

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 3, 2020

Findings Date: April 3, 2020

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: L-11839-20

Facility: FMC Tarboro

FID #: 150155

County: Edgecombe

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

Project: Relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate no more than 4 dialysis stations from BMA East Rocky Mount to Fresenius Medical Clinic (FMC) Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion.

Need Determination

The applicant does not propose to add stations via either the facility need methodology, or the county need methodology published in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, is applicable to this review because the applicant proposes to relocate dialysis stations. Policy ESRD-2 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 State Medical Facilities Plan, and*
- 3. 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 State Medical Facilities Plan.”*

Both BMA East Rocky Mount and FMC Tarboro are in Edgecombe County; as a result, there will be no change in the dialysis station inventory. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Edgecombe County.

(2) Repealed effective July 1, 1987.

- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	Last Full Operating Year CY 2019		2 ND Fully Operating Year CY 2022	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Edgecombe	37	90.24%	40.87	91.08%
Halifax	3	7.32%	3.00	6.69%
Nash	1	2.44%	1.00	2.23%
Total	41	100.00%	44.87	100.00%

Source: Section C, page 17

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

Analysis of Need

In Section C, pages 19-21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 19, the applicant states:

“The facility census of FMC Tarboro has been rapidly increasing. On December 31, 2018, the census of this facility was only 26 patients. A year later, the census was 41 patients. The growth has been extraordinary, and by all indications, growth of this facility will continue. Additional stations are need [sic] at FMC Tarboro in order to meet the dialysis needs of the patients choosing dialysis at this location.”

The information is reasonable and adequately supported based on the following:

- There was a 57.7% growth in the patient census from December 31, 2018 to December 31, 2019.

- FMC Tarboro is currently operating at 102.5% capacity, with 41 patients on 10 stations. Due to the high utilization, the facility is operating a third dialysis shift. The applicant states that a third shift is problematic for facilities in rural areas due to the lack of transportation services.
- The applicant adequately projects the population to be served as 45 patients dialyzing on 14 stations at the facility by the end of the second operating year of the project, which is a utilization rate of 80.4%, or 3.21 patients per station.

Projected Utilization

In Section Q, the applicant provides the projected utilization, as illustrated in the following table.

FMC Tarboro In-Center Projections	
Begin with the facility census of patients residing in Edgecombe County as of December 31, 2019.	37
Project the patient population forward for one year to December 31, 2020 using the Five-Year AACR of 5.3% for Edgecombe County.	$37 \times 1.053 = 39.0$
Add the patients residing in other counties. This is the projected starting census of this facility.	$39.0 + 4 = 43.0$
Project the Edgecombe County patient population forward for one year to December 31, 2021 using the Five-Year AACR of 5.3% for Edgecombe County.	$39.0 \times 1.053 = 41.0$
Add the patients residing in Halifax and Nash counties. This is the projected ending census for Operating Year 1.	$41.0 + 4 = 45$
Project the Edgecombe County patient population forward for one year to December 31, 2022.	$41.0 \times 1.053 = 43.2$
Add the patients residing in Halifax and Nash counties. This is the projected ending census for Operating Year 2.	$43.2 + 4 = 47.2$

The applicant proposes to add four dialysis stations to the existing FMC Tarboro, for a total of 14 dialysis stations upon completion of this project. In Section Q, page 69, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the beginning census as of December 31, 2019. This information is reported in the ESRD Data Collection forms submitted to the Agency.
- The applicant assumes the Edgecombe patient population projected to be served at FMC Tarboro will increase annually at a rate of 5.3 percent, which is the Five-Year Average Annual Change Rate (AACR) for Edgecombe County published in the 2020 SMFP.

- The applicant does not project any change in the number of patients residing in other counties but assumes these patients will continue to dialyze at the facility by choice. The applicant adds these patients to the projected census at the appropriate time.
- The project is scheduled for completion December 31, 2020. The applicant projects the first two full operating years of the project will be January 1, 2021–December 31, 2021 (CY2021) and January 1, 2022–December 31, 2022 (CY2022).

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2021) the facility is projected to serve 45 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 47 in-center patients.

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

- OY1: 3.21 patients per station per week or 80.36% (45 patients / 14 stations = 3.2143/4 = 0.8036 or 80.4%)
- OY2: 3.40 patients per station per week or 83.9% (47 patients / 14 stations = 3.3571/4 = 0.8393 or 83.9%)

The projected utilization of 3.21 patients per station per week at the end of OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on historical utilization.
- The applicant assumes a projected annual growth rate of 5.3 percent for Edgecombe County patient census at FMC Tarboro, which is equal to the Edgecombe County Five-Year AACR as published in the 2020 SMFP. The applicant does not project growth for its patients who do not reside in Edgecombe County.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 22, the applicant states:

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

...

...Medicare (includes Medicare Advantage treatments) represented 79.81% of North Carolina dialysis treatments in Fresenius related facilities in FY 2018; Medicaid treatments represented an additional 6.67% of treatments in our facilities for FY 2018."

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

FMC Tarboro In-Center Patients Projected Payor Mix CY 2022	
Primary Payor Source at Admissions	% of Total Patients
Self-Pay	0.39%
Insurance*	18.41%
Medicare*	65.22%
Medicaid*	9.09%
Other:	3.55%
Medicare/Commercial	
Other: Misc. Incl. VA	3.34%
Total	100.00%

The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical treatment volumes at FMC Tarboro.
- Projections are based on the assumption that there will be no changes to the payor mix as a result of this project.

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

The applicant proposes to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion.

The following tables, summarized from Section A.4, page 7 of the application, show the number of dialysis stations FMC Tarboro and BMA East Rocky Mount will have upon completion of this project and any other related projects still under review or development.

FMC Tarboro		
Stations	Description	Project ID #
10	Total existing certified stations as reported in the SMFP in effect on the day the review will begin	
4	Stations to be added as part of this project	L-11839-20
14	Total stations upon completion of all facility projects	
BMA East Rocky Mount		
Stations	Description	Project ID #
30	Total existing certified stations as reported in the SMFP in effect on the day the review will begin	
-4	# of stations to be deleted as part of this project	
4	# of stations previously approved to be added but not yet certified	L-11483-18
2		L-11580-18
-10	# of stations previously approved to be deleted but not yet certified	L-11374-17
-1	# of stations proposed to be deleted in an application still under review	L-11838-20
21	Total # of stations upon completion of all facility projects	

In Section D, page 25, 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 25, the applicant states:

“The patients remaining at BMA East Rocky Mount will not be adversely impacted by this proposal. The 2020 SMFP indicates that BMA East Rocky Mount qualifies to apply for up to 11 additional dialysis stations in 2020. BMA is preparing an application for nine new stations at BMA East Rocky Mount to be filed on March 16, 2020 for the review commencing on April 1, 2020.”

In Section Q, the applicant provides projected utilization for BMA East Rocky Mount, as illustrated in the following table.

BMA East Rocky Mount In-Center Patient Projections		
	Edgecombe	Nash
Begin with the facility census of patients residing in Edgecombe and Nash Counties as of December 31, 2019.	78	31
Project the patient population forward for one year to December 31, 2020 using the Five-Year AACR of 5.3% for Edgecombe County and 1.1% for Nash County.	$78 \times 1.053 = 82.1$	$31 \times 1.011 = 31.3$
Subtract 32 Edgecombe County patients projected to transfer to FKC Boice-Willis.	$82.19 - 32 = 50.1$	31.3
Sum Edgecombe and Nash counties' projected census, and add the patients residing in other counties. This is the projected census for December 31, 2020, the date the stations are projected to relocate.	$50.1 + 31.3 + 4 = 85.5$	

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the beginning census as of December 31, 2019. This information is reported in the ESRD Data Collection forms submitted to the Agency.
- The applicant assumes the Edgecombe County patient population projected to be served at BMA East Rocky Mount will increase annually at a rate of 5.3 percent, which is the Five-Year AACR for Edgecombe County published in the 2020 SMFP.
- In Project ID# L-11374-17 (develop a new 10-station dialysis facility by relocating 10 stations from BMA Rocky Mount to the new FKC Boice-Willis), the applicant projected that 32 Edgecombe County patients will transfer their services to the new facility that is expected to be certified by December 31, 2020. In this application, the applicant continues to project that these patients will transfer to the new facility.

- The applicant projects the patients from Nash County will increase annually at a rate of 1.1 percent, which is the Five-Year AACR for Nash County published in the 2020 SMFP. The applicant states that patients from Nash County make up to 27.43 percent of the facility census.
- As of December 31, 2019, the facility was serving four patients from Halifax and Warren Counties. The applicant does not project any change in these patients but assumes these patients will continue to dialyze at the facility by choice. The applicant adds these patients to the projected census at the appropriate time.
- The project to relocate the stations from BMA East Rocky Mount is scheduled for completion by December 31, 2020. The projected utilization rate by the end of December 13, 2020 is 4.07 patients per stations per week or a 101.79% utilization rate. (85.5 patients / 21 stations = 4.0714 / 4 = 1.0179 or 101.79%).

Projected utilization is reasonable and adequately based on the following:

- The applicant projects future utilization based on historical utilization.
- The applicant assumes a projected annual growth rate of 5.3 percent for Edgecombe County and 1.1 percent for Nash County patient census at BMA East Rocky Mount, which is equal to the respective Edgecombe County and Nash County Five-Year AACRs as published in the 2020 SMFP.
- The applicant does not project any change in the number of patients residing in other counties but assumes these patients will continue to dialyze at the facility by choice. The applicant adds these patients to the projected census at the appropriate time.
- The applicant projects the patient census assuming 32 patients will transfer their services to the new facility, FKC Boice-Willis.
- The applicant demonstrates that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 2.8 patients per station per week required by 10A NCAC 14C .2203(b).

In Section D, page 28, the applicant states:

“This relocation will not have any impact on the patients dialyzing at the facility, or any of the above listed groups. BMA has committed oto [sic] file a CON application for additional stations in March 2020, for the review commencing April 1, 2020.”

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 following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
 - The applicant adequately demonstrates that 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.

C

The applicant proposes to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion.

In Section E, pages 30-31, 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:

Failure to relocate stations to FMC Tarboro-The applicant states that this was not an effective alternative because of the tremendous growth of the patient population at this facility. The applicant states that the growth in the facility's census in 2019 was greater than 57%, therefore, more capacity is needed to meet the growing need at FMC Tarboro.

Relocate Fewer than Four Stations-The applicant states that this is not an effective alternative because the facility is projected to serve 45 in-center patients by the end of Operating Year 1 for a utilization rate of 3.21 patients per station which exceeds the minimum requirement of 2.8 patients per station.

Relocate Stations to the New FKC Boice-Willis Facility-The applicant states that this was not an effective alternative because patients residing in Tarboro would have to travel approximately 18 miles to receive services at the new FKC Boice-Willis.

Create a New Facility by Relocating ten Stations from BMA East Rocky Mount-The applicant states that is not a cost-effective alternative because a new facility requires a 28 in-center patient census. The applicant states that for patients served at BMA facilities in the area, there were no other locations that would be central to a population of 28 patients. In addition, development of a new facility would not be cost-effective at this time.

On page 30, the applicant states its proposal is the most effective alternative because it is the most cost-effective way to meet the growing needs of the patients choosing dialysis with BMA at FMC Tarboro.

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 no more than 4 in-center stations from BMA East Rocky Mount to Fresenius Medical Clinic Tarboro for a total of no more than 14 stations upon completion of the project.**
 - 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 4 in-center stations at BMA East Rocky Mount for a total of no more than 22 in-center stations at BMA East Rocky Mount upon completion of this project, Project ID# L-11374-17 (relocate 10 stations), Project ID# L-11483-18 (add 4 stations) and Project ID# L-11580-18 (add 2 stations).**
 - 4. 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.

The applicant proposes to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion.

Capital and Working Capital Costs

In Section Q, page 75, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Cost	
Non-Medical Equipment	\$3000
Furniture	\$12,000
Total	\$15,000

In Section F, page 34, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project since it not required for relocating stations to an operational facility.

Availability of Funds

In Section F.2, page 32, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	Bio-Medical Applications of North Carolina, Inc.	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$15,000	\$15,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$15,000	\$15,000

* OE = Owner's Equity

Exhibit F-2 contains a letter from the Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. The letter states that the Consolidated Balance Sheets from Fresenius Medical Care Holdings, Inc., for year ending December 31, 2018, show that Fresenius Medical Care Holdings, Inc. had \$1.8 billion in cash and over \$20 billion in assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, 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 Tarboro	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	6,511	6,824.70
Total Gross Revenues (Charges)	\$40,960,909	\$42,934,451
Total Net Revenue	\$2,268,606	\$2,377,910
Average Net Revenue per Treatment	\$348.43	\$348.43
Total Operating Expenses (Costs)	\$2,169,155	\$2,171,852
Average Operating Expense per Treatment	\$333.15	\$318.23
Net Income/Profit	\$99,451	\$206,058

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

On page 113, the 2020 SMFP defines the service area for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area*

except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Edgecombe County as of December 31, 2018.

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station Per Week
BMA East Rocky Mount	30	109	90.83%	3.6333
Fresenius Medical Clinic Tarboro	10	26	65.00%	2.6000
Dialysis Care of Edgecombe County	35	72	51.43%	2.0571
Fresenius Kidney Care Boice-Willis*	0	0		
Total	75	207		

Source: 2020 SMFP, Table B, page 155

*Fresenius Kidney Care Boice-Willis is a new 10-station dialysis facility. The facility stations were not certified as of December 31, 2018.

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

“This project does not create new dialysis stations, but merely relocates existing dialysis stations. The stations are needed at FMC Tarboro to support the growing patient census at the facility.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposal would not result in an increase in the number of certified dialysis stations in Edgecombe County.
- The applicant adequately demonstrates the need patients have for the additional dialysis stations at this specific location in addition to the approved 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 Q, page 86, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

FMC Tarboro Facility Staffing		
Position	Current # FTEs	Projected # FTEs
	As of January, 2020	OY2 (CY2022)
Administrator (FMC Clinical Manager)	1.0	1.0
Registered Nurses (RNs)	1.5	2.0
Technicians (PCT)	4.0	5.0
Dietician	0.33	0.4
Social Worker	0.33	0.4
Maintenance (Equipment Technician)	0.2	0.2
Administration/Business Office	0.75	0.75
Other: FMC Director Operations	0.15	0.15
Other: In Service	0.15	0.15
Other: Chief Technician	0.15	0.15
Total	8.56	10.20

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2 and H.3, page 38, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 39, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

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 40, the applicant states that the following ancillary and support services are necessary for the proposed services:

FMC Tarboro – Ancillary and Support Services	
Services	Provider
Self-care training (in-center) Home training HH PD Accessible follow-up program	Patients are referred to Edgecombe Home Dialysis for peritoneal dialysis training, and Greenville Dialysis for home hemodialysis
Isolation for hepatitis B positive patients	On site
Nutritional Counseling	On site
Social Work Services	On site
Laboratory Services	On site
Vascular Services Pediatric Nephrology	Referral to Vidant Health
Acute dialysis in an acute care setting	Referred to Vidant Health Edgecombe, and Vidant Health in Greenville
Transplantation Services	Referral to Vidant Health
Emergency Care	Provided by facility staff until ambulance arrival
Blood bank services X-Ray, Diagnostic and Evaluation Services Psychological Counseling	Referral to Vidant Health
Vocational Rehabilitation Counseling and Services	Referral to NC DHHS Vocational Rehabilitation Services Raleigh
Transportation	Edgecombe County Department of Social Services or Angel Wheels

In Section I, page 41, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

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.

C

In Section K, page 43, the applicant states it does not propose to construct new space or upfit or renovate existing space as part of the proposed project. Line drawings are included in Exhibit K-2.

On page 43, the applicant states the facility has an existing space available to accommodate the relocated stations, therefore, construction is not necessary.

On page 43, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 44, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 48, the applicant provides the historical payor mix during CY 2018 for the proposed services, as shown in the table below.

FMC Tarboro In-Center Patients Historical Payor Mix CY 2018	
Primary Payor Source at Admissions	% of Total Patients
Self-Pay	0.39%
Insurance*	18.41%
Medicare*	65.22%
Medicaid*	9.09%
Other: Medicare/Commercial	3.55%
Other: Misc. Incl. VA	3.34%
Total	100.00%

Source: Section L, page 48

*Including any managed care plans

In Section L, page 47, the applicant provides the following comparison.

FMC Tarboro	Percentage of Total Patients Served (all modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered*
Female	60.0%	53.8%
Male	40.0%	46.2%
Unknown	0.0%	0.0%
64 and Younger	52.5%	80.3%
65 and Older	47.5%	19.7%
American Indian	0.0%	0.8%
Asian	0.0%	0.3%
Black or African-American	87.5%	57.8%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	10.0%	36.3%
Other Race	2.5%	4.7%
Declined / Unavailable	0.0%	0.0%

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

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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, in Section L, page 49, the applicant states:

“Fresenius related dialysis facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. BMA facilities are responsible, and do provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”

In Section L, page 49, 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.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

FMC Tarboro In-Center Patients Projected Payor Mix CY 2022	
Primary Payor Source at Admissions	% of Total Patients
Self-Pay	0.39%

Insurance*	18.41%
Medicare*	65.22%
Medicaid*	9.09%
Other: Medicare/Commercial	3.55%
Other: Misc. Incl. VA	3.34%
Total	100.00%

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.39% of total services will be provided to self-pay patients, 68.77% to Medicare patients (including Medicare/Commercial), and 9.09% to Medicaid patients.

On page 50, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical treatment volumes at FMC Tarboro.
- Projections are based on the assumption that there will be no changes to the payor mix as a result of this project.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 50-51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 52, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate no more than 4 dialysis stations from BMA East Rocky Mount to FMC Tarboro for a total of no more than 14 stations at FMC Tarboro upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area*”

except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Edgecombe County as of December 31, 2018.

Facility Name	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station Per Week
BMA East Rocky Mount	30	109	90.83%	3.6333
Fresenius Medical Clinic Tarboro	10	26	65.00%	2.6000
Dialysis Care of Edgecombe County	35	72	51.43%	2.0571
Fresenius Kidney Care Boice-Willis*	0	0		
Total	75	207		

Source: 2020 SMFP, Table B, page 155

*Fresenius Kidney Care Boice-Willis is a new 10-station dialysis facility. The facility stations were not certified as of December 31, 2018.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 53, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider.

...

There are currently three dialysis facilities within Edgecombe County offering in-center dialysis. With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to patients of the area who have expressed their desire to receive dialysis care and treatment at FMC Tarboro.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 54, the applicant states:

“Approval of this application will allow the FMC Tarboro facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

Regarding the impact of the proposal on quality, in Section N, page 54, the applicant states:

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 54, the applicant states:

“All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina... Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

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 based on 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 Section Q, pages 62-67, 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 125 of this type of facility located in North Carolina.

In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and

considering the quality of care provided at all 125 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification 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- The applicant does not propose to establish a new kidney disease treatment center or dialysis facility. Therefore, this performance standard is not applicable to this review.
- (b) *An applicant proposing to increase the number of dialysis stations in:*
(1) *an existing dialysis facility; or*
(2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*
shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.
- C- In Section Q, pages 69-70, the applicant projects FMC Tarboro will serve 45 patients on 14 stations, or a rate of 3.21 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 18-19, and Section Q, pages 69-70, 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.