

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2020

Findings Date: December 17, 2020

Project Analyst: Kim Meymandi

Team Leader: Gloria C. Hale

Project ID #: K-11985-20

Facility: Fresenius Medical Care Tar River

FID #: 130122

County: Franklin

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

Project: Add no more than two dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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 “the applicant” or BMA) proposes to add no more than two dialysis stations to the existing Fresenius Medical Care Tar River (FMC Tar River) facility pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

Need Determination (Condition 2)

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Franklin County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the facility as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for FMC Tar River on page 156 of the 2020 SMFP is 89.58 percent or 3.58 patients per station per week, based on 43 in-center dialysis patients and 12 certified dialysis stations (43 patients / 12 stations = 3.58; 3.58 / 4 = 89.58%).

As shown in Table 9E, on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to four additional stations; thus, the applicant is eligible to apply to add up to four stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new stations to the facility, which is consistent with the 2020 SMFP calculated facility need determination for up to four dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.5 (a) and (d), pages 14-16, Section N, page 54; Section O, pages 56-59; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.5 (b) and (d), pages 15-16, Section C.7, pages 25-26; Section L, pages 48-51; Section N, pages 53-54; and referenced exhibits. The information provided by the applicant is

reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.5 (c) and (d), pages 16-17; Section N, pages 53-54; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of safety and quality, equitable access, and maximum healthcare value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

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

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

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at FMC Tar River.

FMC Tar River Dialysis

# of Stations	Description	Project ID #
14	Total # of existing certified stations as reported in the SMFP in effect on the day the review will begin	
2	# of stations to be added as part of this project	K-11985-20
	# of stations to be deleted as part of this project	
4 ¹	# of stations previously approved to be added but not yet certified	K-11767-19
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
	# of stations proposed to be deleted in an application still under review	
20	Total # of stations upon completion of all facility projects	

¹Project I.D. # K-11767-19 authorized BMA to add four stations. The project was certified March 30, 2020 and deemed complete August 20, 2020.

As outlined in the table above, in this application, the applicant proposes to add two dialysis stations for a total of 20 stations upon the project completion.

Patient Origin

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-Graham counties and Avery-Mitchell-Yancey counties.*” Thus, the service area for this facility is Franklin County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 19, the applicant provides the patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients at FMC Tar River for the last full operating year (CY2019), as summarized in the table below.

FMC Tar River Patient Origin - CY2019

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Franklin	44	89.8%	0	0.0%	5	71.4%
Halifax	1	2.0%	0	0.0%	0	0.0%
Wake	4	8.2%	0	0.0%	0	0.0%
Vance	0	0.0%	0	0.0%	1	14.3%
Virginia	0	0.0%	0	0.0%	1	14.3%
Total	49	100.0%	0	0.0%	7	100.0%

Totals may not sum due to rounding

The applicant states that the projected IC, HH, and PD patient origin is based upon the facility census as of June 30, 2020 and provides the following table from page 20.

FMC Tar River Patient Origin – June 30, 2020

COUNTY	# IC PATIENTS	# HH Patients	# PD Patients
Franklin	52.0	1.0	5.0
Halifax	1.0	0.0	0.0
Vance	0.0	0.0	1.0
Virginia	0.0	0.0	1.0
Total	53.0	1.0	7.0

While FMC Tar River is certified to provide home hemodialysis training and support, as indicated in the table above they did not have any home hemodialysis patients at the end of 2019. The following table summarizes projected patient origin for the second full operating year (CY2023) following project completion, as provided in Section C.3, page 20.

FMC Tar River Projected Patient Origin - CY2023

COUNTY	# IC PATIENTS	% IC Total	# HH Patients	% HH Total	# PD Patients	% PD Total
Franklin	58.0	98.3%	4.4	100%	9.4	82.4%
Halifax	1.0	1.7%	0.0	0.0%	0.0	0.0%
Vance	0.0	0.0%	0.0	0.0%	1.0	8.8%
Virginia	0.0	0.0%	0.0	0.0%	1.0	8.8%
Total	59.0	100.0%	4.4	100.0%	11.4	100.0%

Totals may not sum due to rounding

In Section C, pages 20-24, the applicant provides the assumptions and methodology it used to project IC, HH, and PD patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.3, pages 20-24, 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 24, the applicant states:

“The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. ... BMA has identified the population to be served as 57.5 in-center dialysis patients, and 13.1 home dialysis patients, projected to be dialyzing with the facility as of the end of the first Operating Year of the project. The in-center utilization rate is calculated to be 2.87 patients per station, or 71.85% utilization.”

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

- According to the 2020 SMFP, as of December 31, 2018, FMC Tar River was operating at a rate of 3.58 patients per station per week, or 89.58 percent of capacity.
- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology. The discussion regarding the facility need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant projects a utilization rate of 2.9 in-center patients per station per week dialyzing at FMC Tar River as of the end of the first 12 months of operation following certification of the additional stations which exceeds the performance standards 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 additional stations as set forth in the Performance Standards in Rule 10A NCAC 14C .2203

Projected Utilization

In-Center Projected Utilization

In Section C.3, page 21, and in Form C Utilization subsection of Section Q, the applicant provides the methodology used to project the patient census for OY1 and OY2, as summarized in the table below.

FMC TAR RIVER IN-CENTER PATIENTS

Begin with facility census of Franklin County patients as of June 30, 2020.	52
Project Franklin County patients forward six months to December 31, 2020, using one half the Franklin County AACR of 6.3%	$52 \times 1.0315 = 53.6$
Project Franklin County patients forward for one year to December 31, 2021, using the Franklin County AACR of 6.3%.	$53.6 \times 1.063 = 57.0$
Subtract the patients projected to change to home dialysis	$57.0 - 2 = 55.0$
Add the patient residing in Halifax County. This is the starting census for the project.	$55.0 + 1 = 56.0$
Project Franklin County patients forward one year to December 31, 2022, using the Franklin County AACR of 6.3%	$55.0 \times 1.063 = 58.5$
Subtract the patients projected to change to home dialysis	$58.5 - 2 = 56.5$
Add the patient residing in Halifax County. This is the projected ending census for Operating Year (OY1).	$56.5 + 1 = 57.5$
Project Franklin County patients forward one year to December 31, 2023, using the Franklin County AACR of 6.3%	$56.5 \times 1.063 = 60.0$
Subtract the patients projected to change to home dialysis.	$60.0 - 2 = 58.0$
Add the patient residing in Halifax County. This is projected ending census for Operating Year (OY2).	$58.0 + 1 = 59.0$

In both Section C, pages 19-21, and Section Q, pages 68-70, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the FMC Tar River patient census as of June 30, 2020 which was 53 total IC patients: 52 Franklin County patients and 1 Halifax County patient.
- The Halifax County patient will be carried forward into projections of future patient census. However, the applicant does not project any growth of the Halifax County patients.
- The applicant states the home patient population in North Carolina is increasing and projects that beginning with FY 2021 two patients per year will change from in-center dialysis to home dialysis with one patient choosing home peritoneal dialysis and one choosing home hemodialysis.
- The applicant projects the Franklin County patient census at FMC Tar River will increase by the Franklin County Five Year AACR of 6.3% as published in the 2020 SMFP.

Therefore, at the end of OY1 (CY2022) FMC Tar River is projected to serve 57.5 in-center patients on 20 stations; and at the end of OY2 (CY2023) the facility is projected to serve 59 in-center patients on 20 stations.

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

- OY1: 2.9 patients per station per week, or 71.9% utilization [$57.5 / 20 \text{ stations} = 2.9 / 4 = 0.725$ or 72.5%]
- OY 2: 2.9 patients per station per week, or 73.7% utilization [$59.0 / 20 \text{ stations} = 3.0 / 4 = 0.750$ or 75.0%].

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

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 6.3 percent for Franklin County patients which reflects the Franklin County Five-Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant assumes the patient residing outside of Franklin County will continue to dialyze at FMC Tar River and is added to the projections without any future growth through the first two operating years of the project.

- The projected utilization rate by the end of OY1 and OY2 is above the minimum standard of 2.8 patients per station per week.

Peritoneal and Home Hemodialysis Patients

In both Section C, pages 22-24, and Section Q, pages 71-73, the applicant provides the assumptions and methodology used to project PD and HH utilization, which is summarized below.

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the FMC Tar River PD and HH patient census as of June 30, 2020 which was:
 - Seven total PD patients: Five Franklin County patients and one patient each from Vance County and Virginia, and
 - One total HH patient from Franklin County.
- The non-Franklin County PD patients will be carried forward into projections of future patient census however, the applicant does not project any growth of the non-Franklin County PD patients.
- The applicant projects that two IC patients will change to home dialysis each year beginning in FY 2021 with one choosing PD and the other HH.
- The applicant projects the facility patients who reside in Franklin County will grow at the Five-Year AACR for Franklin County, 6.3%, as published in the 2020 SMFP.

FMC TAR RIVER HOME HEMODIALYSIS PATIENTS

Begin with the Franklin County patient population as of June 30, 2020.	1
Project Franklin County patient population forward six months to December 31, 2020, using one half the Franklin County AACR of 6.3%	$1 \times 1.0315 = 1.03$
Project Franklin County patients forward for one year to December 31, 2021, using the Franklin County AACR of 6.3%.	$1.03 \times 1.063 = 1.10$
Add the patient projected to change to home hemodialysis. This is the starting census for the project.	$1.10 + 1 = 2.10$
Project Franklin County patient population forward one year to December 31, 2022, using the Franklin County AACR of 6.3%	$2.10 \times 1.063 = 2.23$
Add the patient projected to change to home hemodialysis. This is the projected ending census for Operating Year (OY1).	$2.23 + 1 = 3.23$
Project Franklin County patients forward one year to December 31, 2023, using the Franklin County AACR of 6.3%	$3.23 \times 1.063 = 3.43$
Add the patient projected to change to home hemodialysis. This is projected ending census for Operating Year (OY2).	$3.43 + 1 = 4.43$

FMC TAR RIVER HOME PERITONEAL DIALYSIS PATIENTS

Begin with the Franklin County patient population as of June 30, 2020.	5
Project Franklin County patient population forward six months to December 31, 2020, using one half the Franklin County AACR of 6.3%	$5 \times 1.0315 = 5.16$
Project Franklin County patients forward for one year to December 31, 2021, using the Franklin County AACR of 6.3%.	$5.16 \times 1.063 = 5.48$
Add the patient projected to change to home peritoneal dialysis.	$5.48 + 1 = 6.48$
Add the patients residing in Vance County and Virginia. This is the projected starting census for the project.	$6.48 + 2 = 8.48$
Project Franklin County patient population forward one year to December 31, 2022, using the Franklin County AACR of 6.3%	$6.48 \times 1.063 = 6.89$
Add the patient projected to change to home peritoneal dialysis.	$6.89 + 1 = 7.89$
Add the patients residing in Vance County and Virginia. This is the projected ending census for Operating Year (OY1).	$7.89 + 2 = 9.89$
Project Franklin County patients forward one year to December 31, 2023, using the Franklin County AACR of 6.3%	$7.89 \times 1.063 = 8.39$
Add the patient projected to change to home peritoneal dialysis.	$8.39 + 1 = 9.39$
Add the patients residing in Vance County and Virginia. This is the projected ending census for Operating Year (OY2).	$9.39 + 2 = 11.39$

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant projects future utilization based on the most recent historical patient census.
- The applicant utilized a projected annual growth rate of 6.3 percent for Franklin County patients which reflects the Franklin County Five-Year AACR as published in Table 9C of the 2020 SMFP.
- The applicant conservatively does not project growth for its non-Franklin County

PD patients.

Access to Medically Underserved Groups

In Section C.7, pages 25-26, 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 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.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

On page 26, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FMC Tar River
Estimated Percentage of Patients by Group CY 2023

Medically Underserved Groups	Percentage of Total Patients
Low income persons	48.3%
Racial and ethnic minorities	76.7%
Women	43.3%
Handicapped persons	40.0%
The elderly	51.7%
Medicare beneficiaries	96.7%
Medicaid recipients	45.0%

Single patients may be counted in multiple categories

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

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 that maintaining the status quo is not an effective alternative due to the growth rate at the facility.
- *Applying for fewer than two stations* - The applicant states that this alternative did not adequately address the utilization rate and therefore was less effective.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on 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

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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, the certificate holder shall develop no more than two additional in-center dialysis stations for a total of no more than 20 in-center stations at FMC Tar River upon completion of this project.**
 - 3. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below:

Site Costs	\$0.00
Construction Costs	\$16,500.00
Miscellaneous Costs	\$7,500.00
Total	\$24,000.00

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 33-34, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because FMC Tar River is 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	BMA of North Carolina, Inc.	Total
Loans	\$0	\$ 0
Accumulated reserves or OE *	\$24,000	\$24,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$ 24,000	\$24,000

* OE = Owner's Equity

Exhibit F-2 contains a letter dated October 15, 2020, 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, 2019, show that Fresenius Medical Care Holdings, Inc. had \$446 million in cash and over \$25 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 Section Q, Form F.2, page 78, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	OY1 CY2022	OY2 CY2023
Total Treatments	10,153	10,764
Total Gross Revenues (Charges)	\$63,870,686	\$67,718,567
Total Net Revenue	\$3,209,697	\$3,485,347
Average Net Revenue per Treatment	\$316.14	\$323.79
Total Operating Expenses (Costs)	\$3,130,513	\$3,243,595
Average Operating Expense per Treatment	\$308	\$301
Net Income	\$79,184	\$241,752

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 based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for the county need methodology 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-Graham counties and Avery-Mitchell-Yancey counties.*” FMC Tar River is in Franklin County.

Thus, the service area for this application is Franklin County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, there are 3 existing or approved dialysis facilities in Franklin County, one of which is owned and operated by FMC. Information on these dialysis facilities, from Table 9B of the 2020 SMFP, is provided below:

**Franklin County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2018**

Dialysis Facility	Owner	Certified Stations	# of IC Patients	Percent Utilization	Patients Per Station
FMC Tar River	BMA	12	43	89.58%	3.5833
Dialysis Care of Franklin County	DaVita	27	52	48.15%	1.9259
Bunn Dialysis ³	DaVita	0	0	0	0
Total		39	95		

Source: 2020 SMFP, Table 9B

³CON relinquished in 2020

In Section G.2, page 37, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Franklin County. The applicant states it is not projecting to serve patients currently served in another facility but rather the stations are needed to serve the rapidly growing patient census at FMC Tar River. Projected utilization starts with the current patient population of the facility and grows that patient census.

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

- There is a facility need determination in the 2020 SMFP at FMC Tar River for more than the proposed two dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

- (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

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

In Section Q Form H Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for FMC Tar River, as summarized below.

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
	As of 8/2020	OY1 (1/1/2022 to 12/31/2022)	OY2 (1/1/2023 to 12/31/2023)
Administrator	1.00	1.00	1.00
RNs	2.00	3.00	3.00
Home Training Nurse	0.50	1.25	1.25
Technicians (PCT)	5.00	8.00	8.00
Dietician	0.50	0.75	0.75
Social Worker	0.50	0.75	0.75
Maintenance	0.50	0.50	0.50
Admin/Business Office	1.00	1.00	1.00
Other: FMC Dir. Operations	0.15	0.15	0.15
Other: In-Service	0.15	0.15	0.15
Other: Chief Tech	0.15	0.15	0.15
TOTAL	11.45	16.70	16.70

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, page 39, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 40, 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

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

Ancillary and Support Services

In Section I, page 41 the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will be made available.

ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training	Provided by the facility
Home training	
HH	
PD	
Accessible follow-up program	
Isolation for hepatitis B positive patients	
Psychological counseling	Referral to Alliance Behavioral Healthcare
Nutritional counseling	FMC on site
Social Work services	FMC on site
Acute dialysis in an acute care setting	Referral to Rex Vascular or Wake Med Vascular
Emergency care	FMC on site until ambulance can arrive
Blood bank services	Maria Parham, Henderson
Diagnostic and evaluation services	Referral to Wake Radiology or UNC Radiology Wakefield
X-ray services	Referral to Wake Radiology or UNC Radiology Wakefield
Laboratory services	On site blood draw; analysis by Spectra Labs
Pediatric nephrology	Referral to UNC Hospitals
Vascular surgery	Referral to Rex Vascular or Wake Med Vascular
Transplantation services	UNC, Vidant and Duke UMC
Vocational rehabilitation & counseling	Franklin County Vocational Rehabilitation
Transportation	KARTS

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 42, 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.

- (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

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

In Section K, page 44, the applicant states that the project involves renovating 165 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 44, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 45, 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.

In Section K, pages 45-46, 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
- 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.

- (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 ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 49, the applicant provides the historical payor mix for FMC Tar River during the last full operating year (CY2019) for its existing services, as shown in the table below.

**FMC Tar River
 Historical Payor Mix CY 2019**

Payor Source	In-Center		HOME HEMODIALYSIS		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.53	1.08%	0.00	0.00%	0.00	0.00%
Insurance*	3.99	8.14%	1.30	65.31%	1.19	16.94%
Medicare*	28.54	58.24%	0.64	32.65%	4.92	70.30%
Medicaid*	0.68	1.39%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	14.64	29.88%	0.00	0.00%	0.89	12.76%
Miscellaneous (Incl. VA)	0.62	1.27%	0.04	2.04%	0.00	0.00%
Total	49.00	100.00%	2.00⁴	100.00%	7.00	100.00%

Totals may not sum due to rounding

*Including any managed care plans

⁴Facility ended 2019 with no HH patients. However, at some point during the year the facility provided care to two HH patients

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

	Percentage of Total Patients Served by the Facility or Campus during the Last Full OY	Percentage of the Population of the Service Area*
Female	43.3%	50.5%
Male	56.7%	49.5%
Unknown	0.0%	0.0%
64 and Younger	48.3%	82.9%
65 and Older	51.7%	17.1%
American Indian	0.0%	0.9%
Asian	0.0%	0.7%
Black or African-American	75.0%	25.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	21.7%	63.0%
Other Race	3.3%	9.4%
Declined / Unavailable	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>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 50, that the facility is not under any obligation to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3, page 50, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**FMC Tar River
 Projected Payor Mix CY2023**

Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.6	1.08%	0.00	0.00%	0.00	0.00%
Insurance*	4.8	8.14%	2.89	65.31%	1.93	16.94%
Medicare*	34.4	58.24%	1.45	32.65%	8.01	70.30%
Medicaid*	0.8	1.39%	0.00	0.00%	0.00	0.00%
Medicare/Commercial	17.6	29.88%	0.00	0.00%	1.45	12.76%
Miscellaneous (incl. VA)	0.7	1.27%	0.09	2.04%	0.00	0.00%
Total	59.0	100.00%	4.43	100.00%	11.39	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 1.08% of in-center dialysis services will be provided to self-pay patients, 88.12% to Medicare patients (including Medicare/Commercial), and 1.39% to Medicaid patients. In addition, 32.65% and 0.00% of HH services will be provided to Medicare and Medicaid patients, respectively, and 83.06% and 0.00% of PD services will be provided to Medicare (including Medicare/Commercial) and Medicaid patients respectively.

On page 50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix and treatment volumes of FMC Tar River.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 52, the applicant describes the extent to which health professional training programs in the area will 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

BMA proposes to add no more than two dialysis stations to the existing FMC Tar River pursuant to Condition 2 of the facility need methodology for a total of no more than 20 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for the county need methodology 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-Graham counties and Avery-Mitchell-Yancey counties.*” FMC Tar River is in Franklin County. Thus, the service area for this application is Franklin County. Facilities may serve residents of counties not included in their service area.

According to Table 9B of the 2020 SMFP, there are 3 existing or approved dialysis facilities in Franklin County, one of which is owned and operated by BMA. Information on these dialysis facilities, from Table 9B of the 2020 SMFP, is provided below:

**Franklin County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

Dialysis Facility	Owner	Certified Stations	# of IC Patients	Percent Utilization	Patients Per Station
FMC Tar River	BMA	12	43	89.58%	3.5833
Dialysis Care of Franklin County	DaVita	27	52	48.15%	1.9259
Bunn Dialysis ³	DaVita	0	0	0	0
Total		39	95		

Source: 2020 SMFP, Table 9B

³CON relinquished in 2020

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

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 Tar River 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.”

See also Sections B, F, and Q of the application and any exhibits.

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

“Quality of care is not negotiable. ... Our organizational mission statement captures this sentiment very well:

'We deliver superior care that improves that quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.'

See also Sections B and O of the application and any exhibits.

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

"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.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person."

See also Sections B, C and L of the application and any exhibits.

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, quality, and access because it adequately demonstrates the following:

- the need the population to be served has for the proposal, the proposal would not result in an unnecessary duplication of existing and approved health services, and the reasonableness of projected revenues and operating costs which collectively results in a cost-effective proposal.
- the quality of the care to be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

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 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 Form A Facilities, 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 over 120 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O.2, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” 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 Fresenius related facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2203 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 dialysis 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. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

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

- (b) An applicant proposing to increase the number of dialysis stations in:
 - (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 C, pages 20-22, and Form C in Section Q, the applicant projects that FMC Tar River will serve 57.5 in-center patients on 20 stations, or a rate of 2.9 patients per station per week or 72.5% ($57.5 / 20 = 2.875$ or 72.5%), as of the end of the first operating year (CY2022) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

- C- In Section C, pages 20-22, in Section Q, Form C, pages 68-70, the applicant provides the assumptions and methodology it used to project utilization of the facility.