

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 18, 2018

Findings Date: June 18, 2018

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: E-11485-18

Facility: FMC of Hickory

FID #: 955790

County: Catawba

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

Project: Add four dialysis stations for a total of 33 dialysis stations upon completion of this project and Project I.D. #E-11209-16 (relocate six dialysis stations)

### 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) d/b/a FMC of Hickory (FMC Hickory) proposes to add four dialysis stations to the existing facility for a total of 33 dialysis stations upon completion of this project and Project I.D. #E-11209-16 (relocate six dialysis stations).

#### **Need Determination**

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of nine dialysis stations in Catawba County. Therefore, the January 2018 SDR does not indicate a need for additional stations in Catawba County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need

for additional stations. 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 Hickory in the January 2018 SDR is 3.49 patients per station per week, or 87.14 percent, based on 122 in-center dialysis patients and 35 certified dialysis stations [ $122 / 35 = 3.49$ ;  $3.49 / 4 = 0.8714$  or 87.14%].

Below is a table that illustrates the facility need for additional dialysis stations at FMC Hickory:

<b>JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		87.14%
Certified Stations		35
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>35</b>
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR2)		122
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR1)		120
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 - SDR1)	2
(i)	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.0333
	Divide the result of Step (i) by 12	0.0028
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0167
(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	124.0333
(v)	Divide the result of Step (iv) by 3.2 patients per station	38.7604
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>4</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. 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 four new stations; therefore, the application is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.4(a), page 8; Section K.1(g), page 44; Section N.1, page 53; Section O, pages 55-58; 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.4(b), pages 9-10; Section C.3, pages 18-19; Section L, pages 47-51; Section N.1, page 53; 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.4(c), pages 10-11; Section C, pages 14-17; Section F, pages 25-32; Section K, pages 42-44; Section N.1, page 53; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value 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

BMA proposes to add four dialysis stations to the existing FMC Hickory facility for a total of 33 dialysis stations upon completion of this project and Project I.D. #E-11209-16 (relocate six dialysis stations). FMC Hickory serves home hemodialysis (HH) patients, and plans to continue to do so, but does not serve home peritoneal dialysis patients and has no plans to add home peritoneal dialysis services.

**Patient Origin**

On page 365, the 2018 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 is Catawba County. Facilities may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin as provided in Section C, pages 14 and 21.

<b>FMC Hickory Patients by County</b>						
	<b>Historical (12/31/2017)</b>			<b>Projected (Operating Year 2)</b>		
<b>County</b>	<b># of IC Patients</b>	<b># of HH Patients</b>	<b>% of Total</b>	<b># of IC Patients</b>	<b># of HH Patients</b>	<b>% of Total*</b>
Catawba	117	7	89.2%	133	8	85.6% [90.4%]
Burke	5	1	4.3%	5	1	6.6% [3.8%]
Caldwell	6	0	4.3%	6	0	4.6% [3.8%]
Lincoln	3	0	2.2%	3	0	2.6% [1.9%]
<b>Total</b>	<b>131</b>	<b>8</b>	<b>100.0%</b>	<b>147</b>	<b>9</b>	<b>100.0%</b>

Table may not foot due to rounding.

\*The Project Analyst’s calculations are in brackets.

In Section C, pages 14-17, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C, pages 17-18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 18, the applicant states:

*“Dialysis treatment is not optional. It is life sustaining. Absent approval of these stations, some patients would be forced to dialyze on a third, or evening shift, or seek dialysis at another location.*

*...After relocating six stations to the new FKC Newton project, the FMC Hickory facility will have only 29 stations. The 29 stations could provide dialysis care and treatment for 116 patients on traditional dialysis patient schedules. However, BMA has proposed to serve more than 116 patients in each of the first two years of this project.*

*No patient should be forced to dialyze on the third, or evening shift. Dialysis is a difficult lifestyle. However, couple that lifestyle with travel to the facility in winter months on rural roads and dialysis treatment becomes exceedingly challenging.*

*The only alternative to the third, or evening shift is for patients to be referred to another dialysis facility. Patients should not have to choose between dialysis in a convenient setting, close to their residence, or dialysis at an inconvenient time.*

*Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates.*

*Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates.*

*Patients should not have to make such choices. Approval of this application will (sic) patients of continued access to care in a convenient setting, at times which are convenient for the patient.”*

Additionally, in Section B.2, page 6, the applicant demonstrates the need for the proposed project using the facility need methodology.

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

- FMC Hickory is currently operating at a rate of 3.49 patients per station per day, or 87.14 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 14 and 21, the applicant provides historical and projected utilization as illustrated in the following table.

<b>FMC Hickory Patients by County</b>						
	<b>Historical (12/31/2017)</b>			<b>Projected (Operating Year 2)</b>		
<b>County</b>	<b># of IC Patients</b>	<b># of HH Patients</b>	<b>% of Total</b>	<b># of IC Patients</b>	<b># of HH Patients</b>	<b>% of Total*</b>
Catawba	117	7	89.2%	133	8	85.6% [90.4%]
Burke	5	1	4.3%	5	1	6.6% [3.8%]
Caldwell	6	0	4.3%	6	0	4.6% [3.8%]
Lincoln	3	0	2.2%	3	0	2.6% [1.9%]
<b>Total</b>	<b>131</b>	<b>8</b>	<b>100.0%</b>	<b>147</b>	<b>9</b>	<b>100.0%</b>

Table may not foot due to rounding.

\*The Project Analyst's calculations are in brackets.

In Section C.1, pages 14-17, the applicant provides the assumptions and methodology it used to project in-center and HH patient utilization, which are summarized below.

*In-Center*

- The applicant begins its utilization projections by using its facility census as of December 31, 2017.
- The applicant assumes that the patient population currently receiving treatment at FMC Hickory and who currently reside in Catawba County will increase annually at a rate of 8.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Catawba County published in the January 2018 SDR.
- The applicant assumes no population growth for the patients who utilize the facility and live in other counties, but assumes that the patients will continue to dialyze at FMC Hickory and adds them to the calculations when appropriate.
- In its application for FKC Newton (Project I.D. #E-11209-16), the applicant projected that 12 patients residing in Catawba County and dialyzing at FMC Hickory would transfer care to FKC Newton, and the applicant subtracts the 12 patients projected to transfer from the calculations on December 31, 2018 (when FKC Newton is projected to be certified).
- The project is scheduled for completion on December 31, 2018. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 15, the applicant provides the calculations used to arrive at the projected patient census for OY1 and OY2 as summarized in the table below.

<b>FMC Hickory</b>	
Starting point of calculations is Catawba County patients dialyzing at FMC Hickory on December 31, 2017.	117
Catawba County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (8.1%).	$117 \times 1.081 = 126.5$
12 Catawba County patients, projected to transfer care to FKC Newton, are subtracted from the projected patient population.	$126.5 - 12 = 114.5$
The patients from other counties are added. This is the projected census on December 31, 2018 and the starting census for this project.	$114.5 + 14 = 128.5$
Catawba County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (8.1%).	$114.5 \times 1.081 = 123.7$
The patients from other counties are added. This is the projected census on December 31, 2019 (OY1).	$123.7 + 14 = 137.7$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (8.1%).	$123.7 \times 1.081 = 133.8$
The patients from other counties are added. This is the projected census on December 31, 2020 (OY2).	$133.8 + 14 = 147.8$

The applicant rounds down and projects to serve 137 in-center patients on 33 stations, which is 4.2 patients per station per week ( $137 \text{ patients} / 33 \text{ stations} = 4.2$ ), by the end of OY1 and 147 in-center patients on 33 stations, which is 4.5 patients per station per week ( $147 \text{ patients} / 33 \text{ stations} = 4.5$ ), 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 by using its HH patient census as of December 31, 2017.
- As discussed above under in-center patient utilization, the applicant projects that the Catawba County HH population will grow at the Five Year AACR for Catawba County published in the January 2018 SDR (8.1 percent).
- The applicant assumes no population growth for the patient who utilizes services at FMC Hickory and lives in Burke County, but assumes that the patient will continue to dialyze through FMC Hickory and adds the patient to the calculations when appropriate.
- The project is scheduled for completion on December 31, 2018. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, page 17, the applicant provides the calculations it uses to arrive at the projected HH patient census for OY1 and OY2 as summarized in the table below.

<b>FMC Hickory HH Patients</b>	
Starting point of calculations is Catawba County HH patients dialyzing at FMC Hickory on December 31, 2017.	7
Catawba County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (8.1%).	$7 \times 1.081 = 7.6$
The patient from Burke County is added. This is the projected census on December 31, 2018 and the starting census for this project.	$7.6 + 1 = 8.6$
Catawba County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (8.1%).	$7.6 \times 1.081 = 8.2$
The patient from Burke County is added. This is the projected census on December 31, 2019 (OY1).	$8.2 + 1 = 9.2$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (8.1%).	$8.2 \times 1.081 = 8.8$
The patient from Burke County is added. This is the projected census on December 31, 2020 (OY2).	$8.8 + 1 = 9.8$

**Note:** the table on page 17 appears to have a typo – it projects patient population forward to the end of CY 2018 twice. The Project Analyst assumed the applicant meant to project the population forward to the end of the second operating year.

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

- The January 2018 SDR states that FMC Hickory’s utilization was 3.49 patients per station per week (a utilization rate of 87.14 percent) as of June 30, 2017.
- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Catawba County as published in the January 2018 SDR to project growth of Catawba County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development.
- The applicant does not project growth for its patients who do not reside in Catawba County.
- The applicant’s 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.3, page 18, 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 48, 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 Hickory Projected Payor Mix CY 2020</b>			
<b>Payment Source</b>	<b>% Total Patients</b>	<b>% In-Center Patients</b>	<b>% HH Patients</b>
Self-Pay/Indigent/Charity	0.64%	0.22%	0.00%
Medicare	68.79%	68.24%	82.32%
Medicaid	5.10%	5.31%	0.00%
Commercial Insurance	3.82%	3.68%	8.04%
Medicare/Commercial	17.83%	18.71%	0.00%
Misc. (including VA)	4.46%	3.84%	9.64%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

The applicant states on page 48 that the future payor mix is based on FMC Hickory’s historical experience in 2017. 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 (payor 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

BMA proposes to add four dialysis stations to its existing FMC Hickory facility for a total of 33 stations upon completion of this project and related projects.

In Section E, page 24, 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
- Apply for Fewer Than Four Stations
- Relocate Stations from FMC Catawba Valley

On page 24, the applicant states that its proposal is the most effective alternative because the facility need methodology shows a need for four additional stations; applying for fewer than four stations would force more patients to a third/evening shift; and FMC Catawba Valley is also operating in excess of 80 percent and is also applying to add dialysis stations.

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 applicant utilizes the facility need methodology to show the need for additional stations.
- The applicant's projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant adequately demonstrates that transferring stations from another facility in the same county is not a less costly or more effective alternative to increase the number of stations at FMC Hickory.

## **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. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Hickory shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Hickory shall develop no more than four additional dialysis stations for a total of no more than 33 certified stations upon completion of this project and Project I.D. #E-11209-16 (relocate six dialysis stations), which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Hickory 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

BMA proposes to add four dialysis stations to its existing FMC Hickory facility for a total of 33 stations upon completion of this project and related projects.

## **Capital and Working Capital Costs**

In Section F.1, page 25, the applicant states that it projects no capital costs for the proposed project. In Sections F.10 and F.11, page 28, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

## **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues

will exceed operating expenses in the first two operating years of the project, as shown in the table below.

<b>Projected Revenues and Operating Expenses</b>		
<b>FMC Hickory</b>	<b>Operating Year 1 CY 2019</b>	<b>Operating Year 2 CY 2020</b>
Total Treatments	19,710	21,044
Total Gross Revenues (Charges)	\$83,329,260	\$89,239,476
Total Net Revenue	\$5,934,727	\$6,353,875
Average Net Revenue per Treatment	\$301	\$302
Total Operating Expenses (Costs)	\$4,911,440	\$5,153,612
Average Operating Expense per Treatment	\$249	\$245
<b>Net Income/Profit</b>	<b>\$1,023,286</b>	<b>\$1,200,263</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 R 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
- 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 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**

BMA proposes to add four dialysis stations to its existing FMC Hickory facility for a total of 33 stations upon completion of this project and Project I.D. #E-11209-16 (relocate six dialysis stations).

On page 365, the 2018 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 is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, there are three existing dialysis facilities and two approved but not yet operational dialysis facilities in Catawba County, as shown in the table below.

<b>Existing/Approved Dialysis Facilities in Catawba County – Table B January 2018 SDR</b>						
<b>Facility</b>	<b>Owner</b>	<b># Patients</b>	<b>Location</b>	<b># Certified Stations</b>	<b># Approved Stations</b>	<b>% Utilization</b>
Catawba County Dialysis	DaVita	0	Hickory	0	10	0.0%
FMC of Catawba Valley	Fresenius	101	Conover	25	-6	101.0%
FMC Hickory Home	Fresenius	28	Hickory	0	0	--
FMC of Hickory	Fresenius	122	Hickory	35	-6	87.1%
FKC Newton	Fresenius	0	Newton	0	12	0.0%

FMC Hickory Home, which is a separately licensed dialysis facility providing exclusively home peritoneal dialysis (PD) training and support, has no stations. According to Table C of the January 2018 SDR, FMC Hickory Home had 28 PD patients as of June 30, 2017.

In Section G, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Catawba County. The applicant states:

*“The Catawba County ESRD patient population is increasing at a rate of 8.1% meaning that new dialysis stations and new facilities will be needed.*

*The FMC Hickory and FMC Catawba Valley facilities were operating above 90% utilization as of December 31, 2017. The two facilities combined utilization was 3.83 patients per station.*

...

*BMA is not creating unnecessary duplication of existing or approved health services. Rather this application seeks to ensure that adequate dialysis resources are available for the patient population choosing to dialyze at the FMC Hickory facility.”*

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 January 2018 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

In Section H.1, page 34, the applicant provides information about current and projected staffing for the proposed services. The applicant does not project to change its current staffing levels upon project completion.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 35, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 39, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director 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
- 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.

- (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, page 38, the applicant states that 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 Hickory – Ancillary and Support Services</b>	
<b>Services</b>	<b>Provider</b>
In-center dialysis/maintenance	On site
Self-care training (in-center)	Referral to FMC Hickory Home Program
Home training HH PD	On site FMC Hickory Home Program
Accessible follow-up program	On site/FMC Hickory Home Program
Psychological counseling	Catawba County Behavioral Health
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Catawba Valley Medical Center, Frye Regional Medical Center
Emergency care	Crash cart on site/staff trained; ambulance transport to hospital
Blood bank services	Catawba Valley Medical Center, Frye Regional Medical Center
Diagnostic and evaluation services	Catawba Valley Medical Center, Frye Regional Medical Center
X-ray services	Catawba Valley Medical Center, Frye Regional Medical Center
Laboratory services	Spectra
Pediatric nephrology	NC Baptist Hospital
Vascular surgery	Dr. Randal Bast – Horizon Surgical Center
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services and Independent Living Services
Transportation	DSS of Catawba County, Greenway Transportation, Premier Medical Transportation, Specialty Transport

The applicant provides supporting documentation in Exhibits I-1 through I-5.

In Section I, page 40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

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
- Information which was publicly available during the review and used by the Agency

- (9) Based on that review, the Agency concludes that the application is conforming to this criterion. 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 51, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

<b>FMC Hickory Historical Payor Mix CY 2017</b>			
<b>Payment Source</b>	<b>% Total Patients</b>	<b>% In-Center Patients</b>	<b>% HH Patients</b>
Self-Pay/Indigent/Charity	0.64%	0.22%	0.00%
Medicare	68.79%	68.24%	82.32%
Medicaid	5.10%	5.31%	0.00%
Commercial Insurance	3.82%	3.68%	8.04%
Medicare/Commercial	17.83%	18.71%	0.00%
Misc. (including VA)	4.46%	3.84%	9.64%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Catawba	17%	51%	24%	15%	10%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table>; Latest Data 7/1/16 as of 8/22/17

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina, and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014*

*Annual Report*<sup>1</sup> percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>2</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

### **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, page 49, 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:

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<sup>1</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

<sup>2</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)

- 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.

- (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 48, 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>FMC Hickory Projected Payor Mix CY 2020</b>			
<b>Payment Source</b>	<b>% Total Patients</b>	<b>% In-Center Patients</b>	<b>% HH Patients</b>
Self-Pay/Indigent/Charity	0.64%	0.22%	0.00%
Medicare	68.79%	68.24%	82.32%
Medicaid	5.10%	5.31%	0.00%
Commercial Insurance	3.82%	3.68%	8.04%
Medicare/Commercial	17.83%	18.71%	0.00%
Misc. (including VA)	4.46%	3.84%	9.64%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.64 percent of total services will be provided to self-pay, indigent, and charity care patients; 68.79 percent to Medicare patients (not including those who are covered both by Medicare and by commercial insurance), and 5.10 percent to Medicaid patients.

On page 48, 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
- 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.

- (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 50, 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
- 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.

- (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-1.

### **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 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

BMA proposes to add four dialysis stations to its existing FMC Hickory facility for a total of 33 stations upon completion of this project and Project I.D. #E-11209-16 (relocate six dialysis stations).

On page 365, the 2018 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 is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, there are three existing dialysis facilities and two approved but not yet operational dialysis facilities in Catawba County, as shown in the table below.

<b>Existing/Approved Dialysis Facilities in Catawba County – Table B January 2018 SDR</b>						
<b>Facility</b>	<b>Owner</b>	<b># Patients</b>	<b>Location</b>	<b># Certified Stations</b>	<b># Approved Stations</b>	<b>% Utilization</b>
Catawba County Dialysis	DaVita	0	Hickory	0	10	0.0%
FMC of Catawba Valley	Fresenius	101	Conover	25	-6	101.0%
FMC Hickory Home	Fresenius	28	Hickory	0	0	--
FMC of Hickory	Fresenius	122	Hickory	35	-6	87.1%
FKC Newton	Fresenius	0	Newton	0	12	0.0%

FMC Hickory Home, which is a separately licensed dialysis facility providing exclusively home PD training and support, has no stations. According to Table C of the January 2018 SDR, FMC Hickory Home had 28 PD patients as of June 30, 2017.

In Section N, page 53, 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 effect on the competitive climate in Catawba County. The applicant does not project to serve dialysis patients currently being served by another provider. ...*

...

*BMA 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 R 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 Section 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

In Exhibit A-4, 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 112 of this type of facility located in North Carolina.

In Section O, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all of the problems have been corrected. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 112 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 Hickory is an existing facility.

(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 14, the applicant projects that FMC Hickory will serve 137 patients on 33 stations, or a rate of 4.2 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 14-17, 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.