ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: June 11, 2018
Findings Date: June 11, 2018

Project Analyst: Julie M. Faenza
Team Leader: Gloria C. Hale
Assistant Chief: Lisa Pittman

Project ID #: E-11481-18
Facility: FMC of Alexander County
FID #: 090725
County: Alexander
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Add three dialysis stations for a total of 13 dialysis 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) d/b/a FMC of Alexander County (FMC Alexander) proposes to add three dialysis stations to the existing facility for a total of 13 stations upon project completion.

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 deficit of three dialysis stations in Alexander County. Therefore, the January 2018 SDR does not indicate a need for additional stations in Alexander 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 Alexander in the January 2018 SDR is 3.8 patients per station per week, or 95 percent, based on 38 in-center dialysis patients and 10 certified dialysis stations [38 / 10 = 3.8; 3.8 / 4 = 0.95 or 95%].

In Section B.2, page 6, the applicant provides a table that illustrates the facility need for additional dialysis stations at FMC Alexander, as shown below:

JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		95%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		**10**
In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR2)		38
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR1)		27
Step	**Description**	**Result**
(i)	Difference (SDR2 - SDR1)	11
	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.8148
(ii)	Divide the result of Step (i) by 12	0.0679
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.4074
(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	53.4815
(v)	Divide the result of Step (iv) by 3.2 patients per station	16.7130
	and subtract the number of certified and pending stations to determine the number of stations needed	**7**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven 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 three 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), pages 43-44; Section N.1, page 54; Section O, pages 55-59; 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.4(b), pages 9-10; Section C.3, pages 17-18; Section L, pages 48-52; Section N.1, page 54; 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 25-33; Section K, pages 42-44; Section N.1, page 54; 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 three dialysis stations to its existing FMC Alexander facility for a total of 13 stations upon project completion. FMC Alexander serves home peritoneal dialysis (PD) patients, and plans to continue to do so, but does not serve home hemodialysis patients and has no plans to add home hemodialysis 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 Alexander 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 19-20.

FMC Alexander Patients by County						
	Historical (12/31/2017)*			Projected (Operating Year 2)		
County	# of IC Patients	# of PD Patients	% of Total	# of IC Patients	# of PD Patients	% of Total
Alexander	40	3	97.7%	47.7	3.6	98.1%
Iredell	1	0	2.3%	1	0	1.9%
Total	**41**	**3**	**100.0%**	**48**	**3**	**100.0%**

*On page 20, the applicant identifies the number of historical patients as of December 31, 2016. This is most likely a typo; according to the July 2017 SDR, the number of in-center patients as of December 31, 2016 was 27, and the ESRD data collection form for FMC Alexander for December 31, 2017 confirms the number of in-center patients was 41.

In Section C, pages 14-16, the applicant provides the assumptions and methodology it uses to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

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

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 assure 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 Alexander is currently operating at a rate of 3.8 patients per station per day, or 95 percent of capacity.

- The applicant demonstrates eligibility to add dialysis stations to its facility via use of 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 19-20, the applicant provides historical and projected utilization as illustrated in the following table.

FMC Alexander Historical and Projected Utilization						
	Historical (12/31/2017)*			Projected (Operating Year 2)		
County	# of IC Patients	# of PD Patients	% of Total	# of IC Patients	# of PD Patients	% of Total
Alexander	40	3	97.7%	47.7	3.6	98.1%
Iredell	1	0	2.3%	1	0	1.9%
Total	**41**	**3**	**100.0%**	**48**	**3**	**100.0%**

*On page 20, the applicant identifies the number of historical patients as of December 31, 2016. This is most likely a typo; according to the July 2017 SDR, the number of in-center patients as of December 31, 2016 was 27, and the ESRD data collection form for FMC Alexander for December 31, 2017 confirms the number of in-center patients was 41.

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology it uses to project in-center and home PD patient utilization, which are summarized below.

In-Center Patients

- The applicant begins its utilization projections by using its facility census as of December 31, 2017.

- The applicant states that the Alexander County Five Year Average Annual Change Rate (AACR) published in the January 2018 SDR is -2.3 percent; however, the applicant also states that in the six months between June 30, 2017 and December 31, 2017, the patient population of FMC Alexander increased by 11 patients, or 40.74 percent. The applicant states that recent patient population increases are not reflected in the Alexander County Five Year AACR, but that it doesn't believe growth at the current rates will continue.

- The applicant states that it calculated the Alexander County Five Year AACR likely to be published in the July 2018 SDR as 8.59 percent, based on providing service to a total of 46 Alexander County dialysis patients as of December 31, 2017. The applicant states that there are currently 10 additional Alexander County patients listed as dialyzing in facilities not affiliated with the applicant and that the Alexander County Five Year AACR published in the July 2018 SDR may be higher than 8.59 percent. The Project Analyst performed an analysis of the patient population of Alexander County, based on the applicant's statements on page 15 and information in the January 2018 SDR. Based on previous years' data from the January 2018 SDR, and assuming 46 Alexander County dialysis patients, the Five Year AACR for Alexander County in the July 2018 SDR will be 8.58 percent.

- The applicant states that it will use a growth rate of 4.5 percent, just over half of what the July 2018 SDR is projected to show as the updated Alexander County Five Year AACR, to make future utilization projections about Alexander County patients.

- The applicant assumes no population growth for the patient who utilizes the facility and lives in Iredell County, but assumes that the patient will continue to dialyze at FMC Alexander and is added to the calculations when appropriate.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C.1, page 16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

FMC Alexander In-Center Patients	
Starting point of calculations is Alexander County in-center patients dialyzing at FMC Alexander on December 31, 2017.	40
Alexander County patient population is projected forward by one year to December 31, 2018, using the applicant's change rate of 4.5%.	40 X 1.045 = 41.8
Alexander County patient population is projected forward by one year to December 31, 2019, using the applicant's change rate of 4.5%.	41.8 X 1.045 = 43.7
The patient from Iredell County is added. This is the projected in-center census on December 31, 2019 and the starting census for this project.	43.7 + 1 = 44.7
Alexander County patient population is projected forward by one year to December 31, 2020, using the applicant's change rate of 4.5%.	43.7 X 1.045 = 45.6
The patient from Iredell County is added. This is the projected in-center census on December 31, 2020 (OY1).	45.6 + 1 = 46.6
Alexander County patient population is projected forward by one year to December 31, 2021, using the applicant's change rate of 4.5%.	45.6 X 1.045 = 47.7
The patient from Iredell County is added. This is the projected in-center census on December 31, 2021 (OY2).	47.7 + 1 = 48.7

The applicant rounds down and projects to serve 46 in-center patients on 13 stations, which is 3.54 patients per station per week (46 patients / 13 stations = 3.54), by the end of OY1 and 48 in-center patients on 13 stations, which is 3.69 patients per station per week (48 patients / 13 stations = 3.69), 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 Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its home PD census as of December 31, 2017.

- As discussed above under in-center patient utilization, the applicant projects that the Alexander County PD population will grow at its projected change rate of 4.5 percent annually.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C.1, page 16, the applicant provides the calculations it uses to arrive at the projected home PD patient census for OY1 and OY2 as summarized in the table below.

FMC Alexander Home PD Patients	
Starting point of calculations is Alexander County PD patients dialyzing at FMC Alexander on December 31, 2017.	3
Alexander County patient population is projected forward by one year to December 31, 2018, using the applicant's change rate of 4.5%.	3 X 1.045 = 3.1
Alexander County patient population is projected forward by one year to December 31, 2019, using the applicant's change rate of 4.5%. This is the projected home PD patient census on December 31, 2019 and the starting census for this project.	3.1 X 1.045 = 3.3
Alexander County patient population is projected forward by one year to December 31, 2020, using the applicant's change rate of 4.5%. This is the projected home PD patient census on December 31, 2020 (OY1).	3.3 X 1.045 = 3.4
Alexander County patient population is projected forward by one year to December 31, 2021, using the applicant's change rate of 4.5%. This is the projected home PD patient census on December 31, 2021 (OY2).	3.4 X 1.045 = 3.6

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

- The January 2018 SDR states that FMC Alexander's utilization was 3.8 patients per station per week (a utilization rate of 95 percent) as of June 30, 2017.
- The applicant projects future utilization based on historical utilization.
- The applicant uses a reasonable and adequately supported growth rate, based on historical utilization, to project growth of Alexander County dialysis patients.
- 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, pages 17-18, 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 49, 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.

FMC Alexander Projected Payor Mix CY 2021			
Payment Source	**% Total Patients**	**% In-Center Patients**	**% Home PD Patients**
Medicare	72.00%	72.93%	35.99%
Medicaid	2.00%	3.03%	0.00%
Commercial Insurance	4.00%	2.81%	28.03%
Medicare/Commercial	18.00%	17.27%	35.99%
Misc. (including VA)	4.00%	3.96%	0.00%
Total	**100.00%**	**100.00%**	**100.00%**

The applicant states on page 49 that the future payor mix is based on FMC Alexander'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 three dialysis stations to its existing FMC Alexander facility for a total of 13 stations upon project completion.

In Section E, page 23, 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 Up to Seven Additional Dialysis Stations
- Apply for Fewer Than Three Stations
- Offer Home Hemodialysis at the Facility

On pages 23-24, the applicant states that its proposal is the most effective alternative because the existing facility can physically accommodate only three additional stations without extensive and costly renovations to the building; applying for fewer than three stations would not make sense given that utilization is projected to be above 80 percent by the end of the first operating year with three additional stations; and BMA is not aware of any home hemodialysis patients currently living in Alexander 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 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 the other alternatives considered were not less costly or more effective to meet the needs of patients dialyzing and projected to dialyze at FMC Alexander.

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 Alexander County 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 Alexander County shall develop no more than three additional dialysis stations for a total of no more than 13 certified stations upon project completion, which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Alexander County shall install plumbing and electrical wiring through the walls for no more than three dialysis stations which shall include any isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC of Alexander County 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 three dialysis stations to its existing FMC Alexander facility for a total of 13 stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 26, the applicant projects the total capital cost of the project as shown in the table below.

Estimated Capital Cost – Project I.D. #E-11481-18	
Category	**Amount**
Dialysis Machines	Leased
Water Treatment Equipment	$2,250
Other Equipment/Furniture	$9,000
Total	**$11,250**

In Section F.1, page 25, the applicant provides the assumptions it uses to project the capital cost.

In Section F, page 29, the applicant states there are no projected working capital costs because FMC Alexander is an existing facility that is currently operational.

Availability of Funds

In Section F, page 27, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	
Type	**Total**
Loans	$0
Accumulated reserves or OE *	$11,250
Bonds	$0
Other (Specify)	$0
Total Financing	$11,250

* OE = Owner's Equity

Financial Feasibility

In Section R, pages 63-74, 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.

Projected Revenues and Operating Expenses		
FMC Alexander	**Operating Year 1 CY 2020**	**Operating Year 2 CY 2021**
Total Treatments	6,669	6,965
Total Gross Revenues (Charges)	$28,366,644	$29,547,092
Total Net Revenue	$2,075,197	$2,159,066
Average Net Revenue per Treatment	$311	$310
Total Operating Expenses (Costs)	$2,050,941	$2,102,529
Average Operating Expense per Treatment	$308	$302
Net Income/Profit	**$24,256**	**$56,537**

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 for the following reasons:

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

- 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 three dialysis stations to its existing FMC Alexander facility for a total of 13 stations upon project completion.

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 Alexander County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, FMC Alexander is the only existing and/or approved dialysis facility in Alexander County. According to Table B, as of June 30, 2017, FMC Alexander was serving 38 patients on 10 certified dialysis stations for utilization rate of 3.8 patients per station per week, or 95 percent of capacity.

In Section G, page 34, the applicant explains why it believes its proposal will not result in the unnecessary duplication of existing or approved dialysis services in Alexander County. The applicant states:

> *"This application does not create a new dialysis facility in Alexander County. Approval of this application will result in three additional dialysis stations in the Service Area.*
>
> *The projected utilization for the FMC Alexander County facility warrants development of the additional stations."*

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, as calculated using the facility need 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 35, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

FMC Alexander – Current and Projected Facility Staffing		
Position	**Current # of FTEs**	**OY 2 # of FTEs**
Medical Director*	0.0	0.0
Registered Nurse	1.5	2.0
Home Training Nurse	1.0	1.0
Patient Care Tech	3.5	3.5
Dietitian	0.5	0.5
Social Worker	0.5	0.5
Clinical Manager	1.0	1.0
Administration	0.1	0.1
In-Service	0.2	0.2
Clerical	1.0	1.0
Chief Tech	0.1	0.1
Equipment Tech	0.5	0.5
Total	**9.9**	**10.4**

*On page 35, the applicant states that the Medical Director is a contract position and is not an employee of the facility.

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 36, 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:

FMC Alexander – Ancillary and Support Services	
Services	**Provider**
In-center dialysis/maintenance	On site
Self-care training (in-center)	Referral to FMC Hickory for hemodialysis; on site program for PD
Home training HH PD Accessible follow-up program	 FMC Hickory On site FMC Hickory/on site
Psychological counseling	Counseling and Psychology Resources, Solutions of Hickory, New Directions Counseling Services, Anchor of Hope
Isolation – hepatitis	On site or referred to FMC Hickory
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
Transplantation services	NC Baptist Hospital, Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS, Vocational Rehab Services
Transportation	Greenway Transportation, Premier 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

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 52, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

FMC Alexander Historical Payor Mix CY 2017			
Payment Source	**% Total Patients**	**% In-Center Patients**	**% Home PD Patients**
Medicare	72.00%	72.93%	35.99%
Medicaid	2.00%	3.03%	0.00%
Commercial Insurance	4.00%	2.81%	28.03%
Medicare/Commercial	18.00%	17.27%	35.99%
Misc. (including VA)	4.00%	3.96%	0.00%
Total	**100.00%**	**100.00%**	**100.00%**

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.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Alexander	20%	49%	13%	16%	12%	12%
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*[1] 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[2]. In 2015, over 85% of dialysis

[1]http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf
[2]http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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 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 51, 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
- 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 49, 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 Alexander Projected Payor Mix CY 2021			
Payment Source	**% Total Patients**	**% In-Center Patients**	**% Home PD Patients**
Medicare	72.00%	72.93%	35.99%
Medicaid	2.00%	3.03%	0.00%
Commercial Insurance	4.00%	2.81%	28.03%
Medicare/Commercial	18.00%	17.27%	35.99%
Misc. (including VA)	4.00%	3.96%	0.00%
Total	**100.00%**	**100.00%**	**100.00%**

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 72 percent of total services will be provided to Medicare patients (not including those who are covered both by Medicare and by commercial insurance) and two percent to Medicaid patients.

On page 49, 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 because it is based on the historical payor mix for FMC Alexander.

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 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
- 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 53, 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 three dialysis stations to its existing FMC Alexander facility for a total of 13 stations upon project completion.

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 Alexander County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2018 SDR, FMC Alexander is the only existing and/or approved dialysis facility in Alexander County. According to Table B, as of June 30, 2017, FMC Alexander was serving 38 patients on 10 certified dialysis stations for utilization rate of 3.8 patients per station per week, or 95 percent of capacity.

In Section N, page 54, 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 54, the applicant states:

> *"The applicant does not expect this proposal to have effect on the competitive climate in Alexander County. The applicant does not project to serve dialysis patients currently being served by another provider. ...*
>
> *...*
>
> *Fresenius 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 another convenient venue for dialysis care and treatment."*

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, pages 58-59, 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 Alexander 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 16, the applicant projects that FMC Alexander will serve 46 patients on 13 stations, or a rate of 3.54 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 14-16, 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.