

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 18, 2023

Findings Date: July 18, 2023

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala Mitchell

Project ID #: G-12351-23

Facility: BMA of Southwest Greensboro

FID #: 991046

County: Guilford

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

Project: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations upon completion of this project, Project ID# G-12161-21 (add 8 stations) and Project ID# G-12130-21 (relocate 8 stations)

### 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to add no more than two in-center (IC) dialysis stations at the BMA of Southwest Greensboro (BMA SW Greensboro) facility pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to Fresenius Kidney Care (FKC) Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

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

While BMA SW Greensboro 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**

Chapter 9 of the 2023 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 135, the county need methodology shows there is no county need determination for additional dialysis stations in Guilford 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 2023 SMFP, if the utilization rate for the dialysis center as reported in the 2023 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. Table 9A on page 123 of the 2023 SMFP shows the utilization rate reported for BMA SW Greensboro is 84.85 percent or 3.39 patients per station per week based on 112 in-center dialysis patients and 33 certified dialysis stations (112 patients / 33 stations = 3.3939;  $3.39 / 4 = 84.85\%$ ).

As shown in Table 9D on page 136 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at BMA SW Greensboro is up to eight additional stations; thus, the applicant is eligible to apply to add up to eight stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new stations to BMA SW Greensboro, which is consistent with the 2023 SMFP calculated facility need determination for up to eight dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2023 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2023 SMFP, states:

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

### Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, pages 73-74; Section O, page 76-79; 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 31; Section L, pages 65-71; Section N, page 74; 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 23-24; Section N, pages 73-74; 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 Condition 2 of the facility need methodology as applied from the 2023 SMFP.
- The applicant adequately demonstrates how BMA of Southwest Greensboro's projected volumes incorporate the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need and is consistent with Policy GEN-3.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which

all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

**C**

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

**Patient Origin**

The 2023 SMFP, page 113, defines the service area for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.” The facility in this application is in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

<b>BMA SW Greensboro Historical &amp; Projected Patient Origin</b>												
<b>County</b>	<b>Last – CY 2022</b>						<b>Projected – CY 2026</b>					
	<b>IC* Patients</b>		<b>HH Patients</b>		<b>PD Patients</b>		<b>IC* Patients</b>		<b>HH Patients</b>		<b>PD Patients</b>	
	<b>#</b>	<b>%</b>	<b>#</b>	<b>%</b>	<b>#</b>	<b>%</b>	<b>#</b>	<b>%</b>	<b>#</b>	<b>%</b>	<b>#</b>	<b>%</b>
Guilford	104.0	93.7%	0	0.0%	0	0.0%	118.4	96.7%	0	0.0%	0	0.0%
Alamance	1.0	0.9%	0	0.0%	0	0.0%	1.0	0.8%	0	0.0%	0	0.0%
Forsyth	3.0	2.7%	0	0.0%	0	0.0%	3.0	2.5%	0	0.0%	0	0.0%
Other States	3.0	2.7%	0	0.0%	0	0.0%	0.0	0.0%	0	0.0%	0	0.0%
<b>Total</b>	<b>111.0</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>122.4</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>

**Note:** Table may not foot due to rounding.

\* **Source:** Section C, pages 25-26, and clarifying information.

In Section C, pages 26-29, and the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant’s projections are based on the historical patient origin at BMA SW Greensboro.
- The applicant grows the Guilford County patient census by 3.3%, the Five-Year AACR for Guilford County per the 2023 SMFP.
- The applicant assumes the five in-center patients residing in surrounding counties will continue to dialyze at BMA SW Greensboro 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 three in-center patients who received dialysis treatments in CY2022 at BMA SW Greensboro who were residents of another state were assumed to be transient patients and were not counted in future patient population growth projections.

### **Analysis of Need**

In Section C, pages 27-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. Patients will normally receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will generally dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise.*

*The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.”*

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

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2023 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant grows the Guilford County patient census by 3.3%, the Five-Year AACR for Guilford County per the 2023 SMFP.
- The applicant assumes the four in-center patients residing in surrounding counties will continue to dialyze at BMA SW Greensboro 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 three in-center patients who received dialysis treatments in CY2022 at BMA SW Greensboro who were residents of another state 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 C, pages 25-27, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census on December 31, 2022. The applicant states that on December 31, 2022, its in-center patient census was comprised of 104 Guilford County patients, four patients from Alamance and Forsyth counties and three patients from other states.
- The Guilford County Five-Year AACR as published in Table 9B, page 132 of the 2023 SMFP is 3.3 percent. The applicant projects growth of the Guilford County in-center patient population at 3.3 percent.
- The applicant assumes no population growth for the patients residing outside of Guilford County who are dialyzing at BMA SW Greensboro but assumes the patients will continue to dialyze at through BMA SW Greensboro and adds them to the calculations when appropriate.
- The three in-center patients who received dialysis treatments in CY2022 at BMA SW Greensboro who were residents of another state were assumed to be transient patients and were not counted in future patient population growth projections.
- The new stations are projected to be certified by December 31, 2024. OY1 is CY 2025. OY2 is CY 2026.

In Section C, pages 26-27, and in the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

<b>BMA SW Greensboro In-Center Patients</b>	
Begin with the Guilford County patient population as of December 31, 2022.	104
Project the Guilford County patient population forward for one year to December 31, 2023, using the Guilford County Five-Year AACR (3.3%).	$104 \times 1.033 = 107.4$
Project the Guilford County patient population forward for one year to December 31, 2024, using the Guilford County Five-Year AACR.	$107.4 \times 1.033 = 111.0$
Project the Guilford County patient population forward for one year to December 31, 2025, using the Craven County Five-Year AACR.	$111.0 \times 1.033 = 114.6$
Add the four IC patients from other counties. This is the ending patient census for <b>Operating Year 1 (CY2025)</b> .	$114.6 + 4 = \mathbf{118.6}$
Project the Guilford County patient population forward for one year to December 31, 2026, using the Guilford County Five-Year AACR.	$114.6 \times 1.033 = 118.4$
Add the four IC patients from other counties. This is the ending patient census for <b>Operating Year 2 (CY2026)</b> .	$118.4 + 4 = \mathbf{122.4}$

Totals may not sum due to rounding

As shown in the table above, the applicant projects BMA SW Greensboro will serve 118.6 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 3.39 patients per station per week or 84.75% ( $118.6 \text{ patients} / 35 \text{ stations} = 3.39 \text{ patients per station per week} / 4 = 0.8475$  or 84.75%). By the end of OY2 (December 31, 2026), following the applicant's methodology and assumptions, the facility will have 122.4 in-center patients dialyzing at the center for a utilization rate of 87.50% ( $122.4 / 35 = 3.50 / 4 = 0.875$  or 87.50%). 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, 2022, the most recent historical patient census.
- The applicant projects growth of the Guilford County patient census using the Guilford County Five-Year AACR of 3.3%, as published in the 2023 SMFP.
- The applicant adds the four in-center patients residing in other counties for future projections, with no growth.
- The three in-center patients who received dialysis treatments in CY2022 at BMA SW Greensboro who were residents of another state were assumed to be transient patients and were not counted in future patient population growth projections.
- 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 31, the applicant states:

*“.... Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, [people with disabilities], 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, [disability], age or any other grouping/category or basis for being an underserved person.”*

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

<b>Medically Underserved Groups</b>	<b>Estimated % of Total Patients in FY 2</b>
Low-income persons	42.0%
Racial and ethnic minorities	81.0%
Women	41.0%
Persons with disabilities	16.0%
Persons 65 and older	29.0%
Medicare beneficiaries	90.0%
Medicaid recipients	37.0%

**Source:** Section C, page 31.

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

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.
- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

### **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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

In Section E, page 40, 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 would result in higher utilization rates and potentially interrupt patient admissions; thus, this alternative is not the most effective.
- Add fewer stations – the applicant states that this alternative would also result in higher utilization rates as the facility patient census increases; thus, this is not the most effective alternative.
- Add more than two stations- the applicant states that the facility does not have the physical capacity for more than 35 in-center dialysis stations; thus, this is not the least costly or 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 2023 SMFP, the certificate holder shall develop no more than two additional in-center dialysis stations for a total of no more than 35 in-center stations at BMA of Southwest Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 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 July 1, 2024.
4. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

### C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

#### **Capital and Working Capital Costs**

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

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$7,500
<b>Total</b>	<b>\$7,500</b>

On Form F.1a and Form F.1a Capital Cost Assumptions, pages 87-88, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant describes each item that makes up the projected capital cost.

- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.

In Section F.3, page 44, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

### **Availability of Funds**

In Section F.2, page 42, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
<b>Type</b>	<b>Bio-Medical Applications of North Carolina, Inc.</b>	<b>Total</b>
Loans	\$	\$
Accumulated reserves or OE *	\$7,500	\$7,500
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$7,500	\$7,500

\* OE = Owner's Equity

Exhibit F-2 contains a letter dated March 15, 2023, from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of accumulated reserves for the capital needs of the project. The letter in Exhibit F-2 also states that the 2021 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than \$939 million in cash and total assets in excess of \$27.2 billion.

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

- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.
- The letter from the applicant demonstrates the availability of adequate cash and assets to fund the proposed project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, 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.

<b>Projected Revenues and Operating Expenses</b>		
<b>BMA SW Greensboro</b>	<b>Full Fiscal Year 1 CY 2025</b>	<b>Full Fiscal Year 2 CY 2026</b>
Total Treatments	17,288	17,839
Total Gross Revenues (Charges)	\$108,756,545	\$112,222,610
Total Net Revenue	\$7,138,709	\$7,366,219
Average Net Revenue per Treatment	\$413	\$413
Total Operating Expenses (Costs)	\$4,311,417	\$4,407,229
Average Operating Expense per Treatment	\$249	\$247
<b>Net Income</b>	<b>\$2,827,292</b>	<b>\$2,958,991</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 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 adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- 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.

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

The 2023 SMFP, page 113, defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* The facility in this application is in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2023 SMFP, there are 11 existing or approved dialysis facilities in Guilford County. Information on the Guilford County dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

**Guilford County Dialysis Facilities  
 Certified Stations and Utilization as of December 31, 2021**

Dialysis Facility	Owner	# of Certified Stations	# IC Patients	Utilization
BMA of Greensboro	Fresenius	54	153	70.83%
BMA of South Greensboro	Fresenius	44	169	96.02%
BMA of Southwest Greensboro	Fresenius	33	112	84.85%
FMC of East Greensboro	Fresenius	43	124	72.09%
Fresenius Kidney Care Garber-Olin	Fresenius	28	74	66.07%
Fresenius Kidney Care Sandy Ridge*	Fresenius	0	0	0.00%
Fresenius Medical Care High Point	Fresenius	14	53	94.64%
Northwest Greensboro Kidney Center	Fresenius	37	108	72.97%
Central Greensboro Dialysis**	DaVita	0	0	0.00%
High Point Kidney Center of Wake Forest University	WFU	50	141	70.50%
Triad Dialysis Center of Wake Forest University	WFU	40	109	68.13%

Source: Table 9A, Chapter 9, 2023 SMFP, pages 122-123.

\*Certificate of Need was issued January 29, 2022.

\*\*The decision regarding the development of this facility is under appeal. No certificate has been issued.

Agency data shows that eight of the facilities are owned and operated by Fresenius, one by DaVita and two by Wake Forest University.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford County. The applicant states that this application is based upon facility performance and demonstrated need at BMA SW Greensboro and is not specific to Guilford County as a whole. The applicant states:

*“The overall utilization for dialysis facilities in Guilford County was 76.02%, or 3.04 patients per station as of December 31, 2021. Of the nine operational facilities in*

*Guilford County, BMA owns/operates seven of these facilities, six of which were operating above 70% utilization, as of December 31, 2021. Garber-Olin was the only BMA facility operating below 70% utilization on December 31, 2021, however as of December 31, 2022, the facility was serving 81 patients on 28 stations, a utilization of 2.89 patients per station or 72.3% utilization.”*

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

- The applicant proposes to increase the number of dialysis stations in Guilford County based on Condition 2 of the facility need determination in the 2022 SMFP.
- As shown in Table 9D on page 136 of the 2023 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at BMA SW Greensboro is up to eight additional stations; thus, the applicant is eligible to apply to add up to eight stations during the 2023 SMFP review cycle pursuant to Condition 2 of the facility need methodology.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Guilford County.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion 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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

In Section Q Form H, pages 98-99, the applicant provides current and projected full-time equivalent (FTE) positions for the BMA SW Greensboro facility, as summarized in the following table:

POSITION	Current FTE Positions 2/21/2023	FTE POSITIONS CY2025	FTE POSITIONS CY2026
Administrator	1.00	1.00	1.00
RN	3.00	3.00	3.00
Patient Care Technician (PCT)	8.00	8.00	8.00
Dietician	0.75	0.75	0.75
Social Worker	0.75	0.75	0.75
Maintenance	0.50	0.50	0.50
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.10	0.10	0.10
FMC Chief Technician	0.10	0.10	0.10
FMC In-Service	0.10	0.10	0.10
<b>Total</b>	<b>15.30</b>	<b>15.30</b>	<b>15.30</b>

Source: Section Q Form H.

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.2 and H.3, pages 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The facility is an existing facility, and the applicant bases its staffing on its historical experience providing dialysis services at the facility
- The applicant has existing policies in regard to recruitment, training and continuing education

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

## C

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

### **Ancillary and Support Services**

In the table in Section I, page 53, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 53-58, 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 services the applicant currently provides at BMA SW Greensboro.

### **Coordination**

In Section I.2, page 58, the applicant describes its existing relationships with other local health care and social service providers.

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

- The applicant 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 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 65, the applicant provides the historical payor mix for in-center dialysis during CY2022 for BMA SW Greensboro, as summarized in the table below.

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	0.9	0.80%
Insurance *	17.8	16.05%
Medicare *	82.0	73.84%
Medicaid *	7.4	6.70%
Other (VA and Misc.)	2.9	2.61%
Total	111.0	100.00%

\*Including any managed care plans

In Section L, page 67, the applicant provides the following comparison.

BMA SW GREENSBORO	Percentage of Total Patients Served by the Facility	Percentage of the Population of the Service Area
Female	41.0%	52.5%
Male	59.0%	47.5%
Unknown		
64 and Younger	71.0%	84.1%
65 and Older	29.0%	15.9%
American Indian	0.0%	0.8%
Asian	4.0%	5.5%
Black or African American	71.0%	36.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	17.0%	54.8%
Other Race	8.0%	11.6%
Declined / Unavailable	0.0%	

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 68, the applicant states that BMA SW Greensboro 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 68, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against BMA SW Greensboro.

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 68, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**BMA SW Greensboro Projected Payor Mix  
Second Full FY of Operation following Project Completion  
CY2026**

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	1.0	0.80%
Insurance *	19.6	16.05%
Medicare *	90.4	73.84%
Medicaid *	8.2	6.70%
Other (VA and Misc.)	3.2	2.61%
Total	122.4	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 0.80% of BMA SW Greensboro's dialysis services will be provided to self-pay patients, 73.84% to Medicare recipients and 6.70% to Medicaid recipients.

On page 69, 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 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, page 70, 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 two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area 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 documentation of its willingness to provide applicable health professional training programs in the area with access to the facility

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case

of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

**C**

The applicant proposes to add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 35 stations at BMA SW Greensboro upon completion of this project, Project ID# G-12130-21 (relocate eight stations from BMA SW Greensboro to FKC Sandy Ridge) and Project ID# G-12161-21 (add 8 stations).

The 2023 SMFP, page 113, defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay, and Graham counties and Avery, Mitchell, and Yancey counties.”* The facility in this application is in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2023 SMFP, there are 11 existing or approved dialysis facilities in Guilford County. Information on the Guilford County dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

**Guilford County Dialysis Facilities  
 Certified Stations and Utilization as of December 31, 2021**

Dialysis Facility	Owner	# of Certified Stations	# IC Patients	Utilization
BMA of Greensboro	Fresenius	54	153	70.83%
BMA of South Greensboro	Fresenius	44	169	96.02%
BMA of Southwest Greensboro	Fresenius	33	112	84.85%
FMC of East Greensboro	Fresenius	43	124	72.09%
Fresenius Kidney Care Garber-Olin	Fresenius	28	74	66.07%
Fresenius Kidney Care Sandy Ridge*	Fresenius	0	0	0.00%
Fresenius Medical Care High Point	Fresenius	14	53	94.64%
Northwest Greensboro Kidney Center	Fresenius	37	108	72.97%
Central Greensboro Dialysis**	DaVita	0	0	0.00%
High Point Kidney Center of Wake Forest University	WFU	50	141	70.50%
Triad Dialysis Center of Wake Forest University	WFU	40	109	68.13%

Source: Table 9A, Chapter 9, 2023 SMFP, pages 122-123.

\*Certificate of Need was issued January 29, 2022.

\*\*The decision regarding the development of this facility is under appeal. No certificate has been issued.

Agency data shows that eight of the facilities are owned and operated by Fresenius, one by DaVita and two by Wake Forest University.

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

*“The applicant does not expect this proposal to have any effect on the competitive climate in Guilford County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the BMA of Southwest Greensboro facility begins with the current patient population and projects growth of that population consistent with the Guilford County Five Year Average Annual Change Rate published in the 2023 SMFP.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 73-74, 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 who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment.”*

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 74, the applicant states:

*“Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality of 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 74, 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 an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

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

### **C**

In Section Q Form 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 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius Medical Care related facility in North Carolina has been found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and publicly available data 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

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

**-NA-** . BMA SW Greensboro is an existing facility. The applicant is not proposing to establish a new dialysis facility Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of in-center 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 full fiscal year of operation following certification of the additional stations.*

- C- In Section C, page 27, and on Form C in Section Q, the applicant projects that BMA SW Greensboro will serve 118.6 patients on 35 stations, or a rate of 3.39 patients per station per week [ $118.6/35 = 3.39$ ], as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*
- NA- The applicant is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (d) *An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*
- NA- The applicant is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.
- (e) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*
- C- In Section C, pages 25-27, and Section Q, the Form C Utilization subsection, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.