

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 29, 2019

Findings Date: April 29, 2019

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: E-11648-19

Facility: FMC Hickory Home Program

FID #: 110873

County: Catawba

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

Project: Relocate the home hemodialysis program and its two dialysis stations from FMC Hickory to FMC Hickory Home Program, resulting in a freestanding kidney disease treatment center offering training and support exclusively for patients dialyzing at home 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. (hereinafter referred to as “applicant” or “BMA”) proposes to relocate the current home hemodialysis (HH) program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support. At project completion, FMC Hickory Home Program will be a standalone kidney disease treatment center offering training and support exclusively for PD and HH patients dialyzing at home.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2019 SMFP that are applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review:

Policy ESRD-2: Relocation of Dialysis Stations, on page 25 of the 2019 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

Both FMC Hickory Home Program and FMC Hickory are located in Catawba County. Therefore, the application is consistent with Policy ESRD-2.

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 relocate its existing HH program, with its two dedicated dialysis stations, from FMC Hickory to FMC Hickory Home Program. At project completion, FMC Hickory Home Program will be a standalone kidney disease treatment center offering training and support exclusively for PD and HH patients dialyzing at home.

FMC Hickory Home Program was first certified in 2014 as a freestanding kidney disease treatment center to provide exclusively PD patient training and support. Because PD does not involve the use of dialysis stations, there are currently no stations at the existing facility.

BMA proposes to relocate two existing dialysis stations at FMC Hickory, currently used exclusively for HH training and support, to FMC Hickory Home Program, currently used exclusively for PD training and support, which will create a freestanding facility dedicated to training and support exclusively for home dialysis modalities. Previous attempts to create this type of facility were unsuccessful due to the performance standard promulgated in 10A NCAC 14C .2203, requiring dialysis stations and kidney disease treatment facilities to demonstrate a utilization rate of at least 3.2 patients per station per week (or needed to reasonably project that rate of utilization) prior to developing new stations. 10A NCAC 14C .2203 does not distinguish between in-center stations and stations used exclusively for HH patient training and support. A patient dialyzing in an in-center setting typically receives treatment three times per week, with each treatment lasting approximately four hours, allowing for multiple patients to use the same station within the same day. In Section C, pages 15-16, the applicant describes the training schedule for HH patients, and states HH patients typically go through four training treatments per week, with each treatment lasting approximately six hours. The applicant states a prospective HH patient received an average of 25 training sessions, which takes six to seven weeks. The applicant states the training schedule for HH patients does not allow for more than one patient to use the station for the six to seven weeks that training takes. Thus, it is impossible for a station being used exclusively for HH patient training and support to meet the performance standard promulgated in 10A NCAC 14C .2203.

On August 8, 2018, Fresenius Medical Care Holdings, Inc. (FMC) – the parent company of BMA, as well as the parent company of other dialysis facility operators – requested a declaratory ruling from the Agency stating that the requirements of 10A NCAC 14C .2203 will not apply to facilities exclusively serving PD and HH patients. On October 10, 2018, the Agency issued the declaratory ruling FMC had asked for, noting in the declaratory ruling 10A NCAC 14C .2203 was being designated as necessary with substantive public interest so that when it was re-promulgated, the Rule could be changed to make it clear that 10A NCAC 14C .2203 applies only to in-center dialysis stations and a performance standard for HH stations could be added.

Patient Origin

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

The following table illustrates historical and projected patient origin. On page 24, the applicant states the historical HH patient origin is for HH patients dialyzing at FMC Hickory and the historical PD patient origin is for PD patients dialyzing at FMC Hickory Home Program.

Historical and Projected Patient Origin				
	Historical (12/31/2018)		Projected (Operating Year 2)	
	FMC Hickory	Hickory Home Program	Hickory Home Program	
County	# of HH Patients	# of PD Patients	# of HH Patients	# of PD Patients
Catawba	7	26	9	33
Alexander	0	2	0	2
Burke	0	2	0	2
Caldwell	1	3	1	3
Total	8	33	10	40

Source: Section C, pages 15 and 24

In Section C, pages 15-19, 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 15-20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant explains the typical three day per week schedule for in-center patients to receive dialysis and states the failure to receive dialysis services will lead to patient death. On page 20, the applicant states:

“Home dialysis patients – PD and home hemodialysis – require the same regular dialysis treatment regimen. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.

...

Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient residence. The patient has total control of the treatment.

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

Approval of this application will allow BMA to relocate an entire home hemodialysis training and support program, and its two hemodialysis stations, to the FMC Hickory Home Program. This will enhance patient training opportunities and ultimately will assure home patients of continued access to care in a convenient setting, at times which are convenient for the patient.”

In Section C, pages 17-18, the applicant states between June 30, 2017 and June 30, 2018, the statewide HH patient population grew at a rate of 11.7 percent, or from 452 to 505 HH patients, a gain of 53 patients.

This is consistent with publicly available data. The Project Analyst reviewed the 2018 United States Renal Data System (USRDS) Annual Data Report.¹ According to the USRDS, the number of patients nationally with End Stage Renal Disease (ESRD) who used HH as their treatment modality has steadily increased since December 2006. Moreover, when reporting the national patient trends for all home treatment modalities from 1996 to 2016, the USRDS states that since 2007, the year with the lowest utilization of home treatment modalities, the number of ESRD patients utilizing home treatment modalities has “increased appreciably.”

In Section A, page 5, the applicant states both FMC Hickory and FMC Hickory Home Program are located in the same building, but on different floors. In Section C, page 25, the applicant states that, by relocating the existing HH stations from one floor to another, it will create staff efficiencies, which will reduce the cost of healthcare for the patients. The applicant further states all existing patients will continue to go to the same address for their training and treatments.

On page 25, the applicant states:

“The more important aspect of this relocation is the opportunity to create a dialysis center focused exclusively on home therapies for both home hemodialysis and home peritoneal dialysis patients. A center dedicated to both home modalities will allow the patients who share a common dialysis experience – dialyzing at home – to more openly share with each other, and learn from each other. Moreover, a common training area will allow the BMA Staff to have a center focused on patient and family member education. Educational resources, specific to dialysis, and more specific to home dialysis will be immediately available to patients and their family.”

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

- The applicant adequately explains the need patients have for a consolidated home training and support program in a single location.

¹ <https://www.usrds.org/2018/view/Default.aspx> (last accessed April 11, 2019)

- The applicant provides historical utilization data which support the need the patient population has for the proposed services.
- The applicant’s historical utilization data are consistent with available national data.

Projected Utilization

In Section C, pages 15 and 24, the applicant provides historical and projected utilization as illustrated in the following table. On page 24, the applicant states the historical HH patient origin is for HH patients dialyzing at FMC Hickory and the historical PD patient origin is for PD patients dialyzing at FMC Hickory Home Program.

Current and Projected Patient Origin				
	Historical (12/31/2018)		Projected (Operating Year 2)	
	FMC Hickory	Hickory Home Program	Hickory Home Program	
County	# of HH Patients	# of PD Patients	# of HH Patients	# of PD Patients
Catawba	7	26	9	33
Alexander	0	2	0	2
Burke	0	2	0	2
Caldwell	1	3	1	3
Total	8	33	10	40

Source: Section C, pages 15 and 24

In Section C, pages 15-19, the applicant provides the assumptions and methodology it used to project HH and PD patient utilization, which are summarized below.

Home Hemodialysis Patients

- The applicant begins its utilization projections by using its HH patient census at FMC Hickory as of December 31, 2018.
- The applicant projects the Catawba County HH population will grow at the Five Year Average Annual Change Rate (AACR) for Catawba County published in the January 2019 SDR (9.1 percent).
- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 19, the applicant provides the calculations used to arrive at the projected HH patient census for OY1 and OY2 as summarized in the table below.

FMC Hickory HH Patients	
Starting point of calculations is Catawba County HH patients dialyzing at FMC Hickory on December 31, 2018.	7
Catawba County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (9.1%).	$7.1 \times 1.091 = 7.6$
HH patients from other counties dialyzing at FMC Hickory are added. This is the starting census for the project.	$7.6 + 1 = 8.6$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (9.1%).	$7.6 \times 1.091 = 8.3$
HH patients from other counties dialyzing at FMC Hickory are added. This is the projected census on December 31, 2020 (OY1).	$8.3 + 1 = 9.3$
Catawba County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (9.1%).	$8.3 \times 1.091 = 9.1$
HH patients from other counties dialyzing at FMC Hickory are added. This is the projected census on December 31, 2021* (OY2).	$9.1 + 1 = 10.1$

*On page 19, the applicant lists CY 2020 twice. Based on information elsewhere in the application, this is a typo and the Project Analyst has inserted the correct information in this table.

Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its PD patient census at FMC Hickory Home Program as of December 31, 2018.
- The applicant projects the Catawba County PD population will grow at the Five Year AACR for Catawba County published in the January 2019 SDR (9.1 percent).
- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 19, the applicant provides the calculations it uses to arrive at the projected PD patient census for OY1 and OY2 as summarized in the table below.

FMC Hickory Home Program PD Patients	
Starting point of calculations is Catawba County PD patients dialyzing at FMC Hickory Home on December 31, 2018.	26
Catawba County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (9.1%).	$26 \times 1.091 = 28.4$
PD patients from other counties dialyzing at FMC Hickory Home are added. This is the starting census for the project.	$28.4 + 7 = 35.4$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (9.1%).	$28.4 \times 1.091 = 30.9$
PD patients from other counties dialyzing at FMC Hickory Home are added. This is the projected census on December 31, 2020 (OY1).	$30.9 + 7 = 37.9$
Catawba County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (9.1%).	$30.9 \times 1.091 = 33.8$
PD patients from other counties dialyzing at FMC Hickory Home are added. This is the projected census on December 31, 2021* (OY2).	$33.8 + 7 = 40.8$

*On page 19, the applicant lists CY 2020 twice. Based on information elsewhere in the application, this is a typo and the Project Analyst has inserted the correct information in this table.

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

- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Catawba County as published in the January 2019 SDR to project growth of Catawba County HH and PD patients.

Access

In Section C, page 21, 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 56, 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 Hickory Home Program Projected Payor Mix CY 2021			
Payment Source	% Total Patients	% HH Patients	% PD Patients
Self-Pay/Indigent/Charity	1.92%	0.20%	0.52%
Medicare	50.00%	78.91%	43.60%
Medicaid	1.92%	0.00%	0.21%
Commercial Insurance	28.85%	9.63%	34.36%
Medicare/Commercial	15.38%	11.27%	18.51%
Misc. (including VA)	1.92%	0.00%	2.81%
Total	100.00%	100.00%	100.00%

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.

C

BMA proposes to relocate its existing HH program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program.

In Section D, page 27, the applicant states:

“...this proposal will have absolutely no effect on the in-center operations or true utilization ratio for the FMC Hickory facility.

FMC Hickory is currently a 35 station dialysis facility. Of those 35 dialysis stations, only 33 are used in the in-center treatment area. Two dialysis stations have long been reserved and utilized exclusively for home hemodialysis training and support.

While the SDR does calculate utilization statistics based upon all dialysis stations certified at the facility, these utilization statistics are somewhat artificial since two stations are used in the home hemodialysis training program, and are not used for in-center dialysis.”

According to the January 2019 SDR, FMC Hickory had 35 certified stations as of June 30, 2018. There are three projects involving FMC Hickory which were previously approved but still under development as of the date of these findings:

- Project I.D. #E-11209-16 (relocate six stations to FKC Newton)
- Project I.D. #E-11485-18 (add four stations)
- Project I.D. #E-11570-18 (add two stations)

As of the date of these findings, FMC Hickory has 35 certified stations. At the completion of the three previously approved but not yet developed projects, FMC Hickory will have 35 certified stations. The applicant proposes to relocate two stations to FMC Hickory Home Program as part of this project. Upon completion of this project and all affiliated projects, FMC Hickory will have 33 certified stations. Based on the applicant’s statement that it is currently only using 33 stations for its in-center dialysis population, the approved and proposed projects will result in no net gain or loss of stations available to the in-center patient population at FMC Hickory.

In Section D, pages 27-29, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On page 29, the applicant states:

“...regardless of the facility census, the FMC Hickory facility can reasonably accommodate only 33 stations on the in-center dialysis treatment floor. The two stations under discussion in this application are not a part of the in-center dialysis stations, but rather are used exclusively for home hemodialysis training and support. Moreover, those stations are in a different area of the facility. It simply isn’t possible to include these stations as a part of the in-center treatment area. Thus, in a most practical sense, FMC Hickory will not realize a true loss of in-center dialysis capacity.

BMA will make every reasonable effort to provide care and treatment for those patients choosing dialysis at FMC Hickory. BMA will operate a third shift if necessary. BMA will refer patients to another of its dialysis facilities in Catawba County if necessary.”

In Section D, page 29, the applicant provides projected in-center patient utilization of FMC Hickory following completion of the proposed project, as shown in the table below.

FMC Hickory Projected Utilization	
December 31, 2019	
# In-Center Patients	120

In Section D, pages 27-29, the applicant provides the assumptions and methodology used to project utilization, as discussed below.

- The applicant states there were 122 patients dialyzing at FMC Hickory on December 31, 2018. 111 of those patients were Catawba County residents and 11 of those patients were residents of other North Carolina counties.
- The applicant projects the Catawba County patient population of FMC Hickory will grow at a rate of 9.1 percent, which is the Five Year AACR for Catawba County as published in the January 2019 SDR.
- The applicant projects no growth for patients residing in other counties, but adds those patients to the calculations where appropriate.
- The applicant states that, as part of Project I.D. #E-11209-16 (develop a new 12-station dialysis facility, FKC Newton), it projects 12 patients from FMC Hickory will transfer care to FKC Newton once it opens and subtracts those 12 patients from the calculations as of June 30, 2019 (the projected completion date for FKC Newton).

In Section D, page 28, the applicant provides the calculations it uses to arrive at the projected patient census at FMC Hickory for OY1 and OY2 of the proposed project, as summarized in the table below.

FMC Hickory Patients	
Starting point of calculations is the 111 Catawba County patients dialyzing at FMC Hickory on December 31, 2018, and is the starting census for this project.	111
Catawba County patient population is projected forward by six months to June 30, 2019, using one half of the Five Year AACR of 9.1%.	$111 \times 1.0455 = 116.1$
The 12 patients projected to transfer care to FKC Newton upon project completion are subtracted from the Catawba County patient population dialyzing at FMC Hickory.	$116.1 - 12 = 104.1$
Catawba County patient population is projected forward by six months to December 31, 2019, using one half of the Five Year AACR of 9.1%.	$104.1 \times 1.0455 = 108.8$
The patients from other counties are added. This is the projected census at the start of OY1.	$108.8 + 11 = 119.8$
Catawba County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR of 9.1%.	$108.8 \times 1.091 = 118.7$
The patients from other counties are added. This is the projected census on December 31, 2020 (end of OY1).	$118.7 + 11 = 129.7$
Catawba County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR of 9.1%.	$118.7 \times 1.091 = 129.5$
The patients from other counties are added. This is the projected census on December 31, 2021 (end of OY2).	$129.5 + 11 = 140.5$

The applicant rounds up and projects to serve 130 patients on 33 stations, which is 3.9 patients per station per week ($130 \text{ patients} / 33 \text{ stations} = 3.9$), for a utilization rate of 97.5 percent by the end of OY1, and 141 patients on 33 stations, which is 4.3 patients per station per week ($141 \text{ patients} / 33 \text{ stations} = 4.3$), for a utilization rate of 107.5 percent, by the end of OY2.

On page 29, the applicant states:

“BMA recognizes that utilization rates above four patients per station necessarily result in a third dialysis shift. FMC Hickory has operated a third, or evening dialysis shift as the census may have required. Based on past experience, the third shift can reasonably accommodate up [sic] 10 patients. If, and when it becomes necessary to ensure care for the patients of the facility, BMA will operate a third/evening dialysis shift at FMC Hickory.”

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

- The applicant uses the Five Year AACR for Catawba County as published in the January 2019 SDR to project patient utilization.
- The applicant accounts for patients who are proposed to transfer care to a different facility as part of projects under development.
- The applicant accounts for projects under development.

In Section D, page 30, the applicant states the proposed relocation of stations will have no effect on the ability of patients using the existing facility, including low income patients, women, disabled patients, and other underserved patients, to access services, and states it makes dialysis services available to all residents of the service area without qualification.

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 applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 relocate its existing HH program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program.

In Section E, page 31, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo would not allow for an environment focused exclusively on home patient populations and would not allow for operational efficiencies. Therefore, this is not an effective alternative.
- Relocate a Different Number of Stations: the applicant states that, based on the projected patient population, a different number of stations would not be the most effective alternative. Therefore, this is not an effective alternative.

On page 31, the applicant states its proposal is the most effective alternative because it is the most cost effective option and results in more efficiencies for the home dialysis patients of Catawba County.

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

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

Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate two dialysis stations from FMC Hickory to FMC Hickory Home Program.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than two dialysis stations which shall include any isolation stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify two dialysis stations at FMC Hickory for a total of no more than 33 dialysis stations at FMC Hickory following completion of this project, Project I.D. #E-11209-16 (relocate six stations to FKC Newton), Project I.D. #E-11485-18 (add four stations), and Project I.D. #E-11570-18 (add two stations).**
 - 5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to relocate its existing HH program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program.

Capital and Working Capital Costs

In Section F.1, page 32, the applicant projects no capital costs. In Sections F.10 and F.11, page 35, the applicant states there are no projected start-up expenses or initial operating expenses because it is an existing facility which 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 Forms A and B, the applicant projects revenues will exceed operating expenses in the first two full operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FMC Hickory Home Program	Operating Year 1 CY 2020	Operating Year 2 CY 2021
Total Treatments	6,520	7,112
Total Gross Revenues (Charges)	\$26,001,760	\$28,362,656
Total Net Revenue	\$3,075,010	\$3,343,234
Average Net Revenue per Treatment	\$472	\$470
Total Operating Expenses (Costs)	\$1,837,348	\$1,935,121
Average Operating Expense per Treatment	\$282	\$272
Net Income	\$1,237,662	\$1,408,113

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

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 relocate its existing HH program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program.

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

According to Table C of the January 2019 SDR, there are three facilities which provide home dialysis training and support in Catawba County. Information on these three facilities, from Table C of the January 2019 SDR, is provided below:

Catawba County Home Dialysis Patients				
Facilities with Home Dialysis Patients as of June 30, 2018				
Dialysis Facility	Owner	# HH Patients	# PD Patients	Total # Patients
FMC Hickory	Fresenius	9	0	9
FMC Hickory Home Program*	Fresenius	0	32	32
FMC of Catawba Valley	Fresenius	0	0	0

Source: January 2019 SDR, Table C.

*Standalone facility offering exclusively home training and support

In Section G, page 40, 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 it is not proposing to develop new services but instead to relocate existing services. The applicant further states it is the only provider of home dialysis services in Catawba County.

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

- The applicant adequately demonstrates that existing home dialysis training and support services are limited to a small number of locations.
- The proposal would not result in an increase in the number of dialysis stations in Catawba County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H, page 41, the applicant provides information about current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

FMC Hickory Home Program Current and Projected Staffing – FTEs			
	Current	To Be Added	Projected – CY 2021
Home Training Nurse	3.50	1.50	5.00
Dietitian	0.35	0.15	0.50
Social Worker	0.35	0.15	0.50
Clinical Manager	1.00	0.00	1.00
Administrator	0.10	0.00	0.10
In-service	0.10	0.00	0.10
Clerical	1.00	0.00	1.00
Chief Tech	0.10	0.00	0.10
Equipment Technician	0.15	0.00	0.15
Total	6.65	1.80	8.45

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 Sections H.3 and H.4, page 42, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1 and H-2. In Section I, page 46, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating his support for the proposed project and his intent to continue serving as medical director for the facility.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 45, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

FMC Hickory Home Program – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Referral to FMC Hickory
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	On site (currently at FMC Hickory) On site On site
Psychological counseling	Catawba County Behavioral Health
Isolation – hepatitis	NA*
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	Horizon Surgical Center, Dr. Randal Bast
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	NC DHHS, Vocational Rehabilitation and Independent Living Services
Transportation	DSS of Catawba County, Greenway Transportation, Premier Medical Transportation, Specialty Transport

*On page 45, the applicant states that all HH training is performed in individual patient rooms with equipment assigned to the patient and is essentially isolation treatment by its nature.

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

In Section I, pages 46-47, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-2 through I-5.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

- (11) Repealed effective July 1, 1987.

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 59, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

FMC Hickory Home Program Historical Payor Mix CY 2018	
Payment Source	% Total Patients (PD only)
Self-Pay/Indigent/Charity	0.52%
Medicare	43.60%
Medicaid	0.21%
Commercial Insurance	34.36%
Medicare/Commercial	18.51%
Misc. (including VA)	2.81%
Total	100.00%

FMC Hickory Historical Payor Mix CY 2018	
Payment Source	% Total Patients (HH only)
Self-Pay/Indigent/Charity	0.20%
Medicare	78.91%
Commercial Insurance	9.63%
Medicare/Commercial	11.27%
Total	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**
Catawba	17%	51%	25%	13%	10%	13%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table>; Latest Data 7/1/17 as of 7/17/18

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

**"*Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable.*"

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26²) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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

²<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

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 58, 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 58, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 56, 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 Hickory Home Program Projected Payor Mix CY 2021			
Payment Source	% Total Patients	% HH Patients	% PD Patients
Self-Pay/Indigent/Charity	1.92%	0.20%	0.52%
Medicare	50.00%	78.91%	43.60%
Medicaid	1.92%	0.00%	0.21%
Commercial Insurance	28.85%	9.63%	34.36%
Medicare/Commercial	15.38%	11.27%	18.51%
Misc. (including VA)	1.92%	0.00%	2.81%
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 1.92 percent of total services will be provided to self-pay,

indigent, and charity care patients; 65.38 percent to patients covered in part or in whole by Medicare; and 1.92 percent to Medicaid patients.

On pages 56-57, 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 from the existing facility as well as from another facility with the patient population proposed to be served at the completion of this project.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 58, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 60, 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

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 relocate its existing HH program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program.

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

According to Table C of the January 2019 SDR, there are three facilities which provide home dialysis training and support in Catawba County. Information on these three facilities, from Table C of the January 2019 SDR, is provided below:

Catawba County Home Dialysis Patients				
Facilities with Home Dialysis Patients as of June 30, 2018				
Dialysis Facility	Owner	# HH Patients	# PD Patients	Total # Patients
FMC Hickory	Fresenius	9	0	9
FMC Hickory Home Program*	Fresenius	0	32	32
FMC of Catawba Valley	Fresenius	0	0	0

Source: January 2019 SDR, Table C.

*Standalone facility offering exclusively home training and support

In Section N, pages 61-62, 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 61, 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 114 dialysis facilities located in North Carolina.

In Section O, page 66, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 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.

NA

The applicant proposes to relocate its existing HH program at FMC Hickory, with its two dedicated dialysis stations, to FMC Hickory Home Program for the purpose of expanding a facility exclusively serving HH and PD patients. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving HH and PD patients.