approved location. The applicant also owns Sandhills Dialysis, an existing dialysis facility with 16 in-center stations also located in Rockingham. In this application, the applicant proposes to relocate Sandhills Dialysis to the proposed location for Pee Dee Dialysis, which the applicant will not develop. The applicant also proposes to add no more than three dialysis stations to the existing Sandhills Dialysis facility pursuant to the facility need

determination for a total of no more than 25 stations upon completion of this project and Project I.D. # H-11251-16 (add 6 stations).

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is a not a county need determination for additional dialysis stations for Richmond County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. In Table 9B, page 162 of the 2020 SMFP, the utilization rate reported for Sandhills Dialysis is 101.56%, based on 65 in-center dialysis patients and 16 certified dialysis stations [$65 / 16 = 4.06$; $4.06 / 4 = 1.0156$].

As shown in Table 9E on page 172 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Sandhills Dialysis is up to 10 additional stations; thus, the applicant is eligible to apply to add up to 10 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to Sandhills Dialysis, which is consistent with the 2020 SMFP calculated facility need determination for up to ten dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There are three policies in the 2020 SMFP applicable to this review. Policy ESRD-2: Relocation of Dialysis Stations on page 20 of the 2020 SMFP, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities both on pages 30-31 of the 2020 SMFP, are applicable to this review.

Policy ESRD-2 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 State Medical Facilities Plan, 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 State Medical Facilities Plan.*

Both the current location of Sandhills Dialysis and the proposed location of Sandhills Dialysis are in Richmond County; thus, the inventory of dialysis stations will not change in Richmond County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.5 (a) and (d), pages 13-14 and 15-16, Section N.2(b), page 51; Section O, pages 53-54; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.5 (b) and (d), pages 15-16, Section C.7, pages 23-24; Section L, pages 46-49; Section N.2(c), page 51; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.5 (c) and (d), pages 15-16; Section N.2(a), page 51; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

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

Policy GEN-4 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, the Certificate of Need Section 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 of 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 16-17, the applicant explains why it believes its application is consistent with Policy GEN-4. The applicant states that DaVita’s development department is implementing several strategies to ensure its facilities align with energy, water and paper conservation and overall waste reduction. The applicant states it is committed to environmental responsibility and will manage utility consumption and sustainability. The applicant provides supporting documentation in Exhibit B-6. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
 - The applicant adequately demonstrates how Sandhills Dialysis's projected volumes incorporate the concepts of safety and quality, equitable access and maximum healthcare value for resources expended in meeting the facility need.
 - The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposed relocation of stations is within Richmond County.
 - The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the proposal demonstrates how it will promote safety, quality and access to dialysis services as stated above.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 as stated above.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate Sandhills Dialysis and add three dialysis stations to the for a total of 25 stations upon completion of this project and Project ID #H-11251-16 (add 6 stations).

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Sandhills Dialysis:

Sandhills Dialysis

# OF STATIONS	DESCRIPTION	PROJECT ID #
16	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
3	# of stations to be added as part of this project	
0	# of stations to be deleted as part of this project	
6	# of stations previously approved to be added but not yet certified	H-11251-16
0	# of stations previously approved to be deleted but not yet certified	
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
25	Total # of stations upon completion of all facility projects	

As outlined in the table above, in this application, the applicant proposes to add three dialysis stations for a total of 25 stations upon the project completion.

Patient Origin

On page 113, the 2020 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Richmond County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the patient origin for the last full operating year (OY), calendar year (CY) 2019, as summarized in the table below:

Sandhills Dialysis Historical Patient Origin - CY2019

COUNTY	# IN-CTR PATIENTS	% OF TOTAL
Richmond	64	98.5%
South Carolina	1	1.5%
Total	65	100.0%

The following table summarizes projected patient origin for the second full operating year (CY 2023) following project completion, as provided in Section C.3, page 20.

Sandhills Dialysis Projected Patient Origin - CY2023

COUNTY	# IN-CTR PATIENTS	% OF TOTAL
Richmond	72	98.6%
South Carolina	1	1.4%
Total	73	100.0%

In Section C, pages 20-21, the applicant provides the assumptions and methodology it used to project patient origin, which the applicant states is based upon the December 31, 2019 Data Collection Form for ESRD Facilities submitted by Sandhills Dialysis. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 20-22, the applicant describes its need methodology and assumptions for projecting in-center utilization of the facility, summarized as follows:

- The applicant states Condition 2 of the facility need methodology clearly outlines the need the in-center patient population of Sandhills Dialysis has for the proposed three station addition.
- The applicant states the current physical plant at Sandhills Dialysis is unable to accommodate significant renovations, which it needs to effectively serve patients. Therefore, the applicant states it is more cost-effective to relocate and expand the Sandhills Dialysis facility than to develop Pee Dee Dialysis and renovate and expand Sandhills Dialysis at its current site.
- The applicant states that Sandhills Dialysis will have 25 in-center stations, because the applicant will not develop Pee Dee Dialysis and thus the proposed relocation of stations from Sandhills Dialysis to Pee Dee Dialysis will not take place.
- The applicant begins with the patient population at Sandhills Dialysis as of December 31, 2019, as reported on the ESRD Data Collection Form filed with the Agency in February 2020. That census was 65 in-center patients. The facility provides only in-center dialysis.
- The applicant projects growth of the Richmond County in-center patient population based on the 3.0% Five Year Average Annual Change Rate (AACR) as indicated in Table 9C in the 2020 SMFP.
- The applicant assumes the December 31, 2019 patients from counties other than Richmond will continue to dialyze at Sandhills Dialysis but does not assume any growth in patients from these counties.
- Operating Year (OY) 1 is calendar year (CY) 2022, January 1-December 31, 2022 and OY2 is CY 2023, January 1-December 31, 2023.

Projected Utilization

In Section C.3, page 21, the applicant provides a table to illustrate its methodology used to project in-center utilization, as shown below:

	# STATIONS	PATIENTS
The applicant begins with the Richmond County in-center patients as of December 31, 2019.	16	65
Project Richmond County patient population forward one year to December 31, 2020, using the 3.0% Richmond County Five Year AACR.		$64 \times 1.03 = 65.9200$
Add one patient from outside Richmond County. This is the ending census as of December 31, 2020.		$65.92 + 1 = 66.92$
Project Richmond County patient population forward one year to December 31, 2021, using the 3.0% Richmond County Five Year AACR.		$65.92 \times 1.03 = 67.8976$
Add one patient from outside Richmond County. This is the ending census as of December 31, 2021.		$67.8976 + 1 = 68.8976$
Projected certification date for this project and Project ID #H-11251-16 is 1/1/2022. The station count as of this date is 25.	$16 + 6 + 3 = 25$	
Project Richmond County patient population forward one year to December 31, 2022, using the 3.0% Richmond County Five Year AACR.		$67.8976 \times 1.03 = 69.9345$
Add one patient from outside Richmond County. This is the projected ending census as of December 31, 2022, OY 1.		$69.9345 + 1 = 70.9345$
Project Richmond County patient population forward one year to December 31, 2023, using the 3.0% Richmond County Five Year AACR.		$69.9345 \times 1.03 = 72.0325$
Add one patient from outside Richmond County. This is the projected ending census as of December 31, 2023, OY 2.		$72.0325 + 1 = 73.0325$

The applicant projects to serve 71 in-center patients in OY1 and 73 in-center patients in OY2. Thus, the applicant projects that Sandhills Dialysis will have a utilization rate of 71.0% or 2.84 patients per station per week ($71 \text{ patients} / 25 \text{ stations} = 2.84$; $2.84 / 4 = 0.71$ or 71.0%) in OY1. The projected utilization of 2.80 patients per station per week at the end of OY1 meets the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing Sandhills Dialysis patient census as of December 31, 2019.
- The applicant projects the Richmond County patient census at Sandhills Dialysis will increase by the Richmond County Five Year AACR of 3.0%, as reported in Table 9C of the 2020 SMFP.
- The applicant does not project any growth in the number of out-of-county patients in the first two operating years of the project and adds them to the patient census at appropriate points in time.
- The utilization rate by the end of OY1 meets the minimum standard of 2.8 patients per station per week.

Access

In Section C.7, page 23, the applicant states:

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

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

Sandhills 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, handicapped person, elderly and other under-served persons.”

In Section L.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project:

**Sandhills Dialysis
Projected Payor Mix CY2023**

PAYMENT SOURCE	IN-CENTER DIALYSIS	
	# OF PATIENTS	% OF TOTAL
Self-pay	0.0	0.0%
Insurance*	1.1	1.5%
Medicare*	69.7	95.4%
Medicaid*	2.2	3.1%
Other (VA)	0.0	0.0%
Total	73.0	100.0%

*Including any managed care plans
Totals may not sum due to rounding

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.

C

The applicant proposes to relocate Sandhills Dialysis to the proposed location for Pee Dee Dialysis, which the applicant will not develop. The applicant also proposes to add no more than three dialysis stations to the existing Sandhills Dialysis facility pursuant to the facility need determination for a total of no more than 25 stations upon completion of this project and Project I.D. # H-11251-16 (add 6 stations).

In Section D, pages 28-29, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced by relocating the existing facility will be adequately met following completion of the project. On page 28, the applicant states:

“...the project proposes the relocation of Sandhills Dialysis’ existing (16), CON approved (6) and proposed (3) stations to a new site for a total of no more than 25 stations.

The relocation of the Sandhills Dialysis facility will have no effect on the ability of low income persons, racial and ethnic minorities, women, disabled persons, and other under-served group and the elderly to obtain needed health care.”

In Section D, page 28, the applicant states the needs of the current and projected patients will continue to be met at the proposed location, which is in close proximity to their current facility.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 needs of the population currently using the services 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 Sandhills Dialysis and add three dialysis stations for a total of 25 stations upon completion of this project and Project ID #H-11251-16 (add 6 stations).

In Section E, page 30, 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 maintaining the status quo is not an effective alternative because of the growth rate at the facility.
- *Renovate Sandhills Dialysis and develop Pee Dee Dialysis* – The applicant states that due to the physical plant condition, it would be more costly to both renovate Sandhills Dialysis and develop Pee Dee Dialysis.

On page 30, the applicant states that the proposal to relocate Sandhills Dialysis and renovate and expand the facility is the most effective alternative to meet the needs of the dialysis patients.

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 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 shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2 and the facility need determination in the 2020 SMFP, Total Renal Care of North Carolina, LLC shall relocate the entire facility to a new location and develop no more than three additional in-center dialysis stations at Sandhills Dialysis for a total of no more than 25 in-center stations upon completion of this project and Project I.D. # H-11251-16 (add 6 stations to Sandhills Dialysis).**
 - 3. Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than 25 in-center stations.**
 - 4. Prior to the issuance of the Certificate of Need, Total Renal Care of North Carolina, LLC shall relinquish the Certificate of Need issued pursuant to Project ID #H-11494-18 (develop Pee Dee Dialysis).**
 - 5. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate Sandhills Dialysis and add three dialysis stations for a total of 25 stations upon completion of this project and Project ID #H-11251-16 (add 6 stations).

Capital and Working Capital Costs

In Section Q, Form F.1b, the applicant provides a table to illustrate projected capital cost of the project. Since the applicant proposes to relocate Sandhills Dialysis to the site previously approved for the development of Pee Dee Dialysis and proposes to expand Sandhills Dialysis, the capital cost was provided as a cost overrun, incorporating the capital cost associated with the development of Pee Dee Dialysis. The applicant will not develop Pee Dee Dialysis, and will relocate Sandhills Dialysis to the site previously approved for the development of Pee Dee Dialysis. See the following table from Section Q, Form F.1a: projects the total capital cost of the project, as shown in the table below:

Sandhills Dialysis Project Capital Cost

ITEM	PROJECT ID #H-11494-18	PROJECT ID #H-11880-20	DIFFERENCE
Site Costs	\$0	\$148,415	\$148,415
Construction Costs	\$1,616,717	\$1,770,137	\$153,420
Miscellaneous Costs	\$958,152	\$1,115,800	\$157,648
Total	\$2,574,869	\$3,034,352	\$459,483

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

In Section F.3, pages 32-33, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years 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 summarized in the table below.

Sandhills Dialysis Projected Revenue and Operating Expenses

	OY 1 CY 2022	OY 2 CY 2023
Total In-Center Treatments	10,361.56	10,667.96
Total Gross Revenue (charges)	\$2,798,737	\$2,881,498
Total Net Revenue	\$2,651,510	\$2,729,918
Average Net Revenue per Treatment	\$255.90	\$255.90
Total Operating Expenses (costs)	\$2,374,570	\$2,435,114
Average Operating Expense per Treatment	\$229.17	\$228.26
Net Income / Profit	\$276,940	\$294,804

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.

Availability of Funds

In Section F, page 31, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,034,352	\$3,034,352
Bonds	\$ 0	\$ 0
Other (Specify)	\$ 0	\$0
Total Financing	\$3,034,352	\$3,034,352

* OE = Owner's Equity

Exhibit F contains the Consolidated Financial Statements for years ending December 31, 2019 that show DaVita, Inc., parent company to Total Renal Care of North Carolina, LLC currently has \$1.1 billion in cash and cash equivalents and \$17 billion in total assets.

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.
- The applicant adequately demonstrates the availability of 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 Sandhills Dialysis and add three dialysis stations to the for a total of 25 stations upon completion of this project and Project ID #H-11251-16 (add 6 stations).

On page 113, the 2020 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-Graham counties and Avery-Mitchell-Yancey counties.”* Thus, the service area for this facility is Richmond County. Facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis centers in Richmond County, and was approved to develop a third, Pee Dee Dialysis, which the applicant will no longer develop. The following table

shows the existing and approved dialysis facilities in Richmond County, from Table 9B, page 162 of the 2020 SMFP:

Richmond County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	CON ISSUED NOT CERTIFIED	IN-CENTER PATIENTS	PERCENT UTILIZATION
Dialysis Care of Richmond County	30	-4	89	74.17%
Pee Dee Dialysis	0	10	0	0%
Sandhills Dialysis	16	0	65	101.56%

Source: 2020 SMFP, Table 9B.

In Section G.2, page 36, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Richmond County. The applicant states:

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

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

- There is a facility need determination at Sandhills Dialysis, as calculated using the methodology in the 2020 SMFP, for ten additional dialysis stations. The applicant proposes to add three additional dialysis stations.
- The applicant adequately demonstrates that the three proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Sandhills Dialysis, as summarized below.

Sandhills Dialysis Current and Projected Staffing

POSITION	CURRENT # FTES AS OF 12/31/19	PROJECTED # FTES	
		OY 1 (CY 2022)	OY 2 (CY 2023)
Administrator	1.00	1.00	1.00
Registered Nurse	2.00	3.20	3.20
Patient Care Technician	6.00	9.40	9.40
Dietician	0.50	1.00	1.00
Social Worker	0.50	1.00	1.00
Administration/Bus. Office	1.00	1.00	1.00
Biomedical Technician	0.50	0.50	0.50
Total	11.50	17.10	17.10

Source: Section Q, Form H

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 Operating Costs. In Section H, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of continuing education programs. In Section H.4, page 38, the applicant identifies the current medical director for the facility. In Exhibit H-4, the applicant provides a letter from the medical director indicating her intent to continue to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Section I, page 39, the applicant states that the following ancillary and support services are necessary for the proposed services:

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	On site
Home training HH PD Accessible follow-up program	Referral to Dialysis Care of Moore County
Psychological counseling	On site by RN
Isolation – hepatitis	On site
Nutritional counseling	On site by RD
Social Work services	On site by MSW
Acute dialysis in an acute care setting	Referral to Richmond Memorial Hospital
Emergency care	Referral to Richmond Memorial Hospital
Blood bank services	Referral to Richmond Memorial Hospital
Diagnostic and evaluation services	Referral to Richmond Memorial Hospital
X-ray services	Referral to Richmond Memorial Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Referral to Richmond Memorial Hospital
Vascular surgery	Referral to Richmond Memorial Hospital
Transplantation services	Referral to Duke University Medical Center
Vocational rehabilitation & counseling	NC DHHS Division of Vocational Rehab Services
Transportation	ART Transit

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I, the applicant provides supporting documentation for established relationships with local health care providers and for referrals.

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

The applicant proposes to relocate Sandhills Dialysis and add three dialysis stations to the for a total of 25 stations upon completion of this project and Project ID #H-11251-16 (add 6 stations).

In Section K, page 42, the applicant states that the project involves renovating/upfitting 10,720 square feet of existing space. Line drawings are provided in Exhibit K.

On pages 42-43, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 43, 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, and identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 43-44, and in Exhibit K-4, 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.

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.

(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 47, the applicant provides the historical payor mix for Sandhills Dialysis patients during CY 2019 for its existing services, as shown in the table below:

**Sandhills Dialysis
 Historical Payor Mix CY 2019**

PAYMENT SOURCE	IN-CENTER DIALYSIS	
	# OF PATIENTS	% OF TOTAL
Self-pay	0.0	0.0%
Insurance*	1.0	1.5%
Medicare*	62.0	95.4%
Medicaid*	2.0	3.1%
Other (VA)	0.0	0.0%
Total	65.0	100.0%

*Including any managed care plans
 Totals may not sum due to rounding

In Section L.1(a), page 46, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	51.6%	51.0%
Male	48.4%	49.0%
Unknown	0.0%	0.0%
64 and Younger	33.9%	82.1%
65 and Older	66.1%	17.9%
American Indian	0.0%	3.2%
Asian	0.0%	0.9%
Black or African-American	66.1%	32.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	32.3%	61.4%
Other Race	1.6%	2.3%
Declined / Unavailable	0.0%	0.0%

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 47, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 47, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**Sandhills Dialysis
Projected Payor Mix CY2023**

PAYMENT SOURCE	IN-CENTER DIALYSIS	
	# OF PATIENTS	% OF TOTAL
Self-pay	0.0	0.0%
Insurance*	1.1	1.5%
Medicare*	69.7	95.4%
Medicaid*	2.2	3.1%
Other (VA)	0.0	0.0%
Total	73.0	100.0%

*Including any managed care plans
Totals may not sum due to rounding

As shown in the table above, in the second full year of operation, the applicant projects that no in-center dialysis services will be provided to self-pay patients, 95.4% will be provided to Medicare patients, and 3.1% to Medicaid patients.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Sandhills Dialysis.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 50, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate Sandhills Dialysis and add three dialysis stations for a total of 25 stations upon completion of this project and Project ID #H-11251-16 (add 6 stations).

On page 113, the 2020 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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Richmond County. Facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis centers in Richmond County, and was approved to develop a third, Pee Dee Dialysis, which the applicant will no longer develop. The following table shows the existing and approved dialysis facilities in Richmond County, from Table 9B, page 162 of the 2020 SMFP:

Richmond County Dialysis Facilities

DIALYSIS FACILITY	CERTIFIED STATIONS 12/31/18	CON ISSUED NOT CERTIFIED	IN-CENTER PATIENTS	PERCENT UTILIZATION
Dialysis Care of Richmond County	30	-4	89	74.17%
Pee Dee Dialysis	0	10	0	0%
Sandhills Dialysis	16	0	65	101.56%

Source: 2020 SMFP, Table 9B.

Regarding the expected effects of the proposal on competition in the service area, in Section N.1, page 51, the applicant states:

“The relocation and expansion of Sandhills Dialysis will have no effect on competition in Richmond County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.

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

Regarding the impact of the proposal on cost effectiveness, quality, and access to medically underserved groups, in Section N.2, page 51, the applicant states:

“As discussed in Section B, DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The relocation and expansion of Sandhills Dialysis will enhance accessibility to dialysis for current and projected 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.”

Considering all the information in the application, 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 (see Sections B, C, F, N and Q of the application and any exhibits)
- Quality (see Sections B, C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections B, C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.2, pages 53-54, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in one DaVita facility; Waynesville Dialysis Center. The applicant states that a plan of correction was prepared and accepted, and that Waynesville Dialysis Center is currently back in compliance. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- The applicant is not proposing to establish a new kidney disease treatment center or dialysis facility.

(b) An applicant proposing to increase the number of dialysis stations in:
(1) an existing dialysis facility; or
(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;
shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-C- In Section C.3, page 21, the applicant projects that Sandhills Dialysis will serve 71 in-center patients on 25 stations, or a rate of 2.84 patients per station per week, as of the end of the first operating year following project completion. This meets the minimum performance standard of 2.8 patients per station per week.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C.3, pages 20-22, the applicant provides the assumptions and methodology it used to project utilization of the facility.