

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 19, 2022

Findings Date: December 19, 2022

Project Analyst: Donna Donihi

Co-Signer: Gloria C. Hale

Project ID #: J-12239-22

Facility: Johnston Dialysis Center

FID #: 944566

County: Johnston

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

Project: Add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven stations) and Project ID #J-12163-21 (add seven stations)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

The applicant Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations to Johnston Dialysis Center pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID# J-12163-21 (add 7 dialysis stations).

## **Need Determination**

Chapter 9 of the 2022 State Medical Facilities Plan (SMFP) provides a county need methodology for determining the need for new dialysis stations. According to Table 9C, page 139, the county need methodology shows there is not a county need determination for additional dialysis stations in Johnston 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% or 3.0 patients per station per week, as stated in Condition 2. a. In Table 9A, page 126, the utilization rate reported for the facility is 89.39% or 3.57 patients per station per week, based on 118 in-center dialysis patients and 33 certified dialysis stations (118 patients / 33 stations = 3.57;  $3.57 / 4 = 0.89$ ).

As shown in Table 9D, page 141, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to 13 additional stations; thus, the applicant is eligible to apply to add up to 13 stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than four new stations to the facility, which is consistent with the 2022 SMFP calculated facility need determination for up to 13 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 which is applicable to this review. *Policy GEN-3: Basic Principles*, on 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, pages 74-75; Section O, page 77; 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 66-72; Section N, pages 74-75; 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 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's 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 four new stations to the facility, which is consistent with the 2022 SMFP calculated facility need determination for up to 13 stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

**Patient Origin**

On page 115, the 2022 SMFP defines the service area for the county need methodology for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.*” Johnston Dialysis Center is located in Johnston County. Thus, the service area for this application is Johnston County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 25, the applicant provides the historical in-center (IC) dialysis patient origin for Johnston Dialysis Center, as summarized below. The facility does not serve peritoneal dialysis (PD), or home hemodialysis (HH) patients.

**Historical Patient Origin  
(1/1/2021-12/31/2021)**

County	Patients	% of Total
Johnston	104	98.1%
Wake	1	0.9%
Wilson	1	0.9%
<b>Total</b>	<b>106</b>	<b>100.0%</b>

Source: Section C.2, page 25.

The following table illustrates the projected in-center patient origin at Johnston Dialysis Center in the second full fiscal year (FY) of operations, calendar year (CY) 2025, as provided on page 26 of the application.

**Projected Patient Origin  
CY2025**

<b>County</b>	<b>Patients</b>	<b>% of Total</b>
Johnston	127.1	98.5%
Wake	1.0	0.8%
Wilson	1.0	0.8%
<b>Total</b>	<b>129.1</b>	<b>100.0%</b>

Source: Section C.3, page 26

In Section C, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's patient origin projections are reasonable and adequately supported because they are based on the historical (CY2021) patient origin for the facility.

**Analysis of Need**

In Section C, page 29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 29, 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 118.3 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 80%, or 3.2 patients per station and exceeds the minimum required by the performance standard.”*

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

- The 2022 SMFP shows a facility needs determination for up to 13 stations at Johnston Dialysis Center.
- The applicant applies the Johnston County AACR as provided in the 2022 SMFP to project growth in Johnston County patient utilization and projects no growth for the patients from other counties being served at Johnston Dialysis Center.
- Then applicant shows that the facility will need the additional stations to accommodate the existing and projected patient population.

**Projected Utilization**

In Section Q Form C, page 83, the applicant provides the projected utilization, as illustrated in the following table.

<b>Utilization</b>	<b>Last Full FY CY2021</b>	<b>1st Full FY CY2024</b>	<b>2nd Full FY CY2025</b>
<b><i>In-Center Patients</i></b>			
# of Patients at the Beginning of the Year	118	109	118
# of Patients at the End of the Year	106	118	129
Average # of IC Patients during the Year	112	113	124
# of Treatments / Patient / Year	148	148	148
<b><i>Total # of Treatments</i></b>	<b>16,592</b>	<b>16,790</b>	<b>18,307</b>

In Section C, pages 25-27, and Section Q pages 84-86, the applicant provides the assumptions and methodology used to project in-center utilization, which is summarized below.

- The first full FY of operation is CY2024, the period from January 1, thru December 31, 2024. and the second full fiscal year of operation is CY2025.
- Projections begin with the facility census as of March 31, 2022.
- The applicant grows the Johnston County patient census by 9.2%, the 5-year AACR, as found in the 2022 SMFP, page 136.
- The applicant assumes the facility will continue to serve the two in-center patients residing in Wake and Wilson counties but does not project any growth from the patients being served from those counties at Johnston Dialysis Center.

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

<b>Johnston Dialysis Center In-Center Patients</b>	
Begin with the Johnston County patient population as of December 31, 2021.	104
Project the Johnston County patient population forward one year to December 31, 2022, using the Johnston County Five-Year Average Annual Rate Change of 9.2%.	$104.0 \times 1.092 = 113.6$
Subtract 16 patients projected to transfer to FKC East Johnson pursuant to Project ID # J-12128-21.	$113.6 - 16 = 97.6$
Add the 2 patients from other counties. This is the projected ending census for Interim Year 1.	$97.6 + 2 = 99.6$
Project the Johnston County patient population forward one year to December 31, 2023, using the Johnston County Five-Year Average Annual Change Rate.	$97.6 \times 1.092 = 106.5$
Add the 2 patients from other counties. This is the projected ending census for Interim Year 2.	$106.5 + 2 = 108.5$
Project the Johnston County patient population forward one year to December 31, 2024, using the Johnston County Five-Year Average Annual Change Rate.	$106.5 \times 1.092 = 116.3$
Add the 2 patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>	$116.3 + 2 = 118.3$
Project the Johnston County patient population forward one year to December 31, 2025, using the Johnston County Five-Year Average Annual Change Rate	$116.3 \times 1.092 = 127.1$
Add the 2 patients from other counties. <b>This is the projected ending census for Operating Year 2.</b>	$127.1 + 2 = 129.1$

As shown in the table above, the applicant projects Johnston Dialysis Center will serve 118.3 in-center patients by the end of the first full fiscal year of operation, (ending December 31, 2024), for a utilization rate of 3.2 patients per station per week or 80% ( $118.3 \text{ patients} / 37 \text{ stations} = 3.2 \text{ patients per station per week}$ ). The projected utilization of 3.2 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold for the first year following the 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 of the previous year, the most recent historical patient census.
- The applicant projects the growth of the Johnston County patient census using the Five-Year AACR for the county as reported in the 2022 SMFP.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

**Access to Medically Underserved Groups**

In Section C.6, page 32, the applicant discusses access to the facility’s services, stating:

*“Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population that includes low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other traditionally underserved persons.*

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

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

On page 32, the applicant provides the estimated percentage for each medically underserved group it will serve during OY2, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	43.81%
Racial and ethnic minorities	76.19%
Women	49.52%
Persons with Disabilities	43.81%
Persons 65 and older	54.29%
Medicare beneficiaries	38.10%
Medicaid recipients	43.81%

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

- Fresenius’ corporate policy commits to providing services to all patients referred for ESRD services.
- Fresenius’ facilities have historically provided care to all in need of ESRD services, including underserved persons.

**Conclusion**

The Agency reviewed the:



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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of 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 of the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

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.
- Adding fewer than four stations – The applicant states adding fewer stations will not meet the need; thus, this is not the most effective alternative.
- Add more than four stations - the applicant states that the facility cannot accommodate more stations because there is no room; 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
- Information that was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 four additional in-center dialysis stations for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).**
- 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 April 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 any charges for providing health services by the person proposing the service.

C

The applicant, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

**Capital and Working Capital Costs**

In Section F.1, page 43, and Form F.1a in Section Q, the applicant states it will incur the following capital costs for this project.

Construction	\$259,325
Architect	\$23,339
Non-Medical Equipment	\$50,750
Furniture	\$15,070
Contingency	\$42,400
Total	\$390,884

In Section F.3, page 45, the applicant states there will be no working capital costs because it is an existing, operational 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.

**Sources of Capital Cost Financing**

Type	Biomedical Applications of North Carolina, Inc.
Accumulated reserves or OE *	\$390,884
<b>Total Financing</b>	<b>\$390,884</b>

\* OE = Owner's Equity

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

- Exhibit F-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 applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

**Financial Feasibility**

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

**Johnston Dialysis Center Projected Revenue and  
Operating Expenses**

	1 <sup>st</sup> Full FY	2 <sup>nd</sup> Full FY
	CY2024	CY2025
Total In-Center Treatments	16,790	18,307
Total Gross Revenues (Charges)	\$105,625,281	\$115,171,490
Total Net Revenue	\$5,156,867	\$5,622,935
Avg Net Revenue per Treatment	\$307	\$307
Total Operating Expenses (Costs)	\$4,284,227	\$4,473,150
Avg Op. Expense per Treatment	\$255	\$244
Net Income	\$872,640	\$1,149,785

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

- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- FTEs and salaries are based on current staffing.
- 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 the availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

On page 115, the 2022 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.*” Johnston Dialysis Center is located in Johnston County. Thus, the service area for this application is Johnston County. Facilities may serve residents of counties not included in their service area.

The applicant and its parent companies, Fresenius Medical Care (FMC) and Bio-Medical Applications of North Carolina (BMA), currently operate five of six approved facilities in Johnston County according to Table 9A on page 126 of the 2022 SMFP and the information provided by the applicant in Section G, page, 50, Information on these dialysis facilities, from Table 9A of the 2022 SMFP is summarized below.

<b>Johnston County Dialysis Facilities            Certified Stations and Utilization as of December 31, 2021</b>					
<b>Dialysis Facility</b>	<b># Certified Stations</b>	<b>#IC Patients</b>	<b>Utilization by Percent</b>	<b>Patients Per Station</b>	<b># of additional stations approved</b>
Johnston Dialysis Center	33	106	80.30%	3.2121	0
FMC Four Oaks	25	54	54.00%	2.1600	0
FKC East Johnston	10	34	85.00%	3.4000	7
FKC West Johnston	10	19	47.50%	1.9000	2
FMC Stallings station	20	70	87.50%	3.5000	6
Clayton Dialysis	0	0	0.00%	0.0000	10
<b>Total</b>	<b>98</b>	<b>283</b>	<b>72.19%</b>		

Source: Table 9A, 2022 SMFP

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Johnston County. The applicant states that this application is based on facility performance and demonstrated need at Johnston Dialysis Center and is not specific to Johnston County as a whole. The overall utilization for facilities in Johnston County was approximately 72.19% as of December 31, 2021.

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 Johnston Dialysis Center needs additional stations to serve its existing and projected patient population.
- The applicant adequately demonstrates that the proposed additional stations are needed in addition to the existing and approved stations in the county.

**Conclusion**

The Agency reviewed the:

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

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

- (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, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

In Section Q Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the Johnston Dialysis Center facility, as summarized in the following table:

<b>Position</b>	<b>Current FTE Positions</b>	<b>FTE Positions 1st FY 2024</b>	<b>FTE Positions 2nd FY 2025</b>
Administrator	1.00	1.00	1.00
RN	4.00	5.00	5.00
LPN	1.00	1.00	1.00
Patient Care Technician (PCT)	13.00	15.00	15.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.18	0.18	0.18
FMC Chief Technician	0.18	0.18	0.18
FMC In-Service	0.18	0.50	0.50
<b>Total</b>	<b>24.86</b>	<b>27.86</b>	<b>27.86</b>

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 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:

- 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 regarding 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 the reasons stated above.

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

### C

The applicant, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

#### **Ancillary and Support Services**

In the table in Section I, page 54, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 54-59, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at Johnston Dialysis Center.
- The applicant discusses how it provides each necessary ancillary and support service at Johnston Dialysis Center.

#### **Coordination**

In Section, I, page 59, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing healthcare system based on the following:

- The applicant discusses its existing relationships with local health care and social service providers.

- The applicant has agreements in place coordinating lab services, hospital services, and transplant 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.

- (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 that 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 to represent the most reasonable alternative and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy-saving features have been incorporated into the construction plans.

### C

The applicant, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

In Section K, page 62, the applicant states that the project involves renovating existing space. Line drawings are provided in Exhibit K.2.

On page 63, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states it uses its corporate design team to use cost-saving measures within each facility design and facilities are designed to ensure safe and orderly flow for patients.
- The applicant states its design and construction of facilities are a part of doing business and these costs are not passed on to the patients.
- The applicant states it designs and constructs to utilize energy-efficient features and to generate cost savings.

On page 63, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states it will renovate the existing space.
- The applicant states the costs are necessary to provide continued convenient access to care for area patients.

- The applicant states the cost of the project is not being passed on to patients and is being absorbed by the applicant.

On page 63, the applicant identifies any applicable energy-saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 67, the applicant provides the historical payor mix for in-center dialysis during CY2021 for Johnston Dialysis Center, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	4.3	4.06%
Insurance *	5.4	5.13%
Medicare *	77.0	72.60%
Medicaid *	11.9	11.19%
Other (Misc. including VA)	7.4	7.03%
<b>Total</b>	<b>106.0</b>	<b>100.0%</b>

\*Including any managed care plans

In Section L, page 68, the applicant provides the following comparison for facility patients and the service area population.

Johnston Dialysis Center	Percentage of Total Patients Served by the Facility	Percentage of the Population of the Service Area
Female	49.5%	51.0%
Male	50.5%	49.0%
64 and Younger	45.7%	86.4%
65 and Older	54.3%	13.6%
American Indian	0.0%	0.9%
Asian	0.0%	0.9%
Black or African American	60.0%	17.0%
Native Hawaiian/Pacific Islander	0.0%	0.1%
White or Caucasian	23.8%	78.8%
Other Race	16.2%	16.3%
<b>Total</b>	<b>100%</b>	<b>100%</b>

The Agency reviewed the:

- Application
- Exhibits to the application
- Information that 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 the 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 that FMC 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 identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 70, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following the completion of the project, as summarized in the table below.

**Johnston Dialysis Center Payor Mix  
CY2025**

County	IC Patients	
	Patients	% of Total
Self-Pay	5.2	4.06%
Insurance *	6.6	5.13%
Medicare *	93.7	72.60%
Medicaid *	14.4	11.9%
Other (Misc., including VA)	9.1	7.03%
<b>Total</b>	<b>129.1</b>	<b>100.00%</b>

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

As shown in the table above, during the second full fiscal year of operation, the applicant projects in-center services as follows: 4.06% will be provided to self-pay patients, 72.6% to Medicare recipients, and 11.9% to Medicaid recipients.

On pages 70-72, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following the completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant bases payor mix upon treatment volumes rather than patients.
- The applicant bases future payor mix percentages 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.5, 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, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

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 will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- The applicant provides a copy of the letter sent to Johnston Community College offering training opportunities in Exhibit M-2.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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



- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact on 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, Bio-Medical Applications of North Carolina, Inc., proposes to add no more than four dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 37 stations upon completion of this project, Project ID #J-12128-21 (relocate seven dialysis stations) and Project ID #J-12163-21 (add 7 dialysis stations).

On page 115, the 2022 SMFP defines the service area for dialysis stations as, “... *the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.*” Johnston Dialysis Center is located in Johnston County. Thus, the service area for this application is Johnston County. Facilities may serve residents of counties not included in their service area.

Information on the Johnston County dialysis facilities, from Table 9A of the 2022 SMFP, is summarized below:

<b>Johnston County Dialysis Facilities Certified Stations and Utilization as of December 31, 2021</b>					
<b>Dialysis Facility</b>	<b># Certified Stations</b>	<b>#IC Patients</b>	<b>Utilization by Percent</b>	<b>Patients Per Station</b>	<b># of additional stations approved</b>
Johnston Dialysis Center	33	106	80.30%	3.2121	0
FMC Four Oaks	25	54	54.00%	2.1600	0
FKC East Johnston	10	34	85.00%	3.4000	7
FKC West Johnston	10	19	47.50%	1.9000	2
FMC Stallings station	20	70	87.50%	3.5000	6
Clayton Dialysis	0	0	0.00%	0.0000	10
<b>Total</b>	<b>98</b>	<b>283</b>	<b>72.19%</b>		

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 expect this proposal to have any effect on the competitive climate in Johnston County. The applicant does not project to serve dialysis*

*patients currently being served by another provider. The projected patient population for the facility begins with the current patient population, projected patient transfers, and growth of that population consistent with the Johnston County Five Year Average Annual Change Rate published in the 2022 SMFP.”*

Regarding the impact of the proposal on cost-effectiveness, in Section N, pages 74-75, the applicant states:

*“Fresenius Medical Care related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid ...*

*Fresenius Medical Care-related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients ...*

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

See also Sections B, 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:

*“Quality of care is always at the forefront at Fresenius Medical Care-related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high-quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well:*

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

See also Sections B 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.*

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

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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 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 that was publicly available during the review and used by the Agency

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section Q Form 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 dialysis facilities owned, operated, or managed by a Fresenius Medical Care-related entity and located in North Carolina.

In Section O, page 80, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius-related facility has been found to have had an incident related to the quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering the information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

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

-NA- Johnston Dialysis Center 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- On page 29, 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 118.3 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 80%, or 3.2 patients per station, and exceeds the minimum required by the performance standard.”*
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 25-27, and in Section Q Form C Utilization subsection, 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.