

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 26, 2021

Findings Date: October 26, 2021

Project Analyst: Kim Meymandi

Co-Signer: Micheala Mitchell

Project ID #: J-12100-21

Facility: Carolina Dialysis - Lee County

FID #: 110959

County: Lee

Applicant(s): Carolina Dialysis, LLC

Project: Add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion

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.

C

Carolina Dialysis, LLC (hereinafter referred to as “the applicant”) proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion. Carolina Dialysis, LLC is a Limited Liability Company with two members: The University of North Carolina Hospitals (UNCH) and Renal Research Institute, LLC. Renal Research Institute, LLC is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc.

Need Determination (Condition 2)

Chapter 9 of the 2021 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 9B, page 134, the county need methodology shows there is not a county need determination for additional dialysis stations in Lee 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 2021 SMFP, if the utilization rate for the facility as reported in the 2021 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Carolina Dialysis Lee County is 80.88 percent or 3.24 patients per station per week, based on 55 in-center dialysis patients and 17 certified dialysis stations (55 patients / 17 stations = 3.24; $3.24 / 4 = 80.88\%$).

As shown in Table 9D, page 139 of the 2021 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to five additional stations; thus, the applicant is eligible to apply to add up to five stations during the 2021 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than three new stations to the facility, which is consistent with the 2021 SMFP calculated facility need determination for up to five stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2021 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy GEN-3, page 29 of the 2021 SMFP, 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 would promote safety and quality in Section B.7(a), page 22; Section N.2(a), page 71, Section O, pages 73-76, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.7(b), page 23; Section L, pages 65-68; Section N. 2(a), pages 71-72, and referenced exhibits. The information provided by the applicant is

reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.7(c), page 24; Sections F and K, and Section N, pages 70-71, and referenced exhibits. The information provided by the applicant is reasonable and adequately 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. The application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with Condition 2 of the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because Carolina Dialysis Lee County's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

- (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 add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

The following table, summarized from page 16 of the application, shows the current and projected number of dialysis stations at Carolina Dialysis Lee County:

Carolina Dialysis Lee County

# OF STATIONS	DESCRIPTION	PROJECT ID #
17	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	
0	# of stations previously approved to be added but not yet certified	
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	
20	Total # of stations upon completion of all facility projects	

As illustrated in the table above, in this application, the applicant proposes to add three dialysis stations for a total of 20 stations upon project completion.

Patient Origin

On page 113, the 2021 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 facility referred to in this application is located in Lee County. Thus, the service area for this facility consists of Lee County. Facilities may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 26 and 27, the applicant provides the historical and projected in-center (IC) patient origin for Carolina Dialysis Lee County during the last full operating year, January 1, 2020 – December 31, 2020 (CY 2020), and the projected patient origin for the second full operating year following project completion, January 1, 2024 - December 31, 2024 (CY 2024), as summarized in the following table:

Carolina Dialysis Lee County Historical & Projected Patient Origin				
	Historical (CY 2020)		Projected (CY 2024)	
	# of IC Patients	% of Patients	# of IC Patients	% of Patients
Lee	48	76.2%	54.7	78.5%
Chatham	1	1.6%	1	1.4%
Harnett	13	20.6%	13	18.7%
Moore	1	1.6%	1	1.4%
Total	63	100.00%	69.7	100.0%

In Section C, pages 27-28, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported, based on the following:

- The applicant projects patient origin at Carolina Dialysis Lee County based on its existing population.
- The applicant increases the number of projected future patients based on the Five-Year Average Annual Change Rate (AACR) of Lee County.

Analysis of Need

In Section C.4, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need based on the facility and county patient growth rate over the last year. The applicant states:

- The patient population requires frequent treatments. Patients typically receive three (3) treatments per week and either dialyze on a Monday/Wednesday/Friday morning or afternoon or Tuesday/Thursday/Saturday morning or afternoon. If patients do not receive sufficient treatments, it will lead to the patients' demise.
- Carolina Dialysis Lee County's projected patient population for the first full operating year (OY) (01/01/2023 to 12/31/2023) is projected to grow to 67.9 in-center patients with a utilization rate of 84.89%, or 3.3955 patients per station per week.
- The OY projections for patient population is based upon the 3.3% Lee County Five Year Average Annual Change Rate (AACR) as indicated in Table 9B, page 134, of the 2021 SMFP.
- The applicant does not project growth for patients who reside outside of Lee County.

The information is reasonable and adequately supported for the following:

- According to the 2021 SMFP, as of December 31, 2019, Carolina Dialysis was operating at a rate of 3.24 patients per station per week, or 80.88 percent of capacity.
- The applicant adequately demonstrates the need to add three dialysis stations pursuant to the facility need methodology based on its existing and future patient population.

Projected Utilization

In Section Q, pages 79-81, the applicant provides its projected utilization methodology, based on its stated assumptions. The projected in-center utilization is summarized in the following table.

CAROLINA DIALYSIS LEE COUNTY IN-CENTER PATIENTS

Begin with facility census of Lee County patients as of Dec. 31, 2020.	48
Project this population forward one year to December 31, 2021, using the Lee County Five Year AACR of 3.3%.	$48 \times 1.033 = 49.6$
Project the Lee County patients forward one year to December 31, 2022, using the Lee County Five Year AACR of 3.3%	$49.6 \times 1.033 = 51.2$
Add the 15 patients from other counties. This is the projected starting census for this project.	$51.2 + 15 = 66.2$
Project Lee County patients forward one year to December 31, 2023, using the Lee County Five Year AACR of 3.3%.	$51.2 \times 1.033 = 52.9$
Add the 15 patients from other counties. This is the projected ending census for Operating Year 1(OY1).	$52.9 + 15 = 67.9$
Project Lee County patients forward one year to December 31, 2024, using the Lee County Five Year AACR of 3.3%.	$52.9 \times 1.033 = 54.7$
Add the 15 patients from other counties. This is the projected ending census for operating year 2 (OY2).	$54.7 + 15 = 69.7$

Source: Table in Section Q, page 80

At the end of OY1 (CY2023) Carolina Dialysis Lee County is projected to serve 67.9 in-center patients on 20 stations; and at the end of OY2 (CY2024) the facility is projected to serve 69.7 in-center patients on 20 stations.

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

- OY1: 3.4 patients per station per week, or 84.8% utilization [$67.9 \text{ patients} / 20 \text{ dialysis stations} = 3.4$; $3.4 / 4 = 0.848$].
- OY 2: 3.5 patients per station per week, or 87.1% utilization [$69.7 \text{ patients} / 20 \text{ dialysis stations} = 3.49$; $3.49 / 4 = 0.8713$].

The projected utilization of 3.4 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

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

- Carolina Dialysis Lee County was operating at 80.88% capacity as of December 31, 2019, as reported in the 2021 SMFP which exceeds the required minimum utilization of 75%.
- The applicant projects growth in the Lee County patient population using the Lee County Five Year AACR of 3.3% as published in the 2021 SMFP.
- The applicant does not project growth for patients residing outside of Lee County.
- Projected IC utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b) and exceeds this threshold at the end of OY2.

Access

In Section C.6, page 31, the applicant states:

“The applicant and its parent organizations, Carolina Dialysis and Fresenius Medical Care, have a long history of providing dialysis services to the underserved populations of North Carolina.

...

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.

...

Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

On page 32, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second year of operation following completion of the project, as summarized in the following table.

**Carolina Dialysis Lee County
Projected Estimated Percentage of Total Patients for Each Group**

	Estimated Percentage of Patients by Group
Low Income Persons	62.9%
Racial and Ethnic Minorities	83.9%
Women	43.5%
Persons with Disabilities	14.5%
Elderly	40.3%
Medicare Beneficiaries	72.6%
Medicaid Recipients	54.8%

Note: A single patient can be counted in multiple categories.

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 currently serves the needs of medically underserved groups that utilize ESRD services and provides evidence that it will continue to do so.
- The applicant has policies in place to prevent discrimination.

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.

NA

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

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

CA

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

In Section E, page 39, 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 this would result in a higher utilization rate and could potentially interrupt patient admissions to the facility.
- *Apply for fewer than three dialysis stations* – the applicant states this alternative fails to recognize the growth of the ESRD patient population residing in the Carolina Dialysis Lee County area and resulting increase in utilization rates.

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. Carolina Dialysis, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2021 SMFP, the certificate holder shall develop no more than three additional in-center dialysis stations for a total of no more than 20 in-center stations at Carolina Dialysis Lee County upon completion of this project.**
- 3. 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 fifth month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on September 1, 2022 and so forth.**
- 4. 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.

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant provides a table to illustrate projected capital cost of the project, as shown in the table below:

Carolina Dialysis Lee County Capital Cost

ITEM	COST
Medical Equipment	\$45,000
Non-Medical Equipment	\$2,250
Furniture	\$9,000
Total	\$56,250

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

In Section F.3, page 42, 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.

Availability of Funds

In Section F, page 40, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Carolina Dialysis, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$56,250	\$56,250
Bonds	\$ 0	\$ 0
Other (Specify)	\$ 0	\$0
Total Financing	\$56,250	\$56,250

* OE = Owner's Equity

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

- Exhibit F-1 contains a letter, dated July 15, 2021, from a Board Member of Carolina Dialysis, LLC, authorizing the use of accumulated reserves for the capital needs of the project.
- Exhibit F-2 contains a Carolina Dialysis Balance Sheet, dated March 31, 2021 documenting adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, page 85, the applicant projects that revenues will exceed operating expenses in each of the first two operating years of the project, as summarized in the table below.

	OY 1 CY2023	OY 2 CY2024
Total Treatments	9,926	10,180
Total Gross Revenue (charges)	\$62,442,454	\$64,042,176
Total Net Revenue	\$3,440,305	\$3,528,443
Average Net Revenue per Treatment	\$347	\$347
Total Operating Expenses (costs)	\$2,858,733	\$2,921,122
Average Operating Expense per Treatment	\$288	\$287
Net Income / Profit	\$581,572	\$607,321

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

- The applicant bases charges and expenses on historical revenue and expenses for Carolina Dialysis Lee County.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested 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 demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates the 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 add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

On page 113, the 2021 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 Lee County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are two existing or approved dialysis facilities in Lee County, both of which are owned and operated by Carolina Dialysis, LLC. Information on these dialysis facilities, from Table 9A, page 125 of the 2021 SMFP is provided below:

**Lee County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2019**

Dialysis Facility	Owner	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Percent Utilization as of 12/31/2019	Patients Per Station Per Week as of 12/31/2019
Carolina Dialysis Lee County	Carolina Dialysis, LLC	17	55	80.88%	3.2353
Carolina Dialysis Sanford	Carolina Dialysis, LLC	39	121	77.56%	3.1026
Total		56	176		

In Section G, page 47, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Lee County. The applicant states:

“This is an application based on facility performance and demonstrated need at Carolina Dialysis Lee County. The need addressed by this application is not specific to Lee County as a whole.

The in-center census at Carolina Dialysis Lee County was 55 as of December 31, 2019. At the end of 2020, the census was 63 . This is an annualized growth rate of greater than 14%. The growth rate for 2020 significantly exceeded the county five year average annual change rate. This facility census continues to increase; consequently more stations are needed.

An application based upon Facility Need Methodology is appropriate. Adding stations at Carolina Dialysis Lee County will not duplicate services but will ensure an adequate inventory of dialysis stations to meet the growing ESRD patient population.”

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

- There is a need determination in the 2021 SMFP at Carolina Dialysis Lee County for five dialysis stations. The applicant proposes to add three dialysis stations.
- Carolina Dialysis Lee County is currently operating at or above the ESRD performance standard of 2.8 patients per station per week.
- The applicant adequately demonstrates that Carolina Dialysis Lee County will be operating at 2.8 patients per station per week in its projected utilization, which is primarily based on historical Lee County patient utilization increased by the Five-Year AACR of 3.3% for Lee County.
- The applicant adequately demonstrates that the proposed addition of three stations is needed in addition to the existing and approved dialysis services in Lee County.

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

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Carolina Dialysis Lee County, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 5/17/2021	OY1 (1/1/2023 to 12/31/2023)	OY2 (1/1/2024 to 12/31/2024)
Administrator	1.00	1.00	1.00
RNs	2.00	3.00	3.00
LPNs	1.00	1.00	1.00
Technicians (PCT)	7.00	7.00	7.00
Dietician	0.75	0.75	0.75
Social Worker	0.75	0.75	0.75
Maintenance	1.00	1.00	1.00
Admin/Business Office	1.00	1.00	1.00
Other: FMC Dir. Operations	0.15	0.15	0.15
Other: In-Service	0.15	0.15	0.15
Other: Chief Tech	0.15	0.25	0.25
TOTAL	14.95	15.95	15.95

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 49-50, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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 an increase in the FTE staffing positions necessary to accommodate the proposed increase in healthcare services at Carolina Dialysis Lee County.
- The increased costs of annual salary increases are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.
- A letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services is provided.

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 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.

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

Ancillary and Support Services

In Section I, pages 51-56, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is and will continue to be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for dialysis patients located in or near Lee County and how these will be made available.
- The applicant describes how the necessary ancillary and support services will be coordinated with the existing healthcare system.

Coordination

In Section I, page 56, the applicant describes its existing relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant has numerous years of experience serving the needs of dialysis patients.
- The applicant has established relationships with community health care and ancillary service providers where dialysis patients can receive appropriate referrals for necessary services related to their condition.
- The applicant provides a letter from the Medical Director in Exhibit H-4 committing to the continuation of the established relationships.

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.

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

NA

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

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... 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 63, the applicant provides the historical payor mix for Carolina Dialysis Lee County during the last full operating year (CY2020) for its existing services, as shown in the table below.

**Carolina Dialysis Lee County
Historical Payor Mix CY 2020**

Payor Category	Services as Percent of Total
Self-Pay	3.0%
Insurance*	5.8%
Medicare*	76.4%
Medicaid*	8.8%
Other (Including VA and Medicare Advantage Plans)	6.0%
Total	100.00%

*Including any managed care plans

In Section L, page 64, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population in the Service Area *
Female	43.5%	51.2%
Male	56.5%	48.8%
Unknown	0.0%	0.0%
64 and Younger	59.7%	83.2%
65 and Older	40.3%	16.8%
American Indian	0.0%	1.3%
Asian	0.0%	1.4%
Black or African-American	69.4%	20.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	16.1%	57.8%
Other Race	14.5%	19.3%
Declined / Unavailable	0.0%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

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

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

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

page 65, 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 65, the applicant states that during the 18 months immediately preceding the application deadline 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.

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 66, 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.

**Carolina Dialysis Lee County
Projected Payor Mix CY2024**

Payment Source	# of Patients	% of Total
Self-Pay	2.1	3.0%
Insurance*	4.1	5.8%
Medicare*	53.2	76.4%
Medicaid*	6.1	8.8%
Other (Misc. including VA and Medicare advantage)	4.2	6.0%
Total	69.7	100.0%

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 3% of in-center dialysis services will be provided to self-pay patients, 76.4% to Medicare patients, and 8.8% to Medicaid patients.

On page 66, 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 and treatment volumes of Carolina Dialysis Lee County.

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.5, page 68, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 69, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant offers the facility as a clinical learning site for students from Central Carolina Community College.
- The applicant provides a copy of the letter sent to Central Carolina Community College offering training opportunities in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to add no more than three dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

On page 113, the 2021 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 Lee County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are two existing or approved dialysis facilities in Lee County, both of which are owned and operated by Carolina Dialysis, LLC. Information on these dialysis facilities, from Table 9A, page 125 of the 2021 SMFP is provided below:

**Lee County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2019**

Dialysis Facility	Owner	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Percent Utilization as of 12/31/2019	Patients Per Station Per Week as of 12/31/2019
Carolina Dialysis Lee County	Carolina Dialysis, LLC	17	55	80.88%	3.2353
Carolina Dialysis Sanford	Carolina Dialysis, LLC	39	121	77.56%	3.1026
Total		56	176		

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 70, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Lee County. The applicant does not project to serve dialysis patients currently being served by another provider.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 71, the applicant states:

“Approval of this application will allow the facility to continue serving patients residing in the area of the facility. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 71, the applicant states:

“Quality care is not negotiable. ... Our organizational mission statement captures this sentiment very well:

‘We deliver superior care that improves that quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 71, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

See also Sections B, C 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:

- 1) 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.
- 2) 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.
- 3) 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 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. The applicant identifies over 120 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 76, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” 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 Fresenius related 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.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

10 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- Carolina Dialysis Lee County is an existing facility. Therefore, this Rule is not applicable to this review.

(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, page 28, and Form C in Section Q, the applicant projects that Carolina Dialysis Lee County will serve 67.9 in-center patients on 20 stations, or a rate of 3.4 patients per station per week or 84.9% ($67.9 / 20 = 3.395/4 = 0.849$ or 84.9%), as of the end of the first operating year (CY2023) following project completion. This

exceeds the minimum performance standard requirement of 2.8 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 27-28, in Section Q, Form C, pages 80-81, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.