

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 28, 2024

Findings Date: July 2, 2024

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: F-12469-24

Facility: Fresenius Kidney Care Huntersville Dialysis

FID #: 240030

County: Mecklenburg

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

Project: Develop a new 10-station dialysis facility by relocating six stations from FMC North Charlotte, three stations from BMA Nations Ford and one station from BMA Beatties Ford

### 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.

NA

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA), proposes to develop a new 10-station dialysis facility, Fresenius Kidney Care Huntersville Dialysis (FKC Huntersville), by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and no more than one dialysis station from BMA Beatties Ford. All three facilities are in Mecklenburg County. The proposed facility, FKC Huntersville, will also be in Mecklenburg County. BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

FKC Huntersville proposes to provide in-center dialysis but does not propose to provide either a peritoneal dialysis program or a home hemodialysis program.

The applicant does not propose to develop any beds or services, acquire any medical equipment or offer a new institutional health service for which there is a need determination in the 2024 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

#### **Patient Origin**

On page 113 the 2024 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.*” FKC Huntersville will be in Mecklenburg County. Thus, the service area for this application is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The applicant is proposing to develop a new facility, therefore, there is no historical patient origin to report. The following table illustrates the historical patient origin of the three dialysis facilities contributing dialysis stations to FKC Huntersville. The applicant provides the patient origin as reported on the December 31, 2023 ESRD data collection forms submitted to the Agency in February 2024.

<b>Historical Patient Origin 01/01/2023-12/31/2023</b>		
<b>FMC North Charlotte</b>		
<b>County</b>	<b># of In-Center Patients</b>	<b>% of Total</b>
Mecklenburg	124.0	93.2%
Cabarrus	6.0	4.5%
Gaston	1.0	0.8%
Iredell	1.0	0.8%
Rowan	1.0	0.8%
<b>Total</b>	<b>133.0</b>	<b>100.0%</b>
<b>BMA Nations Ford</b>		
Mecklenburg	93.1	97.9%
South Carolina	1.0	2.1%
<b>Total</b>	<b>84.0</b>	<b>100.0%</b>
<b>BMA Beatties Ford</b>		
Mecklenburg	82.0	94.3%
Cabarrus	1.0	1.1%
Gaston	3.0	3.4%
Lincoln	1.0	1.1%
<b>Total</b>	<b>87.0</b>	<b>100.0%</b>

Source: Section C, page 26

The following table illustrates the projected patient origin for the proposed FKC Huntersville.

<b>FKC Huntersville Projected Patient Origin 2<sup>nd</sup> Full FY 01/01/2028-12/31/2028 (CY2028)</b>		
<b>County</b>	<b># of In-Center Patients</b>	<b>% of Total</b>
Mecklenburg	30.7	100.0%
<b>Total</b>	<b>30.7</b>	<b>100.0%</b>

Source: Section C, page 27

In Section C, pages 27-29, the applicant provides the assumptions and methodology used to project FKC Huntersville’s patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on the residence of patients dialyzing at BMA facilities in the service area that would be better served at the proposed facility.
- Geographically, FKC Huntersville will be more accessible resulting in a shorter commute for some patients.
- The applicant states that the patient origin projections are based on the ZIP code residence of BMA patients who have expressed their support for the project and their

intention to transfer their care to the proposed facility. Copies of the letters of support are included in Exhibit C-3 of the application.

- The applicant uses the 1.1% Mecklenburg County Five Year Average Annual Change Rate (AACR) as published in the 2024 SMFP, to project patient growth for the Mecklenburg County patient population.

### Analysis of Need

In Section C, pages 30-31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant identifies the existing Mecklenburg County BMA facilities and the residence locations of its in-center patients that could be served more conveniently that will allow for a shorter commute to dialysis services at the proposed FKC Huntersville. Additionally, the applicant obtained letters from 30 existing BMA patients expressing their willingness to transfer their care to the proposed FKC Huntersville.

The information is reasonable and adequately supported because it is based on the residence of dialysis patients that would be better served at FKC Huntersville and letters from 30 existing in-center BMA patients currently served at other Mecklenburg County facilities who have expressed an interest in transferring their care to the proposed FKC Huntersville facility. The applicant provided documentation in Exhibit C-3 of the application.

### Projected Utilization

In Section C, page 29, and Section Q, page 96, the applicant provides projected utilization, as illustrated in the following table.

	patients
Begin with the Mecklenburg County patient population who have signed letters of support and have expressed an interest in transferring their care to the facility upon completion of the project, December 31, 2026.	30
Project the Mecklenburg County patient population forward to December 31, 2027, using the Mecklenburg County Five-Year AACR. <b>This is the projected ending census for Operating Year 1 (OY1).</b>	$30 \times 1.011 = 30.3$
Project the Mecklenburg County patient population forward to December 31, 2028, using the Mecklenburg County Five-Year AACR. <b>This is the projected ending census for Operating Year 2 (OY2).</b>	$30.3 \times 1.011 = 30.7$

In Section C, pages 27-28, and Section Q, pages 94-97, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant states that there are a significant number of dialysis patients residing in Charlotte that would be better served by the proposed facility because it would reduce their commute time to dialysis services.

- The applicant assumes that the Mecklenburg County dialysis patients who support the project and provided letters expressing their support, will transfer their dialysis care to FKC Huntersville. The applicant identifies these potential patients by ZIP code, as illustrated in the table below.

Facility	Patient Residence ZIP Code		
	28216	28269	Totals
FMC North Charlotte	2	3	5
BMA Nations Ford		1	1
BMA Beatties Ford	20	4	24
<b>Total</b>	<b>22</b>	<b>8</b>	<b>30</b>

Source: Section C, page 27

- The applicant identifies five BMA facilities in Mecklenburg County that are highly utilized and have a need determination for dialysis stations identified in the 2024 SMFP. However, they cannot be expanded because the facilities are of maximum capacity. As illustrated in the table below, the 2024 SMFP identifies a need determination for six dialysis stations at FMC North Charlotte and three at BMA Nations Ford. The applicant assumes that relocating the nine stations to the proposed FKC Huntersville would better serve the patients who reside in the area.

Facility	# Certified Stations	Census	Utilization	2024 Facility Need Determination
BMA Nations Ford	28	90	80.36%	3
FMC North Charlotte	40	136	85.00%	6
FMC Matthews	21	80	95.24%	6
FMC Aldersgate	16	51	79.69%	4
BMA East Charlotte	32	105	82.03%	18
<b>Total</b>	<b>137</b>	<b>462</b>	<b>84.31%</b>	<b>37</b>

Source: Section C, page 28

- Metrolina Nephrology Associates (MNA) has a long-standing relationship with BMA and currently serves as the medical director of the majority of BMA facilities in Mecklenburg County. MNA physicians also refer patients and have agreed to serve as the medical director for the proposed FKC Huntersville.
- The applicant projects growth of the Mecklenburg County patient census using the Mecklenburg County Five-Year AACR of 1.1%, as published in the 2024 SMFP.
- The applicant projects that the new stations will be certified as of December 31, 2026. OY1 of the project will be January 1, 2027 - December 31, 2027 and OY2 will be January 1, 2028 - December 31, 2028.

At the end of OY1, FKC Huntersville is projected to serve 30.3 IC patients on 10 stations. At the end of OY2 the facility is projected to serve 30.7 IC patients on 10 stations.

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

- OY1: 3.03 IC patients per station per week or 75.75% (30.3 IC patients / 10 stations =  $3.03/4 = 0.7575$  or 75.75%)
- OY2: 3.07 IC patients per station per week or 76.75% (30.7 IC patients / 10 stations =  $3.07/4 = 0.7675$  or 76.75%)

The projected utilization of 3.03 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(a).

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

- The applicant projects future patient population based on existing BMA patients who have expressed a desire to transfer their care to the proposed facility.
- The applicant identified a segment of the Mecklenburg County dialysis patient population who would be better served at the proposed FKC Huntersville because of easier accessibility to services resulting from a short commute.
- The applicant projects the growth of the Mecklenburg County patient census using the Mecklenburg County Five Year AACR of 1.1%, as reported in the 2024 SMFP.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(a).

### **Access to Medically Underserved Groups**

In Section C, page 33, the applicant states:

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

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	84.3%
Racial and ethnic minorities	94.4%
Women	32.6%
Persons with Disabilities	14.6%
Persons 65 and Older	32.6%
Medicare beneficiaries	80.9%
Medicaid recipients	84.3%

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 Fresenius corporate policy commits to provide services to all patients referred for dialysis services.
- Fresenius' facilities have historically provided care to all in need of dialysis 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 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.

### C

The applicant proposes to develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

The following table, summarized from data on page 40 of the application, shows the projected number of stations to be relocated upon project completion.

	<b>FMC North Charlotte</b>	<b>BMA Nations Ford</b>	<b>BMA Beatties Ford</b>
Total Number of existing, approved, and proposed dialysis stations as of the application deadline	40	28	43
Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	6	3	1
Total number of dialysis stations upon completion of this project	34	25	42

In Section D, pages 41-47, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project.

FMC North Charlotte

On page 42, the applicant provides a table which shows projected FMC North Charlotte utilization assuming the relocation of six stations and five in-center transfer patients to FKC Huntersville, which is summarized below:

<b>FMC North Charlotte</b>	
Begin with the Mecklenburg County patient population as of December 31, 2023	124
Project Mecklenburg County patient population forward one year to December 31, 2024 using the Mecklenburg County Five-Year AACR of 1.1%.	$124.0 \times 1.011 = 125.4$
Project Mecklenburg County patient population forward one year to December 31, 2025 using the Mecklenburg County Five-Year AACR of 1.1%.	$125.4 \times 1.011 = 126.7$
Project Mecklenburg County patient population forward one year to December 31, 2026 using the Mecklenburg County Five-Year AACR of 1.1%.	$126.7 \times 1.011 = 128.1$
Subtract five in-center patients projected to transfer their care to the new FKC Huntersville Dialysis facility.	$128.1 - 5 = 123.1$
Add the nine patients from other counties. <b>This is the projected patient census for the date the stations are projected to be relocated from FMC North Charlotte.</b>	$123.1 + 9 = \mathbf{132.1}$



As shown in the table above, FMC North Charlotte is projected to have a utilization rate of 3.88 patients per station per week or 97.13% (132.1 patients / 34 stations = 3.88 / 4 = 0.9713 or 97.13%) following completion of the proposed project on December 31, 2026. The applicant states that the population presently served at FMC North Charlotte will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On pages 42-43, the applicant states:

*“BMA intends to apply for six stations to backfill the six stations being relocated to FKC Huntersville Dialysis. FMC North Charlotte intends to apply for the six stations on July 15, 2024, for the review planned to begin on August 1, 2024. This application to develop FKC Huntersville Dialysis will not adversely affect the patients remaining at the FMC North Charlotte facility.”*

BMA Nations Ford

On page 44, the applicant provides a table which shows projected BMA Nations Ford utilization assuming the relocation of three stations and the one in-center transfer patient to FKC Huntersville, which is summarized below:

<b>BMA Nations Ford</b>	
Begin with the Mecklenburg County patient population as of December 31, 2023	93
Project Mecklenburg County patient population forward one year to December 31, 2024 using the Mecklenburg County Five-Year AACR of 1.1%.	$93.0 \times 1.011 = 94.0$
Project Mecklenburg County patient population forward one year to December 31, 2025 using the Mecklenburg County Five-Year AACR of 1.1%.	$94.0 \times 1.011 = 95.1$
Project Mecklenburg County patient population forward one year to December 31, 2026 using the Mecklenburg County Five-Year AACR of 1.1%.	$95.1 \times 1.011 = 96.1$
Subtract the one in-center patient projected to transfer their care to the new FKC Huntersville Dialysis facility.	$96.1 - 1 = 95.1$
Add the two patients from other counties. <b>This is the projected patient census for the date the stations are projected to be relocated from BMA Nations Ford.</b>	$95.1 + 2 = 97.1$

As shown in the table above, BMA Nations Ford is projected to have a utilization rate of 3.88 patients per station per week or 97.10% (97.1 patients / 25 stations = 3.88 / 4 = 0.971 or 97.1%) following completion of the proposed project on December 31, 2026. The applicant states that the population presently served at FMC Hickory will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On pages 44-45, the applicant states:

*“BMA intends to apply for three stations to backfill the three stations being relocated to FKC Huntersville Dialysis. BMA Nations Ford intends to apply for the three stations on July 15, 2024, for the review planned to begin on August 1, 2024. This application to develop FKC Huntersville Dialysis will not adversely affect the patients remaining at the BMA Nations Ford facility.”*

BMA Beatties Ford

On page 46, the applicant provides a table which shows projected BMA Beatties Ford utilization assuming the relocation of one station and 24 in-center transfer patients to FKC Huntersville, which is summarized below:

<b>BMA Beatties Ford</b>	
Begin with the Mecklenburg County patient population as of December 31, 2023	82
Project Mecklenburg County patient population forward one year to December 31, 2024 using the Mecklenburg County Five-Year AACR of 1.1%.	$82.0 \times 1.011 = 82.9$
Project Mecklenburg County patient population forward one year to December 31, 2025 using the Mecklenburg County Five-Year AACR of 1.1%.	$82.9 \times 1.011 = 83.8$
Project Mecklenburg County patient population forward one year to December 31, 2026 using the Mecklenburg County Five-Year AACR of 1.1%.	$83.8 \times 1.011 = 84.7$
Subtract the 24 in-center patients projected to transfer their care to the new FKC Huntersville Dialysis facility.	$84.7 - 24 = 60.7$
Add the five patients from other counties. <b>This is the projected patient census for the date the stations are projected to be relocated from BMA Nations Ford.</b>	$60.7 + 5 = 65.7$

As shown in the table above, BMA Beaties Ford is projected to have a utilization rate of 1.56 patients per station per week or 39.10% ( $65.7 \text{ patients} / 42 \text{ stations} = 1.56 / 4 = 0.3910$  or 39.10%) following completion of the proposed project on December 31, 2026. The applicant states that the population presently served at BMA Beaties Ford will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On pages 46-47, the applicant states:

*“BMA is evaluating options for utilizing the BMA Beatties Ford facility given the growth in the area home therapy patient population. This application to develop FKC Huntersville Dialysis will not adversely affect the patients remaining at the BMA Beatties Ford facility.”*

In Section D, pages 41-47, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the patient census for FMC North Charlotte, BMA Nations Ford, and BMA Beatties Ford, respectively, as of December 31, 2023.
- The applicant projects growth of the Mecklenburg County patient census using the Mecklenburg County Five-Year AACR of 1.1%, as published in the 2024 SMFP.
- The applicant assumes that the nine in-center patients residing outside of Mecklenburg County dialyzing at FMC North Charlotte will continue to do so due to patient choice. The applicant does not project growth for this segment of the patient population.
- The applicant subtracts the five in-center patients from FMC North Charlotte that signed letters of support and expressed their interest in transferring their care to FKC Huntersville upon project completion.
- The applicant assumes that the two in-center patients residing in Lancaster, South Carolina dialyzing at BMA Nations Ford will continue to do so due to patient choice. South Carolina is contiguous Mecklenburg County. The applicant does not project growth for this segment of the patient population.
- The applicant subtracts the one patient from BMA Nations Ford that signed a letter of support and expressed his interest in transferring his care to FKC Huntersville upon project completion.
- The applicant assumes that the five in-center patients residing outside of Mecklenburg County dialyzing at BMA Beatties Ford will continue to do so due to patient choice. The applicant does not project growth for this segment of the patient population.
- The applicant subtracts the 24 patients from BMA Beatties Ford that signed letters of support and expressed their interest in transferring their care to FKC Huntersville upon project completion.

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

- The projections of each facility’s patient census are based on the number patients who support the project and expressed their interest in transferring their care to FKC Huntersville upon project completion.

- The applicant adequately demonstrates how a segment of dialysis patients residing in the service area would be better served at the proposed facility based on an improved accessibility to services.
- Two of the facilities in which the number of stations will decrease are eligible to apply for a certificate of need to replace the number of stations that will be relocated to the proposed facility.
- The applicant projects the growth of the Mecklenburg County patient census using the Mecklenburg County Five Year AACR of 1.1%, as reported in the 2024 SMFP.

### **Access to Medically Underserved Groups**

In Section D, page 47, the applicant states:

*“This application to develop FKC Huntersville Dialysis will not have any effect on the ability of any members of the above identified groups to have convenient access to dialysis care.”*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project for the following reasons:

- The applicant is an established provider of dialysis services in Mecklenburg County currently serving the underserved.
- The applicant identifies the percentage of patients within each of the demographic groups currently served by the facilities contributing stations to the proposed FKC Huntersville.

### **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 demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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 develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

In Section E, page 50, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

Not Develop FKC Huntersville Dialysis-The applicant states that developing the facility will ensure access to dialysis care for patients residing in the area and subsequently shorten the commute to dialysis treatment three times a week.

Develop FKC Huntersville Dialysis with more than 10 In-Center Dialysis Stations-The applicant states that developing more than 10 in-center stations would draw more patients from a further distance which defeats the purpose of developing the facility in Huntersville.

Include Home Therapies at the New Location-The applicant does not include a home therapy program as part of this proposal. The applicant states that adding a home therapy program would require developing additional space that will increase the capital costs of the project. The applicant currently operates a freestanding facility in Mecklenburg County dedicated to home hemodialysis and peritoneal dialysis services.

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 applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **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. **The certificate holder shall develop a new 10-station kidney disease treatment center to be known as Fresenius Kidney Care Huntersville Dialysis by relocating no more than six in-center dialysis stations from Fresenius Medical Care of North Charlotte, three stations from BMA Nations Ford and one station from BMA Beatties Ford.**
  3. **Upon completion of this project, the certificate holder shall take the necessary steps to decertify six stations at Fresenius Medical Care of North Charlotte for a total of no more than 34 in-center stations upon completion of the project.**
  4. **Upon completion of this project, the certificate holder shall take the necessary steps to decertify three stations at BMA Nations Ford for a total of no more than 25 in-center stations upon completion of the project.**
  5. **Upon completion of this project, the certificate holder shall take the necessary steps to decertify one station at BMA Beatties Ford for a total of no more than 42 in-center stations upon completion of the project.**
  6. **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 December 2, 2024.**
  7. **The certificate holder shall install plumbing and electrical wiring through the walls for no more than 10 in-center and home hemodialysis stations.**
  8. **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.

The applicant proposes to develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

**Capital and Working Capital Costs**

In Section Q, page 107, the applicant projects the total capital cost of the project, as summarized below.

Construction/Renovation Contract(s)	\$2,433,624
Architecture/Engineering Fees	\$148,418
Non-Medical Equipment	\$664,681
Furniture	\$59,356
Other: Generator	\$119,693
Other: Contingency	\$127,106
<b>Total</b>	<b>\$3,552,878</b>

In Section Q, page 108, 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 uses Fresenius Real Estate and Construction Service team to estimate construction costs.
- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.

In Section F, page 54, the applicant projects that start-up costs will be \$158,860 and initial operating expenses will be \$989,660 for a total working capital of \$1,148,520. On pages 55-56, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant projects start-up expenses based on the cost of a 4-week supply of clinical supplies and pharmaceutical expenses needed upon opening of the facility.
- The applicant includes staff salaries for new direct patient care staff in its projected start-up expenses, as well as other anticipated positions, such as the social worker, dietitian and technical staff.
- The initial operating expenses were calculated based on six months of the first year's expenses.

**Availability of Funds**

In Section F, pages 52 and 56, the applicant states that the capital and working capital cost will be funded by Bio-Medical Applications of North Carolina, Inc. through accumulated reserves.

In Exhibit F-2, the applicant provides a letter dated January 15, 2024, from Bryan Mello, the Vice President of Corporate Tax-North America for Fresenius Medical Care Holdings, parent company for BMA, documenting Mr. Mello’s authority to commit the funds for the capital and working capital costs of the project. Exhibit F-2 includes Fresenius’ 2023 Consolidated Balance Sheet documenting over \$700 million in cash and total assets of over \$26 billion.

The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full operating years following completion of the project. In Form F.2, the applicant projects that revenues will not exceed operating expenses in the first two operating years following completion of the project, as shown in the table below.

	<b>1<sup>st</sup> Full Fiscal Year (CY2027)</b>	<b>2<sup>nd</sup> Full Fiscal Year (CY2028)</b>
Total Treatments	4,464	4,514
Total Gross Revenues (Charges)	\$28,085,666	\$28,398,609
Total Net Revenue	\$1,550,492	\$1,567,547
Average Net Revenue per Treatment	\$347	\$347
Total Operating Expenses (Costs)	\$1,979,320	\$2,003,110
Average Operating Expense per Treatment	\$443	\$444
Net Income	(\$428,828)	(\$435,563)

On page 112, the applicant states:

*“Fresenius Medical Care Holdings, Inc. has the financial means to absorb the financial losses of the FKC Huntersville Dialysis facility until it returns to a profitable status.”*

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

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- Gross revenue of \$6,291 per treatment is based on the base rate for dialysis services.
- Bad Debt is based on the historical performance of BMA Beatties Ford and FMC North Charlotte with contractual adjustments based on payor class and modality for each year.
- FTEs and salaries are based on staffing experience and are projected based on average annual salary increases of 2.0%. Payroll taxes and benefits are 36% of the staff expense.



- 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.
- Supplemental information requested by the Agency

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- Although the applicant does not show net income by the second operating year, the applicant has cash reserves to absorb those losses until the project becomes profitable.
- 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 costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

The applicant proposes to develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

On page 113 the 2024 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.”* FKC Huntersville will be in Mecklenburg County. Thus, the service area for this application is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, pages 124-125 of the 2024 SMFP, there are 24 existing or approved dialysis facilities in Mecklenburg County, 12 of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2024 SMFP, is provided below:

<b>Mecklenburg County Dialysis Facilities            Certified Stations and Utilization as of December 31, 2022</b>				
<b>Dialysis Facility</b>	<b>Location</b>	<b>#of In-Center Patients</b>	<b># of Certified Stations</b>	<b>Utilization</b>
BMA Beatties Ford	Charlotte	90	41	54.88%
BMA Nations Ford	Charlotte	90	28	80.36%
BMA East Charlotte	Charlotte	105	32	82.03%
BMA West Charlotte	Charlotte	87	29	75.00%
Brookshire Dialysis	Charlotte	40	11	90.91%
Charlotte Dialysis	Charlotte	79	33	59.85%
Charlotte East Dialysis	Charlotte	102	34	75.00%
DSI Charlotte Latrobe	Charlotte	70	24	72.92%
DSI Glenwater Dialysis	Charlotte	88	42	52.38%
FMC Charlotte	Charlotte	88	48	48.53%
FMC Matthews	Matthews	80	21	95.24%
FMC North Charlotte	Charlotte	136	40	85.00%
FKC Mallard Creek	Charlotte	20	12	41.67%
FKC Regal Oaks	Charlotte	56	17	82.35%
FKC Southeast Mecklenburg	Pineville	49	17	72.06%
FMC Aldersgate	Charlotte	51	16	79.69%
FMC Southwest Charlotte	Charlotte	67	26	64.42%
Huntersville Dialysis	Huntersville	65	27	60.09%
INS Charlotte	Charlotte	0	0	00.00%
INS Victory Home	Charlotte	0	0	00.00%
Mint Hill Dialysis	Mint Hill	56	21	66.67%
North Charlotte Dialysis Center	Charlotte	94	33	71.21%
South Charlotte Dialysis	Charlotte	72	27	66.67%
Sugar Creek Dialysis	Charlotte	39	0	00.00%

In Section G, page 61, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg. The applicant states:

*“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations within Mecklenburg County. These stations have been previously approved and do not duplicate services. The overall utilization for facilities in Mecklenburg County was 70.26% as of December 31, 2022.”*

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 proposal would not result in a surplus of stations or increase an existing surplus of stations in Mecklenburg County.

- The applicant adequately demonstrates that the proposed relocation of the 10 stations for the development of a new dialysis facility is needed in addition to the operational dialysis facilities in Mecklenburg 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 the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

### C

The applicant proposes to develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

In Section Q, page 119, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE CY2027	Projected FTE CY2028
Administrator (FMC Clinic Manager)	1.00	1.00
Registered Nurse (RNs)	2.00	2.00
Technicians (PCT)	3.00	3.00
Dietitian	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administrative/Business Office	0.50	0.50
FMC Director of Operations	0.20	0.20
FMC Chief Technician	0.20	0.20
FMC In-service	0.20	0.20
<b>Total</b>	<b>8.60</b>	<b>8.60</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 Section Q. In Section H, pages 62-63, 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 applicant is a well-established employer and has historically recruited appropriate staff by offering a wide range of personal benefits and competitive salaries.
- Due to the pandemic-related staff shortages, the applicant has implemented initiatives to recruit staff, such as sign-on and retention bonuses, increased starting pay, and corporate reviews of salary scales.
- New employees participate in an extensive training program that includes clinical and corporate policy, and safety precautions.

### **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 develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

### **Ancillary and Support Services**

In Section I, page 64, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 64-69, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant discusses how it will provide each necessary ancillary and support service at FKC Huntersville.
- The applicant currently provides dialysis services at multiple facilities in Mecklenburg County that have the necessary ancillary and support services in place.

## **Coordination**

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant will work with physicians of MNA who will have admitting and rounding privileges at the FKC Huntersville facility. The MNA physicians will also provide referrals to the facility.
- The applicant is an established provider of dialysis services in Mecklenburg County and has long-standing relationships with the medical community.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

The applicant proposes to develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

In Section K, page 72, the applicant states that the project involves constructing 9,724 square feet of new space. Line drawings are provided in Exhibit K-2.

On pages 74-75, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed based on the applicant's representations and supporting documentation.

On pages 72-73, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states that the building will already be developed, and the existing space can be cost-effectively renovated by the applicant's experienced facility and construction services team.

In Section K, page 73, 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 because developing the new facility is considered the "*necessary part of doing business*" and those costs will be borne by the applicant, and not by the patients who will be served.

On pages 73-74, 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

FKC Huntersville will be a new facility and therefore has no historical payor mix to report. In Section L, pages 78-79, the applicant provides the historical payor mix for CY2022 (01/01/2022-12/31/2022) for the three facilities contributing stations to the proposed FKC Huntersville, as shown in the table below. On page 77, the applicant states FY2022 payor mix data is used because financial accounting for FY2023 was not complete at the time this application was submitted.

<b>Historical Payor Mix 01/01/2022-12/31/2022</b>						
<b>Payor Source</b>	<b>FMC North Charlotte</b>		<b>BMA Nations Ford</b>		<b>BMA Beatties Ford</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	18.0	13.27%	12.8	14.27%	1.1	1.21%
Insurance*	11.9	8.76%	8.0	8.86%	7.9	8.79%
Medicare*	94.3	69.33%	59.9	66.55%	70.5	78.31%
Medicaid*	8.3	6.12%	7.4	8.19%	5.5	6.08%
Other (VA)	3.4	2.52%	1.9	2.12%	5.1	5.61%
<b>Total</b>	<b>136.0</b>	<b>100.00%</b>	<b>90.0</b>	<b>100.00%</b>	<b>90.0</b>	<b>100.00%</b>

\*Including any managed care plans.

In Section L, pages 79-80, the applicant provides the following comparison.

	% of Total Patients served			Percentage of the Population of the Service Area
	FMC North Charlotte	BMA Nations Ford	BMA Beatties Ford	
Female	41.7%	42.7%	32.6%	51.6%
Male	58.3%	57.3%	67.4%	48.4%
Unknown				
64 and Younger	65.7%	56.1%	67.4%	87.8%
65 and Older	34.3%	43.9%	32.6%	12.2%
American Indian	0.0%		0.0%	0.9%
Asian	0.0%	1.2%	1.1%	6.7%
Black or African American	89.8%	63.4%	85.4%	33.2%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.0%	0.1%
White or Caucasian	10.2%	12.2%	5.6%	44.9%
Other Race		23.2%	7.9%	17.1%
Decline / Unavailable				

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

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 81, the applicant states:



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

In Section L, page 81, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 81, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>FKC Huntersville Projected Payor Mix 2<sup>nd</sup> Full FY, CY2028</b>		
<b>Payor Source</b>	<b># of Patients</b>	<b>% of Total</b>
Self-pay	2.2	7.24%
Insurance*	2.7	8.77%
Medicare*	22.6	73.82%
Medicaid*	1.9	6.10%
Other (VA)	1.2	4.07%
<b>Total</b>	<b>30.7</b>	<b>100.00%</b>

\*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.24% of total services will be provided to self-pay patients, 73.82% to Medicare patients and 6.10% to Medicaid patients.

On pages 81-82, 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 projects payor mix based on the most recent performance at BMA Beatties Ford and FMC North Charlotte. Both facilities are located in the proposed service area and will contribute nine of the 10 dialysis stations proposed, where many of the patients have expressed interest in transferring their care to the new facility.
- The applicant calculates payor mix based upon treatment volumes as opposed to the number of patients. The applicant considers possible change in payor source during the fiscal year.

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 83, 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 develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

In Section M, page 84, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because the applicant provides documentation of its intention 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 application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new 10-station dialysis facility, FKC Huntersville, by relocating no more than six dialysis stations from FMC North Charlotte, three stations from BMA Nations Ford, and one dialysis station from BMA Beatties Ford.

On page 113 the 2024 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.*” FKC Huntersville will be in Mecklenburg County. Thus, the service area for this application is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, pages 124-125 of the 2024 SMFP, there are four existing or approved dialysis facilities in Mecklenburg County, 12 of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2024 SMFP, is provided below:

<b>Mecklenburg County Dialysis Facilities  Certified Stations and Utilization as of December 31, 2022</b>				
<b>Dialysis Facility</b>	<b>Location</b>	<b>#of In-Center Patients</b>	<b># of Certified Stations</b>	<b>Utilization</b>
BMA Beatties Ford	Charlotte	90	41	54.88%
BMA Nations Ford	Charlotte	90	28	80.36%
BMA East Charlotte	Charlotte	105	32	82.03%
BMA West Charlotte	Charlotte	87	29	75.00%
Brookshire Dialysis	Charlotte	40	11	90.91%
Charlotte Dialysis	Charlotte	79	33	59.85%
Charlotte East Dialysis	Charlotte	102	34	75.00%
DSI Charlotte Latrobe	Charlotte	70	24	72.92%
DSI Glenwater Dialysis	Charlotte	88	42	52.38%
FMC Charlotte	Charlotte	88	48	48.53%
FMC Matthews	Matthews	80	21	95.24%
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FKC Regal Oaks	Charlotte	56	17	82.35%
FKC Southeast Mecklenburg	Pineville	49	17	72.06%
FMC Aldersgate	Charlotte	51	16	79.69%
FMC Southwest Charlotte	Charlotte	67	26	64.42%
Huntersville Dialysis	Huntersville	65	27	60.09%
INS Charlotte	Charlotte	0	0	00.00%
INS Victory Home	Charlotte	0	0	00.00%
Mint Hill Dialysis	Mint Hill	56	21	66.67%
North Charlotte Dialysis Center	Charlotte	94	33	71.21%
South Charlotte Dialysis	Charlotte	72	27	66.67%
Sugar Creek Dialysis	Charlotte	39	0	00.00%

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85, the applicant states:

*“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 Mecklenburg County Five Year Average Annual Change Rate published in the 2024 SMFP.*

*The 2024 SMFP reports there are currently 22 operational dialysis facilities with in-center dialysis stations within Mecklenburg County. 12 of these facilities are operated by Fresenius Medical Care.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 86, the applicant states:

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

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

Regarding the impact of the proposal on quality, in Section N, page 86, the applicant states:

*“Quality of care is always in 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.”*

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 86, the applicant states:

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

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

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

C

In Section Q, pages 121-124, 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 a total of 132 of this type of facility located in North Carolina.

In Section O, page 91, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

## **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

### **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.*
- C- In Section C, page 29, and Section Q, page 96, the applicant projects 30.3 in-center patients will be served by the proposed facility by the end of the first operating year, CY2027, for a utilization rate of 3.03 patients per station per week or 75.75% (30.3 patients / 10 stations = 3.03 patients per station / 4 = 0.7575 or 75.75%). The projected utilization of 3.03 patients per station per week exceeds the 2.8 in-center patients per station per week threshold required by 10A NCAC 14C .2203(a).
- (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.*
- NA- The applicant is not proposing to increase the number of in-center dialysis stations.
- (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 27-29, and Section Q, pages 94-97, the applicant provides the assumptions and methodology used to project utilization.