

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 9, 2024

Findings Date: February 9, 2024

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12463-23

Facility: Carolina Dialysis Pittsboro

FID #: 981038

County: Chatham

Applicant: Carolina Dialysis, LLC

Project: Add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station)

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” or “Carolina Dialysis Pittsboro”), proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

Need Determination (Condition 2)

Chapter 9 of the 2023 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 136, the county need methodology shows there is a county need determination for additional dialysis stations in Chatham County.

However, the applicant is eligible to apply for additional stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2023 SMFP, if the utilization rate for the facility as reported in the 2023 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 the facility is 77.08% or 3 patients per station per week, based on 37 in-center dialysis patients and 12 certified dialysis stations (37 patients/12 stations = 3.08, $3.08 / 4 = 77.08\%$).

The applicant proposes to add no more than one new station to the facility, which is consistent with the 2023 calculated facility need determination for one station; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2023 SMFP that is applicable to this review, Policy GEN-3: *Basic Principles*.

Policy *GEN-3*, page 30 of the 2023 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 will promote safety and quality in Section B, page 21; Section N, page 73; Section O, pages 75 -78; 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, pages 22 - 23; Section C, pages 31-32; Section L, pages 64-70; Section N, page 73; 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, pages 22-23; Section N, page 73; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 Condition 2 of the facility need methodology as applied from the 2023 SMFP.
- The applicant adequately demonstrates how the applicant projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3.

(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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

Patient Origin

On page 113, the 2023 SMFP defines the service area for dialysis stations as "*the service area is the county in which the dialysis station is located.*" Thus, the service area for this facility consists of Chatham County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

County	Carolina Dialysis Pittsboro		Second Full FY	
	Historical CY 2022		CY 2027	
	# In-center Patients	% of Total	Patients	% of Total
Chatham	27.0	81.8%	38.8	97.4%
Alamance	1.0	3.0%	1.0	2.6%
Orange	5.0	15.2%	0	0.0%
Total	33.0	100.0%	39.8	100.0%

Source: Section C, pages 25-26

The applicant does not propose to offer home hemodialysis or peritoneal dialysis training or support services.

In Section C, pages 25-26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based the historical (CY2022) patient origin for the facility.

Analysis of Need

In Section C, pages 29-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The need that this population has for the proposed services is a function of the individual patient’s need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 38.4 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 73.8%, or 2.95 patients per station and exceeds the minimum required by the performance standard.”

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2023 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant adequately demonstrates need based on the facility’s projected growth in the patient population.

Projected Utilization

In Section C, pages 27-28, and Section Q, pages 83-84, the applicant provides the projected utilization for Carolina Dialysis Pittsboro, as illustrated in the following table.

Carolina Dialysis Pittsboro	In-Center patients
Begin with the Chatham County patient population as of May 2, 2023.	31
Project the Chatham County patient population forward 7 months to December 31, 2023, using a 3.7% growth rate commensurate with the facility's recent experience.	$31 \times [0.037/12] \times 7 + 31 = 31.7$
Add the 4 patients from other counties. This is the projected ending census for Interim Year 1.	$31.7 + 4 = 35.7$
Project the Chatham County patient population forward to December 31, 2024, using a 3.7% growth rate commensurate with the facility's recent experience.	$31.7 \times 1.037 = 32.8$
Add the 4 patients from other counties. This is the projected ending census for Interim Year 2.	$32.8 + 4 = 36.8$
Project the Chatham County patient population forward to December 31, 2025, using a 3.7% growth rate commensurate with the facility's recent experience.	$32.8 + 1.037 = 34.1$
Add the two Chatham County patients expected to transfer to Carolina Dialysis Pittsboro from other facilities.	$34.1 + 2 = 36.1$
Subtract the two Orange County and one Durham County patients projected to transfer to CD-Carrboro on December 31, 2025.	$4 - 3 = 1$
Add one patient from another county. This is the projected ending census for Interim Year 3.	$36.1 + 1 = 37.1$
Project the Chatham County patient population forward to December 31, 2026, using a 3.7% growth rate commensurate with the facility's recent experience.	$36.1 \times 1.037 = 37.4$
Add one patient from another county. This is the projected ending census for Operating Year 1.	$37.4 + 1 = 38.4$
Project the Chatham County patient population forward to December 31, 2027, using a 3.7% growth rate commensurate with the facility's recent experience.	$37.4 \times 1.037 = 38.8$
Add the one patient from another county. This is the projected ending census for Operating Year 2.	$38.8 + 1 = 39.8$

In Section C, pages 26- 27, and Section Q, pages 82-84, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The 2023 SMFP, Table 9D indicates that Carolina Dialysis Pittsboro qualifies to apply for up to one additional dialysis station pursuant to Condition 2 of the Facility Need Methodology. This is an application for one additional dialysis station to backfill the station to be relocated to Carolina Dialysis Carrboro pursuant to Project ID# J-12386-23.

- In Section D of Project ID# J-12386-23, the applicant began projections of the future patient population to be served at the Carolina Dialysis Pittsboro facility with the facility census as of May 2, 2023. As of May 2, 2023, the facility was serving a total of 35 in-center patients, an increase of two patients or 6.1% since December 31, 2022. Of those 35 patients, 31 were Chatham County residents, an increase of four patients or 14.8% since December 31, 2022.
- Carolina Dialysis Sanford in Lee County is currently serving two Chatham County patients that have signed letters of support expressing an interest in transferring to the Carolina Dialysis Pittsboro facility (See Exhibit C-3). These patients are expected to transfer their care to Carolina Dialysis Pittsboro upon certification of the additional station. These patients will be added to the future Chatham County patient projections at the appropriate points in time.
- The Chatham County Five Year Average Annual Change Rate (5-Year AACR) reported in the 2023 SMFP is -2.3%. However, the applicant will project growth of the Chatham County patient population using a 3.7% growth rate, based on the facility’s recent experience. A growth rate of 3.7% is more than the 5-Year AACR in the SMFP, but less than the recent growth at the facility.
- As of May 2, 2023, the facility was also serving four in-center patients residing in Alamance, Durham, and Orange County. Alamance County is contiguous to Chatham County; thus, it is reasonable to conclude that patients residing in this county would continue dialysis at Carolina Dialysis Pittsboro facility as a function of patient choice. The patient is assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. This patient will be added to projections of future patient populations at appropriate points in time. The applicant will not carry the Durham and Orange patients forward in future projections as those patients are expected to transfer to the Carolina Dialysis Carrboro facility pursuant to Project ID# J-12386-23 upon project completion.
- The new stations are projected to be certified as of December 31, 2025.
 Operating Year 1 is the period from January 1-December 31, 2026
 Operating Year 2 is the period from January 1-December 31, 2027

Based upon these calculations, BMA projects to serve the following number of patients for the Operating Years 1 & 2.

	Operating Year 1	Operating Year 2
In-center	38.4	39.8

Projected utilization is reasonable and adequately supported based on the following:

- Carolina Dialysis Pittsboro bases the projections of the future patient population to be served on the facility census as of December 31, 2023.
- Carolina Dialysis Pittsboro projects growth of the Chatham County patient population based on a growth rate of 3.7%, which is less than its most recent experience.
- **Access to Medically Underserved Groups**

In Section C, pages 32, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is our 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.”

The applicant provides the estimated percentage during the second OY following completion of the project. For each medically underserved group, as shown in the following table.

Group	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low- income persons	31.4%
Racial and ethnic minorities	5.7%
Women	37.1%
Persons with Disabilities	34.3%
Persons 65 and older	74.3%
Medicare beneficiaries	77.1%
Medicaid recipients	28.6%

Source: Section C, page 32

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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 services. 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.

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the need methodology for a total of no more than 13 stations upon completion of this project and Project ID# J-12386-23 (relocate one station).

In Section E, page 41, 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 applicant could have chosen not to file for additional stations at Carolina Dialysis Pittsboro. Failure to apply for additional stations at Carolina Dialysis Pittsboro would ultimately result in higher utilization rates. The applicant has demonstrated that the projected utilization for the end of Operating Year 1 is 2.95 patients per station; the projected utilization for the end of Operating Year is 3.06 patients per station. If Carolina Dialysis Pittsboro had chosen to not apply for additional stations, utilization on 13 dialysis stations would be projected to be 2.95 patients per station at the end of Operating 1, and 3.06 patients per year at the end of Operating Year 2. Failure to apply for additional stations, utilization rates, potentially interrupts patient admissions to the facility and is the least effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. 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 2023 SMFP, the certificate holder shall develop no more than one additional dialysis station for a total**

of no more than 13 stations at Carolina Dialysis Pittsboro upon completion this project and Project ID# J-12386-23 (relocate one station).

- 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. The first progress report shall be due on September 1, 2024.**
- 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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

Capital and Working Capital Costs

In Section F, page 42, the applicant states there is no projected capital cost for the project.

In Section F, page 42, the applicant states there will be no start-up costs or initial operating expenses because the station to be added will simply replace an existing station approved to be relocated to another facility.

Financial Feasibility

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

	1 st Full FY CY 2026	2 nd Full FY CY 2027
Total Treatment	5,583	5,784
Total Gross Revenues (Charges)	\$6,291	\$6,291
Total Net Revenue	\$1,607,264	\$1,665,156
Average Net Revenue per Treatment	279	288
Total Operating Expenses (Costs)	\$2,373,136	\$2,424,059
Average Operating Expense per Treatment	425	419
Net Income	(\$765,872)	(\$758,903)

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. In Section Q, page 90, the applicant states,

“Carolina Dialysis and Fresenius Medical Care are aware that the Carolina Dialysis Pittsboro facility is currently operating in a financial loss position. Adding capacity and increasing our patient census will help in our efforts to return the facility to a profitable status. In the meantime, our parent company, Fresenius Medical Care Holdings, Inc. is prepared to absorb the financial losses of the Carolina Dialysis Pittsboro facility.”

The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3, and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

The 2023 SMFP, page 113, defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located*.” Thus, the service area for this facility consists of Chatham County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2023 SMFP, there are 2 existing or approved dialysis facilities in Chatham County. Information on the Chatham County dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021
Carolina Dialysis Pittsboro	12	37	77.08%
Carolina Dialysis Siler City	26	61	58.65%

Source: Table 9A, Chapter 9, 2023 SMFP, page 120

In Section G.2, pages 48-49, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Chatham County. The applicant states,

“Given the utilization and growth of the facility, Carolina Dialysis does not believe adding one station will duplicate any services. Rather, the additional station is a backfill of an existing station approved for relocation to another facility and thus will ensure continued adequate access to dialysis care for the patient population of the area. As of May 2, 2023, the facility was serving a total of 35 in-center patients, an increase of two patients or 6.1% since December 31, 2022. Of those 35 patients, 31 were Chatham County residents, an increase of four patients or 14.8% since December 31, 2022. This growth is expected to continue at this facility.”

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:

- The applicant proposes to increase the number of dialysis stations in Chatham County based on Condition 2 of the facility need determination in the 2023 SMFP.
- As shown in Table 9D on page 136 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Carolina Dialysis Pittsboro is one additional station.
- The applicant adequately demonstrates that the proposal dialysis station is needed in Chatham County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

In Section Q, Form H, page 98, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 6/16/2023	Year 1 2026	Year 2 2027
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	2.00	2.00	2.00
Technicians (PCT)	4.00	4.00	4.00
Dietician	0.28	0.28	0.28
Social Worker	0.40	0.40	0.40
Maintenance	0.60	0.60	0.60
Administration/Clerical	1.00	1.00	1.00
Other (FMC Director of Operations)	0.15	0.15	0.15
Other (FMC Chief Technician)	0.10	0.10	0.10
Other (FMC in-Service)	0.15	0.15	0.15
Total	9.68	9.68	9.68

Source: Section Q, Form H, page 99

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. In Section H, pages 50-51, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility.

- The applicant has existing policies in regard to recruitment, training, and continuing education.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

Ancillary and Support Services

In Section I, page 52, the applicant identifies the necessary ancillary and support services for the proposed services. On page 52-55, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on its established relationships with other physicians and hospitals in the area and its agreements for lab services, hospital affiliation and transplant.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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 64, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.

Carolina Dialysis Pittsboro Historical Payor Mix 01/01/2022-12/31/2022		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.5	1.63%
Insurance*	0.6	1.86%
Medicare*	27.3	82.75%
Medicaid*	2.3	7.05%
Other (Misc. including VA)	2.2	6.71%
Total	33.0	100.00%

Source: Section L, page 64

* Including any managed care plans.

In Section L, page 66, the applicant provides the following comparison.

Carolina Dialysis Pittsboro	Percentage of Total Patients Served (All modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	37.1%	51.6%
Male	62.9%	48.4%
Unknown		
64 and Younger	25.7%	74.1%
65 and Older	74.3%	25.9%
American Indian	0.0%	1.2%
Asian	2.9%	2.6%
Black or African-American	48.6%	11.7%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	48.6%	82.3%
Other Race	0.0%	14.1%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 69, the applicant states:

“The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”

In Section L, page 67, 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, page 67, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Carolina Dialysis Pittsboro Projected Payor Mix 01/01/2027-12/31/2027		
Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.6	1.63%
Insurance*	0.7	1.86%
Medicare*	32.9	82.75%
Medicaid*	2.8	6.71%
Other Misc. including VA	2.7	6.71%
Total	39.8	100.00%

*Including any managed care plans

As shown in table above, during the second full fiscal year of operation, the applicant projects that 1.63% of total services will be provided to self-pay patients, 82.75% to Medicare patients and 6.71% to Medicaid patients.

On page 68, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (CY2022) payor mix for the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 69, 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

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

In Section M, page 71, 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. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- All health related education and training programs are welcome to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment.
- The applicant provides a copy of a letter sent to Central Carolina Community College encouraging the school to include the dialysis facility in their clinical rotations for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to add no more than one dialysis station pursuant to Condition 2 of the facility need methodology for a total of no more than 13 stations upon completion this project and Project ID# J-12386-23 (relocate one station).

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is in the county in which the dialysis station is located*”. Thus, the service area for this facility consists of Chatham County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2023 SMFP, there are 2 existing or approved dialysis facilities in Chatham County. Information on the Chatham County dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021
Carolina Dialysis Pittsboro	12	37	77.08%
Carolina Dialysis Siler City	26	61	58.65%

Source: Table 9A, Chapter 9, 2023 SMFP, page 120

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Chatham County...The SMFP reports there are currently two operational dialysis facilities with in-center dialysis stations within Chatham County. Both facilities are operated by Carolina Dialysis. With this application, the applicant seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at Carolina Dialysis Pittsboro.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, the applicant states:

“Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, these patients will have shorter commute to and from dialysis treatment.”

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 73, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities...Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

See also Section 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 73, 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.”

See also Section B, L, and C 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

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

- (19) Repealed effective July 1, 1987.

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

C

In Section Q, pages 101- 105, the applicant identifies the kidney disease treatment facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 125 of this type of facility located in North Carolina.

In Section O, page 78, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities that resulted in a finding of immediate jeopardy. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 125 facilities, the applicant provided 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 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 dialysis facility for in-center hemodialysis services 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 full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

- NA- Carolina Dialysis Pittsboro 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, pages 26-27 and Form C in Section Q, the applicant projects that Carolina Dialysis Pittsboro will serve 38 patients on 13 stations, or a rate of 2.92 in-center patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis and does not plan to begin offering those services in this application. Therefore, this Rule does not apply.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant does not propose to increase the number of home hemodialysis stations or peritoneal dialysis and does not plan to begin offering those services in this application. Therefore, this Rule does not apply.
- (e) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 26-28, and immediately following Form C in Section Q, 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.