

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 4, 2019

Findings Date: November 4, 2019

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: F-11781-19

Facility: Fresenius Medical Care Gastonia

FID #: 955615

County: Gaston

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

Project: Add no more than 2 dialysis stations for a total of no more than 39 stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to add two dialysis stations to Fresenius Medical Care Gastonia (FMC Gastonia) for a total of 39 dialysis stations at FMC Gastonia upon project completion.

#### Need Determination

The 2019 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 the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of four dialysis stations in Gaston County. Therefore, the July 2019 SDR does not indicate a need for additional stations in Gaston County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most

recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for FMC Gastonia in the July 2019 SDR is 3.97 patients per station per week, or 99.36 percent, based on 155 in-center dialysis patients and 39 certified dialysis stations [ $155 / 39 = 3.97$ ;  $3.97 / 4 = 0.9936$  or 99.36%].

Application of the facility need methodology indicates that up to a potential maximum of 15 additional stations are needed for this facility, as illustrated in the following table.

<b>OCTOBER 1 REVIEW – JULY 2019 SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		99.36%
Certified Stations		39
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>39</b>
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		155
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		147
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1088
(ii)	Divide the result of Step (i) by 12	0.0091
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.1088
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	171.8707
(v)	Divide the result of Step (iv) by 3.2 patients per station	53.7096
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>15</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 15 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations and is therefore consistent with the facility need determination for dialysis stations.

### Policies

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 31 of the 2019 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 12; Section N, pages 53-55; Section O, pages 56-59; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, pages 12-13; Section C, pages 23-24; Section L, pages 48-51; Section N, pages 53-55; 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 13-14; Section C, pages 18-21; Section F, pages 31-35; Section K, pages 44-46; Section N, pages 53-55; 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 for the reasons stated above.

(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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add two dialysis stations to FMC Gastonia for a total of 39 dialysis stations upon project completion.

FMC Gastonia currently offers both home hemodialysis training (HH) and home peritoneal dialysis training (PD) and plans to continue to offer both HH and PD following completion of the proposed project.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Gaston County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

FMC Gastonia – Current and Projected Patient Origin								
County	Current (12/31/2018)				Projected (Operating Year 1 – CY 2021)			
	# of IC* Patients	# of HH Patients	# of PD Patients	% of Total	# of IC* Patients	# of HH Patients	# of PD Patients	% of Total
Gaston	145	22	12	87.7%	128	22	7	82.6%
Burke	1	0	0	0.5%	1	0	0	0.5%
Cabarrus	1	0	0	0.5%	1	0	0	0.5%
Cleveland	1	5	1	3.4%	3	9	1	6.8%
Lincoln	1	1	2	2.0%	2	3	2	3.7%
Mecklenburg	4	2	1	3.4%	4	2	1	3.7%
South Carolina	2	3	0	2.5%	2	2	0	2.1%
<b>Total</b>	<b>155</b>	<b>33</b>	<b>16</b>	<b>100.0%</b>	<b>141</b>	<b>38</b>	<b>11</b>	<b>100.0%</b>

Table may not foot due to rounding.

Source: Section C, page 17; Section Q, Form C

\*IC = In-Center

In Section C, pages 18-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 22, 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. As a general rule, patients will receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... 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. This question specifically addresses the need that the population to be served has for the proposed project. BMA has identified the population to be served as 141.2 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”*

The information is reasonable and adequately supported for the following reasons:

- According to the July 2019 SDR, as of December 31, 2018, FMC Gastonia was operating at a rate of 3.97 patients per station per day, or 99.36 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility via the facility need methodology. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C, pages 17 and on Form C in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

FMC Gastonia – Historical and Projected Patient Utilization								
County	Current (12/31/2018)				Projected (Operating Year 1 – CY 2021)			
	# of IC* Patients	# of HH Patients	# of PD Patients	% of Total	# of IC* Patients	# of HH Patients	# of PD Patients	% of Total
Gaston	145	22	12	87.7%	128	22	7	82.6%
Burke	1	0	0	0.5%	1	0	0	0.5%
Cabarrus	1	0	0	0.5%	1	0	0	0.5%
Cleveland	1	5	1	3.4%	3	9	1	6.8%
Lincoln	1	1	2	2.0%	2	3	2	3.7%
Mecklenburg	4	2	1	3.4%	4	2	1	3.7%
South Carolina	2	3	0	2.5%	2	2	0	2.1%
<b>Total</b>	<b>155</b>	<b>33</b>	<b>16</b>	<b>100.0%</b>	<b>141</b>	<b>38</b>	<b>11</b>	<b>100.0%</b>

Table may not foot due to rounding.

Source: Section C, page 17; Section Q, Form C

\*IC = In-Center

In Section C, pages 18-21, the applicant provides the assumptions and methodology used to project in-center, HH, and PD patient utilization, which are summarized below.

*In-Center*

- The applicant begins its utilization projections with the in-center patient facility census as of June 30, 2019. On page 18, the applicant states that, as of June 30, 2019, it was serving 138 Gaston County patients and 13 patients residing outside of Gaston County.
- The applicant assumes the Gaston County patient population dialyzing at FMC Gastonia will increase annually at a rate of 4.8 percent, which is the Five Year Average Annual Change Rate (AACR) for Gaston County published in the July 2019 SDR.
- The applicant assumes no population growth for FMC Gastonia patients living outside of Gaston County but assumes the patients will continue to dialyze at FMC Gastonia and adds them to the calculations when appropriate.
- In its application for FKC North Gaston (Project I.D. #F-11266-16), the applicant projected 24 Gaston County patients dialyzing at FMC Gastonia would transfer care to FKC North Gaston. The applicant states FKC North Gaston was certified as of July 18, 2019 and subtracts the 24 Gaston County patients as of June 30, 2019.
- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 19, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

<b>FMC Gastonia IC Projected Utilization</b>	
Starting point of calculations is Gaston County patients dialyzing in-center at FMC Gastonia on June 30, 2019.	138
24 Gaston County patients, projected to transfer care to FKC North Gaston, are subtracted from the Gaston County patient population.	$138 - 24 = 114$
Gaston County patient population is projected forward by six months to December 31, 2019, using one-half of the Gaston County Five Year AACR (4.8%).	$114 \times 1.024 = 116.7$
Gaston County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.8%).	$116.7 \times 1.048 = 122.3$
The patients from outside Gaston County are added. This is the projected census on December 31, 2020 and the starting census for this project.	$122.3 + 13 = 135.3$
Gaston County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.8%).	$122.3 \times 1.048 = 128.2$
The patients from outside Gaston County are added. This is the projected census on December 31, 2021 (OY1).	$128.2 + 13 = 141.2$
Gaston County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.8%).	$128.2 \times 1.048 = 134.4$
The patients from outside Gaston County are added. This is the projected census on December 31, 2022 (OY2).	$134.4 + 13 = 147.4$

The applicant rounds down and projects to serve 141 in-center patients on 39 stations, which is 3.62 patients per station per week ( $141 \text{ patients} / 39 \text{ stations} = 3.62$ ), by the end of OY1 and 147 in-center patients on 39 stations, which is 3.77 patients per station per week ( $147 \text{ patients} / 39 \text{ stations} = 3.77$ ), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

*Home Hemodialysis Patients*

- The applicant begins its utilization projections with the HH patient facility census as of June 30, 2019. On page 20, the applicant states that, as of June 30, 2019, it was providing training and support to 22 Gaston County HH patients and 16 HH patients residing outside of Gaston County.
- The applicant assumes the Gaston County HH patient population will increase annually at the Five Year AACR for Gaston County published in the July 2019 SDR (4.8 percent).
- The applicant assumes no population growth for FMC Gastonia HH patients living outside of Gaston County but assumes the patients will continue to rely on FMC Gastonia for training and support and adds them to the calculations when appropriate.
- In its application for FKC North Gaston (Project I.D. #F-11266-16), the applicant projected two Gaston County HH patients dialyzing at FMC Gastonia would transfer care to FKC North Gaston. The applicant states FKC North Gaston was certified as of July 18, 2019 and subtracts the two Gaston County HH patients as of June 30, 2019.

- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 21, the applicant provides the calculations used to project the HH patient census for OY1 and OY2 as summarized in the table below.

<b>FMC Gastonia HH Projected Utilization</b>	
Starting point of calculations is Gaston County HH patients at FMC Gastonia on June 30, 2019.	22
Two Gaston County HH patients, projected to transfer care to FKC North Gaston, are subtracted from the Gaston County HH patient population.	$22 - 2 = 20$
Gaston County HH patient population is projected forward by six months to December 31, 2019, using one-half of the Gaston County Five Year AACR (4.8%).	$20 \times 1.024 = 20.5$
Gaston County HH patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.8%).	$20.5 \times 1.048 = 21.5$
The HH patients from outside Gaston County are added. This is the projected census on December 31, 2020 and the starting census for this project.	$21.5 + 16 = 37.5$
Gaston County HH patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.8%).	$21.5 \times 1.048 = 22.5$
The HH patients from outside Gaston County are added. This is the projected census on December 31, 2021 (OY1).	$22.5 + 16 = 38.5$
Gaston County HH patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.8%).	$22.5 \times 1.048 = 23.6$
The HH patients from outside Gaston County are added. This is the projected census on December 31, 2022 (OY2).	$23.6 + 16 = 39.6$

*Home Peritoneal Dialysis Patients*

- The applicant begins its utilization projections with the PD patient facility census as of June 30, 2019. On page 20, the applicant states that, as of June 30, 2019, it was providing training and support to eight Gaston County PD patients and four PD patients residing outside of Gaston County.
- The applicant assumes the Gaston County PD patient population will increase annually at the Five Year AACR for Gaston County published in the July 2019 SDR (4.8 percent).
- The applicant assumes no population growth for FMC Gastonia PD patients living outside of Gaston County but assumes the patients will continue to rely on FMC Gastonia for training and support and adds them to the calculations when appropriate.
- In its application for FKC North Gaston (Project I.D. #F-11266-16), the applicant projected two Gaston County PD patients dialyzing at FMC Gastonia would transfer care to FKC North Gaston. The applicant states FKC North Gaston was certified as of July 18, 2019 and subtracts the two Gaston County PD patients as of June 30, 2019.



- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 21, the applicant provides the calculations used to project the PD patient census for OY1 and OY2 as summarized in the table below.

<b>FMC Gastonia PD Projected Utilization</b>	
Starting point of calculations is Gaston County PD patients at FMC Gastonia on June 30, 2019.	8
Two Gaston County PD patients, projected to transfer care to FK North Gaston, are subtracted from the Gaston County PD patient population.	$8 - 2 = 6$
Gaston County PD patient population is projected forward by six months to December 31, 2019, using one-half of the Gaston County Five Year AACR (4.8%).	$6 \times 1.024 = 6.1$
Gaston County PD patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.8%).	$6.1 \times 1.048 = 6.4$
The PD patients from outside Gaston County are added. This is the projected census on December 31, 2020 and the starting census for this project.	$6.4 + 4 = 10.4$
Gaston County PD patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.8%).	$6.4 \times 1.048 = 6.7$
The PD patients from outside Gaston County are added. This is the projected census on December 31, 2021 (OY1).	$6.7 + 4 = 10.7$
Gaston County PD patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.8%).	$6.7 \times 1.048 = 7.1$
The PD patients from outside Gaston County are added. This is the projected census on December 31, 2022 (OY2).	$7.1 + 4 = 11.1$

Projected utilization is reasonable and adequately supported for the following reasons:

- The July 2019 SDR states that FMC Gastonia's utilization was 3.97 patients per station per week (a utilization rate of 99.36 percent) as of December 31, 2018.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Gaston County as published in the July 2019 SDR to project growth of Gaston County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development which may impact projected utilization at FMC Gastonia.
- The applicant does not project growth for its patients who do not reside in Gaston County.

- The applicant’s in-center projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, pages 23-24, the applicant states:

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

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

In Section L, page 50, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>FMC Gastonia Projected Payor Mix CY 2022</b>						
<b>Type of Dialysis</b>	<b>In-Center</b>		<b>Home Hemodialysis</b>		<b>Home Peritoneal Dialysis</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.14	0.77%	0.11	0.27%	0.14	1.24%
Medicare*	101.99	69.21%	28.99	73.27%	5.57	50.29%
Medicaid*	8.91	6.05%	0.53	1.35%	0.00	0.00%
Commercial Insurance*	10.85	7.36%	6.22	15.71%	3.07	27.73%
Medicare/Commercial	21.08	14.30%	2.55	6.43%	2.23	20.17%
Misc. (including VA)	3.40	2.31%	1.17	2.96%	0.06	0.57%
<b>Total</b>	<b>147.37</b>	<b>100.00%</b>	<b>39.57</b>	<b>100.00%</b>	<b>11.07</b>	<b>100.00%</b>

\*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.

- The applicant adequately explains why the population to be served needs the services proposed in this application.
  - Projected utilization is reasonable and adequately supported.
  - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) and adequately supports its assumptions.
- (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, handicapped persons, 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 two dialysis stations to FMC Gastonia for a total of 39 dialysis stations upon project completion.

In Section E, pages 29-30, 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 maintaining the status quo would lead to higher utilization rates and potentially restrict patient admissions; therefore, this is not an effective alternative.
- Apply for Fewer than Two Stations: the applicant states the facility need methodology indicates a need for more than two stations and it projects a utilization rate above 80 percent by the end of the first operating year. The applicant states applying for fewer stations would lead to higher utilization rates and potentially restrict patient admissions; therefore, this is not an effective alternative.
- Relocate Stations from Another Gaston County Facility: the applicant states that, as of December 31, 2018, all but one of its facilities in Gaston County were operating above 80 percent utilization, and that as of June 30, 2019, all its facilities in Gaston County were operating above 80 percent utilization; therefore, this is not an effective alternative.

On page 30, the applicant states its proposal is the most effective alternative because it is a cost-effective approach and is necessary to meet the need for dialysis patients in Gaston County.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the July 2019 Semiannual Dialysis Report, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations at Fresenius Medical Care Gastonia for a total of no more than 39 certified stations at Fresenius Medical Care Gastonia upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. 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 two dialysis stations to FMC Gastonia for a total of 39 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F, page 31, the applicant projects no capital costs to develop the proposed project. In Section F, pages 32-33, the applicant states there are no projected start-up expenses or initial operating expenses because it is an existing, operational facility.

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>FMC Gastonia</b>	<b>Full Fiscal Year 1 CY 2021</b>	<b>Full Fiscal Year 2 CY 2022</b>
Total Treatments	27,653	28,746
Total Gross Revenues (Charges)	\$173,967,328	\$180,842,948
Total Net Revenue	\$9,388,834	\$9,750,598
Average Net Revenue per Treatment	\$340	\$339
Total Operating Expenses (Costs)	\$7,982,388	\$8,224,682
Average Operating Expense per Treatment	\$289	\$286
<b>Net Income/Profit</b>	<b>\$1,406,446</b>	<b>\$1,525,916</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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 add two dialysis stations to FMC Gastonia for a total of 39 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Gaston County. Facilities may serve residents of counties not included in their service area.

There are five existing or approved facilities which provide dialysis and/or dialysis home training and support in Gaston County, all of which are owned and/or operated by BMA. Information on these facilities is provided below:

<b>Gaston County Dialysis Facilities</b>					
<b>Certified Stations and Utilization as of December 31, 2018</b>					
<b>Dialysis Facility</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># Patients</b>	<b>Patients/Station</b>	<b>Utilization</b>
BMA Kings Mountain	Kings Mountain	18	66	3.6667	91.67%
FKC North Gaston*	Dallas	0	0	0	0.00%
FMC Belmont	Belmont	19	72	3.7895	94.74%
FMC Gastonia	Gastonia	39	155	3.9744	99.36%
FMC South Gaston	Gastonia	28	86	3.0714	76.79%

Source: Section G, page 36; July 2019 SDR, Table B.

\* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

In Section G, pages 36-37, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Gaston County. On page 37, the applicant states:

*“The July 2019 SDR does report a surplus of four dialysis stations in Gaston County. The SDR also reports that the Gaston County ESRD Census for December 31, 2018 was 383, and that this census was increasing at a rate of 4.8%. The growth of the Gaston County ESRD patient population results in a projection of 18.3 new dialysis patients for 2019. If this growth rate is sustained, (and there is no indication that the growth rate will not be sustained), and assuming the home patient [sic] population percentage remains the same, Gaston County will need five new dialysis stations each year (at 80% utilization). The current surplus of stations will be quickly eroded.*

*Approval of this application [will] not cause unnecessary duplication of services, but will ensure an adequate inventory of dialysis stations exists fo [sic] the ESRD patient populatoin [sic] of the county.”*

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

- There is a facility need determination, as calculated using the methodology in the July 2019 SDR, for the proposed dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

### 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

On Form H in Section Q, the applicant provides information about current and projected staffing for the proposed services. The applicant does not project to change its staffing levels in response to the proposed project.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 38, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-3.1 and H-3.2. In Section H, page 39, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing his support for the proposed project and indicating his intent to continue serving as medical director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

In Section I, pages 40-41, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

<b>FMC Gastonia – Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training	
HH	On site
PD	On site
Accessible follow-up program	On site
Psychological counseling	Monarch Counseling of Gaston County
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	CaroMont Regional Hospital
Emergency care	Provided by facility staff until ambulance arrival
Blood bank services	CaroMont Regional Hospital
Diagnostic and evaluation services	CaroMont Regional Hospital
X-ray services	CaroMont Regional Hospital
Laboratory services	On site (Spectra)
Pediatric nephrology	Atrium Health
Vascular surgery	Metrolina Vascular
Transplantation services	Carolinas Medical Center, Wake Forest Baptist Hospital, UNC Healthcare
Vocational rehabilitation & counseling	Gaston County Vocational Rehabilitation
Transportation	Access (Gaston County), 5-Star Transportation

The applicant provides supporting documentation in Exhibits I-2 through I-4.

In Section I, page 41, 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.



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 handicapped persons, 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 49, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

<b>FMC Gastonia Historical Payor Mix CY 2018</b>						
<b>Type of Dialysis</b>	<b>In-Center</b>		<b>Home Hemodialysis</b>		<b>Home Peritoneal Dialysis</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	1.20	0.77%	0.09	0.27%	0.20	1.24%
Medicare*	107.27	69.21%	24.18	73.27%	8.05	50.29%
Medicaid*	9.37	6.05%	0.45	1.35%	0.00	0.00%
Commercial Insurance*	11.41	7.36%	5.19	15.71%	4.44	27.73%
Medicare/Commercial	22.17	14.30%	2.12	6.43%	3.23	20.17%
Misc. (including VA)	3.57	2.31%	0.98	2.96%	0.09	0.57%
<b>Total</b>	<b>154.99</b>	<b>100.00%</b>	<b>33.01</b>	<b>100.00%</b>	<b>16.01</b>	<b>100.00%</b>

\*Including any managed care plans

In Section L, page 48, the applicant provides the following comparison.

	Percentage of Total Patients Served by FMC Gastonia during the Last Full OY	Percentage of the Population of Gaston County
Female	50.0%	51.8%
Male	50.0%	48.2%
Unknown	0.0%	0.0%
64 and Younger	58.8%	83.9%
65 and Older	41.2%	16.1%
American Indian	0.0%	0.6%
Asian	0.7%	1.6%
Black or African-American	51.4%	17.6%
Native Hawaiian or Pacific Islander	0.00%	0.1%
White or Caucasian	42.6%	71.8%
Other Race	4.1%	8.3%
Declined / Unavailable	1.4%	0.0%

Sources: BMA Internal Data, US Census Bureau

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 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 handicapped persons 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, the applicant states in Section L, pages 49-50, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 50, the applicant states that during the last five years 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.

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.

- (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 50, 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.

FMC Gastonia Projected Payor Mix CY 2022						
Type of Dialysis	In-Center		Home Hemodialysis		Home Peritoneal Dialysis	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	1.14	0.77%	0.11	0.27%	0.14	1.24%
Medicare*	101.99	69.21%	28.99	73.27%	5.57	50.29%
Medicaid*	8.91	6.05%	0.53	1.35%	0.00	0.00%
Commercial Insurance*	10.85	7.36%	6.22	15.71%	3.07	27.73%
Medicare/Commercial	21.08	14.30%	2.55	6.43%	2.23	20.17%
Misc. (including VA)	3.40	2.31%	1.17	2.96%	0.06	0.57%
<b>Total</b>	<b>147.37</b>	<b>100.00%</b>	<b>39.57</b>	<b>100.00%</b>	<b>11.07</b>	<b>100.00%</b>

\*Including any managed care plans

On page 50, the applicant provides the assumptions and methodology it uses 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 for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) 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.

- (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 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

In Section M, page 52, 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.

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 two dialysis stations to FMC Gastonia for a total of 39 dialysis stations upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Gaston County. Facilities may serve residents of counties not included in their service area.

There are five existing or approved facilities which provide dialysis and/or dialysis home training and support in Gaston County, all of which are owned and/or operated by BMA. Information on these facilities is provided below:

<b>Gaston County Dialysis Facilities</b>					
<b>Certified Stations and Utilization as of December 31, 2018</b>					
<b>Dialysis Facility</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># Patients</b>	<b>Patients/Station</b>	<b>Utilization</b>
BMA Kings Mountain	Kings Mountain	18	66	3.6667	91.67%
FKC North Gaston*	Dallas	0	0	0	0.00%
FMC Belmont	Belmont	19	72	3.7895	94.74%
FMC Gastonia	Gastonia	39	155	3.9744	99.36%
FMC South Gaston	Gastonia	28	86	3.0714	76.79%

Source: Section G, page 36; July 2019 SDR, Table B.

\* Facility under development or which was not operational at the time of data collection for the July 2019 SDR.

In Section N, pages 53-55, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 53, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Gaston County. The applicant does not project to serve dialysis patients currently being served by another provider. ...*

...

*Fresenius [the parent company of the applicant] related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering a convenient venue for dialysis care and treatment, and promoting access to care."*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C and L of the application and any exhibits).

#### 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.

- (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

On Form A in Section Q, 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 127 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 127 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.
- (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.

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

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- FMC Gastonia is an existing facility. Therefore, this Rule is not applicable to this review.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section C, page 18, the applicant projects that FMC Gastonia will serve 141 patients on 39 stations, or a rate of 3.62 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.



- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
  
- C- In Section C, pages 18-21, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.