

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2022

Findings Date: December 20, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Gloria C. Hale

Project ID #: P-12243-22

Facility: New Bern Dialysis

FID #: 955965

County: Craven

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Add no more than 3 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 40 dialysis 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

Bio-Medical Applications of North Carolina, Inc. (BMA or “the applicant”), proposes to add no more than three in-center (IC) dialysis stations to the New Bern Dialysis facility pursuant to Condition 2 of the facility need methodology for a total of no more than 40 IC dialysis stations upon project completion.

BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

While New Bern Dialysis currently provides IC dialysis, the facility does not currently provide either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program nor does the applicant propose to add either a PD or HH program as part of this proposed project.

Need Determination (Condition 2)

Chapter 9 of the 2022 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, the county need methodology shows there is not a county need determination for additional dialysis stations in Craven 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 2022 SMFP, if the utilization rate for the facility as reported in the 2022 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 81.08 percent or 3.24 patients per station per week, based on 120 in-center dialysis patients and 37 certified dialysis stations (120 patients / 37 stations = 3.24; $3.24 / 4 = 0.8108$ or 81.0%).

As shown in Table 9D, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to ten additional stations; thus, the applicant is eligible to apply to add up to ten stations during the 2022 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 2022 SMFP calculated facility need determination for up to ten stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2022 SMFP that is applicable to this review, *Policy GEN-3: Basic Principles*.

Policy GEN-3, page 30 of the 2022 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 75; Section O, pages 77-80; 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, page 22; Section C, page 32; Section L, pages 67-72; Section N, page 75; 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 F, pages 43-48; Section N, page 75; 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
- 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:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2022 SMFP.
- The applicant adequately demonstrates how the facility's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 based on how it describes the facility's policies and programs, which promote the concepts of quality, equitable access and maximum value for resources.

- (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 at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” New Bern Dialysis is in Craven County. Thus, the service area for this facility consists of Craven County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

New Bern Dialysis: Historic and Projected Patient Origin

County	Historical- Last Full FY (CY2021)		Second Full FY of Operation following Project Completion (CY2025)	
	Patients	% of Total	Patients	% of Total
Craven	94.0	83.9%	122.3	91.7%
Beaufort	1.0	0.9%	1.0	0.8%
Jones	6.0	5.4%	6.0	4.5%
Pamlico	4.0	3.6%	4.0	3.0%
Georgia	1.0	0.9%		
South Carolina	1.0	0.9%		
Virginia	1.0	0.9%		
Other States	4.0	3.6%		
Total	112.0	100.0%	133.3	100.0%

Source: Tables on pages 25 and 26 of the application.

In Section C, pages 26-27, and in Section Q, pages 83-85, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization. The applicant’s assumptions are reasonable and adequately supported based on the following:

- Projections are based on the historical patient origin (CY2021) and begin with the facility census as of December 31, 2021, as reported in the 2021 ESRD Data Collection Forms submitted to the Agency.
- The applicant grows the Craven County patient census by 6.8%, the Five-Year Average Annual Change Rate (AACR) for Craven County per the 2022 SMFP.
- The applicant assumes the eleven in-center patients residing in surrounding counties will continue to dialyze at New Bern Dialysis by choice but does not project any growth in that patient population and adds these patients to projections of future patient populations at the appropriate time.

- The seven in-center patients who received dialysis treatments in CY2021 at New Bern Dialysis who were residents of other states were assumed to be transient patients and were not counted in future patient population growth projections.
- The proposed new stations are projected to be certified as of January 1, 2024.
- Operating Year (OY) 1 is the period from January 1-December 31, 2024.
- Operating Year 2 is the period from January 1-December 31, 2025.

Analysis of Need

In Section C, pages 28-29, 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 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 125.5 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 78.4%, or 3.14 patients per station [sic] [per week] 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 2022 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant grows the Craven County patient census by 6.8%, the Five-Year AACR for Craven County per the 2022 SMFP.
- The applicant assumes the eleven in-center patients residing in surrounding counties will continue to dialyze at New Bern Dialysis by choice but does not project any growth in that patient population and adds these patients to projections of future patient populations at the appropriate time.
- The seven in-center patients who received dialysis treatments in CY2021 at New Bern Dialysis who were residents of other states were assumed to be transient patients and were not counted in future patient population growth projections.
- Then applicant shows that the facility will need the additional stations to accommodate projected growth in patient population.

Projected Utilization

In Section Q, pages 83-86, the applicant provides projected utilization, as illustrated in the following table.

Form C Utilization	Last Full FY CY2021	Interim OY 1/1/22- 12/31/22	Interim OY 1/1/23- 12/31/23	First Full OY 1/1/24- 12/31/24	Second Full OY 1/1/25- 12/31/25
# of Patients at the Beginning of the Year	120	112	111	118	126
# of Patients at the End of the Year	112	111	118	126	133
Average # of Patients during the Year	116	112	115	122	129
# of Treatments / Patient / Year	148	148	148	148	148
Total # of Treatments	15,784	16,531	16,991	18,036	19,152

In Section C, page 26, and Section Q, page 84, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- The first full FY is OY1, the period from January 1-December 31, 2024.
- The second full FY is OY2, the period from January 1-December 31, 2025.
- Projections begin with the facility census as of December 31, 2021, as reported in the 2021 ESRD Data Collection Forms submitted to the Agency.
- The applicant grows the Craven County patient census by 6.8%, the Five-Year AACR for Craven County per the 2022 SMFP.
- The applicant assumes the eleven in-center patients residing in surrounding counties will continue to dialyze at New Bern Dialysis by choice but does not project any growth in that patient population and adds these patients to projections of future patient populations at the appropriate time.
- The seven in-center patients who received dialysis treatments in CY2021 at New Bern Dialysis who were residents of other states were assumed to be transient patients and were not counted in future patient population growth projections.

The applicant provides a table in Section C, page 27, and in Section Q, page 85, illustrating the application of its assumptions and methodology.

New Bern Dialysis In-Center Patients	
Begin with the Craven County patient population as of December 31, 2021.	94
Project the Craven County patient population forward for one year to December 31, 2022, using the Craven County Five-Year AACR (6.8%).	$94.0 \times 1.068 = 100.4$
Project the Craven County patient population forward for one year to December 31, 2023, using the Craven County Five-Year AACR.	$100.4 \times 1.068 = 107.2$
Project the Craven County patient population forward for one year to December 31, 2024, using the Craven County Five-Year AACR.	$107.2 \times 1.068 = 114.5$
Add the eleven IC patients from other counties. This is the ending patient census for Operating Year 1 (CY2024) .	$114.5 + 11 = \mathbf{125.5}$
Project the Craven County patient population forward for one year to December 31, 2025, using the Craven County Five-Year AACR.	$114.5 \times 1.068 = 122.3$
Add the eleven IC patients from other counties. This is the ending patient census for Operating Year 2 (CY2025) .	$122.3 + 11 = \mathbf{133.3}$

Totals may not sum due to rounding

As shown in the table above, the applicant projects New Bern Dialysis will serve 125.5 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 3.14 patients per station per week or 78.5% ($125.5 \text{ patients} / 40 \text{ stations} = 3.14 \text{ patients per station per week} / 4 = 0.785 \text{ or } 78.5\%$). By the end of OY2 (December 31, 2025), following the applicant’s methodology and assumptions, the facility will have 133.3 in-center patients dialyzing at the center for a utilization rate of 83.25% ($133.3 / 40 = 3.33 / 4 = 0.8325 \text{ or } 83.25\%$). The projected utilization exceeds the 2.8 in-center patients per station per week threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on the ending census as of December 31, 2021, the most recent historical patient census.
- The applicant projects growth of the Craven County patient census using the Craven County Five-Year AACR of 6.8 %, as published in the 2022 SMFP.
- The applicant adds the 11 in-center patients residing in other counties for future projections, with no growth.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access to Medically Underserved Groups

In Section C, page 32, 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 health insurer.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	51.38%
Racial and ethnic minorities	69.72%
Women	44.04%
Persons with Disabilities	58.72%
Persons 65 and Older	52.29%
Medicare beneficiaries	80.73%
Medicaid recipients	51.38%

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 because New Bern Dialysis is an existing dialysis facility in Craven County currently providing services to medically underserved groups.

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 at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

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 alternatives considered were:

- Maintain the status quo – the applicant states that failure to apply for additional stations leads to higher utilization rates and can lead to interruption of patient admission; thus, this alternative is not the most effective.
- Add more than three stations - the applicant states that this alternative would not be cost effective because the facility cannot accommodate more than 40 stations; thus, this is not the most effective alternative.
- Add fewer than three stations – the applicant states that this alternative would also fail to recognize the growing patient population at the facility and would result in interruption of patient admissions at New Bern Dialysis due to lack of capacity; thus, this is not the most effective alternative.

Based on the explanations above, the applicant determined that its project as proposed is the most effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is conforming or conditionally 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

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. Bio-Medical Applications of North Carolina, Inc. (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 2022 SMFP, the certificate holder shall develop no more than three additional in-center dialysis stations for a total of no more than 40 in-center stations at New Bern Dialysis 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. The first progress report shall be due on January 1, 2023.
 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 at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 88, the applicant projects the total capital cost of the project, as shown in the table below.

New Bern Dialysis Capital Costs	
Non-Medical Equipment	\$2,250
Furniture	\$9,000
Total	\$11,250

In Section Q, page 89, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on the cost of what is required to add the three additional stations. The applicant states that this includes patient chairs, TVs, computers and office furniture.

In Section F, page 45, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project because New Bern Dialysis is an existing facility.

Availability of Funds

In Section F, page 43, the applicant states that the capital cost will be funded, as shown in the table below.

Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$11,250	\$11,250
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$11,250	\$11,250

* OE = Owner's Equity

Exhibit F-2 contains a letter dated July 15, 2022, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. The letter states that in their 2021 Consolidated Balance Sheets, Fresenius Medical Care Holdings, Inc. had over \$939 million in cash and over \$27.2 billion in total assets to fund the capital cost of the proposed project.

Financial Feasibility

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

New Bern Dialysis	1st FFY (CY 2024)	2nd FFY (CY 2025)
Total Treatments	18,036	19,152
Total Gross Revenues (Charges)	\$113,463,755	\$120,482,851
Total Net Revenue	\$4,896,460	\$5,199,364
Average Net Revenue per Treatment	\$271	\$271
Total Operating Expenses (Costs)	\$4,597,550	\$4,755,906
Average Operating Expense per Treatment	\$255	\$248
Net Income	\$298,909	\$443,459

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. 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 Forms 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 for the following reasons:

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

C

The applicant proposes to add no more than three dialysis stations at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” New Bern Dialysis is in Craven County. Thus, the service area for this facility consists of Craven County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A, page 123 of the 2022 SMFP, there are two existing or approved dialysis facilities in Craven County, both of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

Dialysis Facility	In-Center Patients (12-31-20)	# of Certified Stations (12-31-20)	Utilization (12-31-20)
FMC Craven County	85	28	75.89%
New Bern Dialysis	120	37	81.08%

Source: 2022 SMFP, Table 9A, page 123.

In Section G, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Craven County. The applicant states:

“This is an application based upon the facility performance and demonstrated need at the New Bern Dialysis facility...The applicant has not projected to serve patients currently served in another facility, or served by another provider.”

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 adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.
- There is a facility need determination in the 2022 SMFP for the proposed three dialysis stations.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 three dialysis stations at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

In Section Q, pages 99-100, 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
	As of 4/14/2022	2nd Full Fiscal Year CY 2025
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurses (RNs)	7.00	7.00
Technicians (PCT)	12.00	14.00
Medical Records	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Maintenance	1.00	1.00
Administration/Business Office	1.00	1.00
Other (FMC Director of Operations)	0.13	0.13
Other (FMC) Chief Technician)	0.10	0.10
Other (FMC In-Service)	0.25	0.25
TOTAL	25.48	27.48

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 F.4. In Section H.2 and H.3, pages 52-53, 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:

- New Bern Dialysis is an existing facility in Craven County that has demonstrated its ability to attract qualified staff by offering a wide range of personnel benefits and maintaining competitive salaries.
- In response to the pandemic’s impact on staffing, Fresenius Medical Care, parent company to BMA, has implemented initiatives such as, sign-on and retention bonuses, increased starting salaries and intensified recruiting efforts.
- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.

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 three dialysis stations at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

Ancillary and Support Services

In Section I, page 54, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 54-59, 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. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

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 67, the applicant provides the historical payor mix for New Bern Dialysis during CY 2021 for the proposed services, as shown in the table below.

New Bern Dialysis: Historical Payor Mix-CY2021

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.3	0.27%
Insurance *	6.2	5.57%
Medicare *	95.0	84.84%
Medicaid *	3.6	3.19%
Other (Misc. including VA)	6.9	6.13%
Total	112.0	100.00%

*Including any managed care plans

In Section L, page 68, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	44.0%	49.5%
Male	56.0%	50.5%
Unknown	na	na
64 and Younger	47.7%	80.3%
65 and Older	52.3%	19.7%
American Indian	0.0%	0.7%
Asian	0.0%	2.9%
Black or African American	68.8%	21.4%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	29.4%	71.8%
Other Race	0.0%	10.6%
Declined / Unavailable	0.0%	na

*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>

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, 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 69, 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.

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 70, 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.

Payor Source	In-Center Dialysis	
	# of Patients	% of Total
Self-Pay	0.4	0.27%
Insurance *	7.4	5.57%
Medicare *	113.1	84.84%
Medicaid *	4.2	3.19%
Other (Misc. including VA)	8.2	6.13%
Total	133.3	100.00%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.27% of total dialysis services will be provided to self-pay patients, 84.84% of total dialysis services to Medicare patients and 3.19% of total dialysis services to Medicaid patients.

On pages 70-71, 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 based on the following:

- The applicant calculates payor mix based upon treatment volumes as opposed to the number of patients. The applicant considers possible change in payor source during the fiscal year.
- Payor mix projections are based on recent facility performance.

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 72, 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 three dialysis stations at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The facility has a history of allowing health-related education and training programs to visit the facility to observe the operation of the unit while patients receive treatment.
- The applicant provides a copy of a letter sent to Craven Community College encouraging the school to include New Bern Dialysis facility in their clinical rotations for nursing students in Exhibit M-1.

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 three dialysis stations at New Bern Dialysis pursuant to Condition 2 of the facility need methodology for a total of no more than 40 stations upon completion of this project.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” New Bern Dialysis is in Craven County. Thus, the service area for this facility consists of Craven County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A, page 123 of the 2022 SMFP, there are two existing or approved dialysis facilities in Craven County, both of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

Dialysis Facility	In-Center Patients (12-31-20)	# of Certified Stations (12-31-20)	Utilization (12-31-20)
FMC Craven County	85	28	75.89%
New Bern Dialysis	120	37	81.08%

Source: 2022 SMFP, Table 9A, page 123.

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

“The applicant does not project to serve dialysis patients currently being served by another provider.

...

“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 New Bern Dialysis.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 75, 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 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 75, the applicant states:

“Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

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 75, 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 Sections 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
- 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 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 Form O, 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 of this type of facility located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius 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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 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, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard 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 27 and Section Q Form C Utilization, the applicant projects that New Bern Dialysis will serve 125.5 in-center patients on 40 stations, or a rate of 3.14 ($125.5 / 40 = 3.14$) in-center patients per station per week, as of the end of the first operating year following project completion, thus exceeding the standard of 2.8 in-center 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 25-27, and Section Q, pages 83-86, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.