

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 3, 2019

Findings Date: May 3, 2019

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: K-11669-19

Facility: FMC Tar River

FID #: 130122

County: Franklin

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

Project: Add no more than two dialysis stations for a total of no more than 14 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to add two dialysis stations to Fresenius Medical Care Tar River (FMC Tar River) for a total of 14 dialysis stations upon project completion.

Need Determination

The 2019 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 D in the January 2019 Semiannual Dialysis Report (SDR), there is a surplus of one dialysis station in Franklin County. Therefore, there is no county need determination for new dialysis stations in Franklin County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization

rate reported for FMC Tar River in the January 2019 SDR is 3.7000 patients per station per week. This utilization rate was calculated based on 37 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2018 (37 patients / 10 stations = 3.7 patients per station per week). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a potential maximum of two additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		92.50%
Certified Stations		10
Pending Stations		2
Total Existing and Pending Stations		12
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		37
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		30
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.4667
(ii)	Divide the result of step (i) by 12	0.0389
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.2333
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	45.6333
(v)	Divide the result of step (iv) by 3.2 patients per station	14.2604
	and subtract the number of certified and pending stations to determine the number of stations needed	2

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations and therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles* on page 31 of the 2019 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a and d), pages 8 and 10, respectively, Section K.1(g), page 44, Section N, page 53, Section O, pages 55-58, and Exhibits O-1 and O-2. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b and d), pages 8-10, Section C.3, pages 16-17, Section L, pages 47-51 and Section N, page 53. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 9-10, Section C.3, pages 16-17, Section K, pages 42-43 and Section N.1, page 55. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

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 above stated reasons.

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

C

BMA proposes to add no more than two dialysis stations to FMC Tar River for a total of no more than 14 dialysis stations upon project completion. FMC Tar River currently offers home hemodialysis (HHD) training and peritoneal dialysis (PD) training and support services.

Patient Origin

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

In Section C.8, page 19 and Section C.1, page 13, the applicant provides historical and projected patient origin for in-center (IC) patients, HHD patients and PD patients; in operating years 1 and 2 (OY1) and (OY2), as summarized in the following tables:

FMC Tar River			
Current Patient Origin			
As of December 31, 2018			
County	IC Patients	HHD Patients	PD Patients
Franklin	40	1	2
Halifax	1	0	0
Nash	0	0	1
Vance	1	1	0
Wake	1	0	0
Virginia	0	0	1
Total	43	2	4

Source: Section C.8, page 19

**FMC Tar River
 Projected Patient Origin
 OYs 1-2 (CY2020 – CY2021)**

County	OY1 CY2020			OY2 CY2021			County Patients as % of Total	
	IC Patients	HHD Patients	PD Patients	IC Patients	HHD Patients	PD Patients	OY1 CY2020	OY2 CY2021
Franklin	44.2	3.3	4.5	46.6	4.6	6.0	89.7%	90.5%
Halifax	1.0	0.0	0.0	1.0	0.0	0.0	1.7%	1.6%
Nash	0.0	0.0	1.0	0.0	0.0	1.0	1.7%	1.6%
Vance	1.0	1.0	0.0	1.0	1.0	0.0	3.4%	3.2%
Wake	1.0	0.0	0.0	1.0	0.0	0.0	1.7%	1.6%
Virginia	0.0	0.0	1.0	0.0	0.0	1.0	1.7%	1.6%
Total	47	4	6	49	5	8	100.0%	100.0%

Note: The applicant rounds down to the nearest whole number

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project patient origin for IC, HHD and PD patients.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, page 6, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the July 2018 SDR and the January 2019 SDR. The facility need methodology shows a need for two additional dialysis stations and the proposed project is for two additional dialysis stations.

In Section C.2, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”

In Section C.1, pages 13-14, the applicant states:

- The applicant assumes that the Franklin County patient population is increasing at a rate greater than the Five Year Average Annual Change Rate (AACR) for Franklin County patients which is 3.6 percent as published in the January 2019 SDR. The applicant assumes a 10 percent growth rate, which is more than double the Five Year AACR for Franklin County. However, the applicant states 10 percent is less than 25 percent of the actual growth rate experienced from December 2017 through December 2018 which the applicant states was 43.33 percent.
- The applicant states FMC Tar River has doubled its home census since opening in December 2016. As of December 2018, facility had two HHD patients and four PD patients. The applicant assumes that two IC patients will transition to HHD (one patient to HHD and one patient to PD) per year.

- The applicant assumes that patients from other counties dialyzing at FMC Tar River are at the facility by choice and will continue to do so. The applicant does not project any increase in this patient population and they will be added in at appropriate points in time.
- The applicant assumes the one PD patient from Virginia will continue to utilize the homes services at FMC Tar River as a matter of choice.

On page 14, the applicant states the project years as,

OY1: January 1, 2019-December 31, 2019 (CY 2019)
 OY2: January 1, 2020-December 31, 2020 (CY 2020)

However, those project years are not consistent with the operating years as stated in other parts of the application, therefore, the years as stated on page 14 were assumed to be in error.

- Project years associated with this proposal are as follows, as reported in Section R:

OY1: January 1, 2020-December 31, 2020 (CY 2020)
 OY2: January 1, 2021-December 31, 2021 (CY 2021)

The information is reasonable and adequately supported.

Projected Utilization

In Section C, page 14, the applicant provides the methodology used to project in-center patient utilization using the assumptions noted above, summarized as follows:

Begin December 31, 2018 with the 40 Franklin County patients.	40
Project the Franklin County in-center patients forward 12 months to December 31, 2020 using 10 percent.	$40 \times 1.10 = 44$
Subtract two patients projected to transition to home dialysis.	$44 - 2 = 42$
Project the Franklin County patient population forward one year to December 31, 2021 using 10 percent.	$42 \times 1.10 = 46.2$
Subtract two patients projected to transition to home dialysis.	$46.2 - 2 = 44.2$
Add the three patients from other counties projected to continue to dialyze at FMC Tar River. This is the ending census for Operating Year 1 .	$44.2 + 3 = 47.2$
Project the Franklin County patient population forward one year to December 31, 2022 using 10 percent	$47.2 \times 1.10 = 51.92$
Subtract two patients projected to transition to home dialysis.	$51.92 - 2 = 49.92$
Add the three patients from other counties projected to continue to dialyze at FMC Tar River. This is the ending census for Operating Year 2 .	$49.92 + 3 = 52.92$

The applicant rounded down to the nearest whole number for OY1 and OY2. Therefore, at the end of OY1 (CY 2020) and OY2 (CY 2021) the facility is projected to serve 47 and 49 in-center patients, respectively.

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

- OY1: 3.36 patients per station per week, or 83.9% [47 patients / 14 stations = 3.357; 3.357 / 4 = 0.8392].
- OY2: 3.5 patients per station per week, or 87.5% [49 patients / 14 stations = 3.5; 3.5 / 4 = 0.875].

The projected utilization of 3.36 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Peritoneal & Home Hemo Dialysis

The following tables illustrate application of the methodology used to project PD and HHD patient utilization in Section C, page 15:

Home PD

Begin December 31, 2018 with the 2 Franklin County PD patients	2
Project the Franklin County PD patients forward 12 months to December 31, 2019, using 10 percent.	$2 \times 1.10 = 2.2$
Add 1 patient from in-center dialysis projected to transition to PD services	$2.2 + 1 = 3.2$
Add existing PD patients from Nash County (1) and Virginia (1)	$3.2 + 2 = 5.2$
Project the Franklin County PD patients forward one year to December 31, 2020.	$3.2 \times 1.10 = 3.5$
Add 1 patient from in-center dialysis projected to transition to PD services	$3.5 + 1 = 4.5$
Add out of county patients. End of OY1	$4.5 + 2 = 6.5$
Project the Franklin County PD patients forward one year to December 31, 2021.	$4.5 \times 1.10 = 4.95$
Add 1 patient from in-center dialysis projected to transition to PD services	$4.95 + 1 = 5.95$
Add out of county patients. End of OY2	$5.95 + 2 = 7.95$

HHD

Begin December 31, 2018 with the 1 Franklin County HHD patient	1
Project the Franklin County HHD patients forward 12 months to December 31, 2019 using 10 percent.	$1 \times 1.10 = 1.1$
Add 1 patient from in-center dialysis projected to transition to HHD services	$1.1 + 1 = 2.1$
Add the 1 existing patient from Vance County	$2.1 + 1 = 3.1$
Project the Franklin County HHD patients forward one year to December 31, 2020 using 10 percent.	$2.1 \times 1.10 = 2.3$
Add 1 patient from in-center dialysis projected to transition to HHD services	$2.3 + 1 = 3.3$
Add out of county patient. End of OY1	$3.3 + 1 = 4.3$
Project the Franklin County patient population forward one year to December 31, 2021 using 10 percent	$3.3 \times 1.10 = 3.6$
Add 1 patient from in-center dialysis projected to transition to HHD services	$3.6 + 1 = 4.6$
Add out of county patient. End of OY2	$4.6 + 1 = 5.6$

The assumptions for PD and HHD projected utilization above, from page 15, is summarized below:

- The applicant begins with the existing Franklin County PD and HHD patients.
- The applicant uses the same 10 percent growth rate to project growth in the PD and HHD patient population as the applicant did to project growth for its in-center patient population.
- The applicant holds the existing patients from other NC counties who dialyze at the facility by choice and are proposed to remain at the facility constant.
- The applicant proposes to serve 4 HHD and 6 PD patients in **OY1** and 5 HHD and 8 PD patients in **OY2**. Patients are rounded down to the nearest whole number.

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

- The applicant begins with the existing Franklin County IC, PD and HHD patients as of the January 2019 SDR.
- The Franklin County patients are projected to increase at a rate of 10 percent per year, which is less than the historical growth rate experienced at FMC Tar River.
- The applicant holds the existing patients from other NC counties and out of state constant who dialyze at the facility by choice and are proposed to remain at the facility.
- The resulting utilization rate at FMC Tar River by the end of the first year of operation exceeds the minimum standard of 3.2 patients per station per week required by 10A NCAC 14C .2203.

Access

In Section C.3, page 16, the applicant states,

“Fresenius related facilities in North Carolina have historically provided ... care and services to all patients 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.”

In Section L.1, page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

FMC TAR RIVER PROJECTED PAYOR MIX - OY2	
PAYOR CATEGORY	% OF TOTAL PATIENTS
Self-Pay/ Indigent/Charity	3.1%
Medicare	56.3%
Medicaid	6.3%
Commercial Insurance	6.3%
Medicare/Commercial	26.6%
Miscellaneous (incl. VA)	1.6%
Total	100.00%

Conclusion

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose to reduce or eliminate a service, nor does the applicant propose to relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

BMA proposes to add no more than two dialysis stations to FMC Tar River for a total of no more than 14 dialysis stations upon project completion.

In Section E, page 23, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - the applicant considered not applying for additional stations at FMC Tar River; however, the applicant states to do so is to ignore the patient population dialyzing at the facility and eventually result in a lack of capacity and ability to accept patients. Therefore, this alternative was rejected.
- Relocate Existing Stations from Wake County - the applicant states the January 2019 SDR shows a surplus of one station in Franklin County, thus the applicant could not relocate stations from a Wake County facility where some Franklin County patients receive services. Therefore, this alternative was rejected.

On page 23, the applicant states that its proposal is the least costly and most effective alternative because the proposed project will address both the issues of growth and access to the facility and not require any capital expenditures.

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 facility is operating above 80% capacity,
- the applicant's application of the facility need methodology, as published in the January 2019 SDR, indicates a need for two additional stations, and
- the applicant adequately address why stations cannot be relocated from other facilities in contiguous Wake County.

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 above stated reasons. 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 and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**

2. **Pursuant to the facility need determination in the January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations for a total of no more than 14 certified stations at FMC Tar River, which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add no more than two dialysis stations to FMC Tar River for a total of no more than 14 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, pages 25, the applicant projects the total capital cost of the project as shown in the table below.

Water Treatment Equipment	\$1,500
Equipment/Furniture	\$6,000
Total	\$7,500

In Section F, page 28, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project as FMC Tar River is an existing facility.

In Section F.2, page 26, 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 *	\$7,500	\$7,500
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$7,500	\$7,500

* OE = Owner's Equity

Exhibit F.1 contains a letter dated March 15, 2019, from the Senior Vice President & Treasurer of Fresenius Medical Holdings, Inc. (FMH), which states,

“This is to inform you that Fresenius Medical Holdings, Inc., is the parent company of ... and Bio-Medical Applications of North Carolina, Inc.

As Senior Vice President, I am authorized and do hereby authorize ... and commit cash reserves for the capital cost of \$7,500 as may be needed for this project.”

Exhibit F.7 contains a copy of the audited financial statements for FMH for the year ending December 31, 2017. The report indicates that as of December 31, 2017, FMH had \$569,818,000 in cash and cash equivalents, \$19.8 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown below in the table.

FMC TAR RIVER		
	OY 1 (CY 2020)	OY 2 (CY 2021)
Total Treatments*	6,817	7,113
Total Gross Revenues (Charges)	\$31,694,552	\$35,153,031
Total Net Revenue	\$2,326,306	\$2,540,813
Average Net Revenue per Treatment	\$341	\$357
Total Operating Expenses (Costs)	\$2,248,509	\$2,387,962
Average Operating Expense per Treatment	\$330	\$336
Net Income	\$77,797	\$152,851

Source: Application Form C assumptions. *Treatments adjusted for missed treatments.

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 sufficient funds for the operating needs of the proposal.
 - The applicant adequately demonstrates 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 FMC Tar River for a total of no more than 14 dialysis stations upon project completion.

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

Currently, there are three existing and approved dialysis facilities in Franklin County, one of which is owned and operated by BMA. The other two facilities are owned and operated by DaVita, one of which is approved but not yet operational, as shown in the following table:

FRANKLIN COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
Bunn Dialysis	DaVita	Bunn	10*	0.00%
Dialysis Care of Franklin County	DaVita	Louisburg	27	52.78%
FMC Tar River	FMC	Louisburg	10	92.50%

Source: Table B, January 2018 SDR. *Certificate of need approved, not developed as of June 1, 2018; the SDR cut-off date.

As shown in the table above, only one of the two operational dialysis facilities operated with a utilization rate of 90% or higher. Dialysis Care of Franklin County operated with 52.78% utilization and the stations to be located at Bunn Dialysis are currently under development.

In Section G.2, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Franklin County. The applicant states:

“Considering the patient residence locations across the county and the growth of the ESRD patient population within Franklin County, BMA believes these stations are necessary, cost effective and will not unnecessarily duplicate existing health services.”

In Section C.2, page 16, the applicant states, “*Failure to add these stations will lead to higher utilization rates at the facility.*”

The applicant is proposing to add two dialysis stations based on facility need, and demonstrates on page 14, that the facility was serving 43 in-center patients weekly on 12 dialysis stations, which is 3.5833 patients per station, or 89.58% as of December 31, 2018 [$43 / 12 = 3.5833$; $3.5833 / 4 = 0.8958$]. Despite the addition of two additional stations the facility continued to operate above 80% utilization. The applicant does not propose the development of a new dialysis facility; rather, this application seeks to address the needs of this facility by adding new stations.

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

- The applicant demonstrates the need for the additional two stations based on the facility need methodology.
- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing or approved stations in Franklin County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 34, the applicant provides the current and projected staffing table for the facility and shows in the following table that FMC Tar River is projected to add 1.25 full time equivalent (FTE) positions as a result of this proposal.

FMC TAR RIVER CURRENT AND PROPOSED FTE STAFFING			
POSITION	CURRENT POSITIONS	ADJUSTMENTS	PROPOSED OY2 FTE POSITIONS
Registered Nurse	2.00	0	2.00
Home Training Nurse	1.00	0.50	1.50
Patient Care Technician	4.00	0.75	4.70
Dietician	0.40	0	0.40
Social Worker	0.40	0	0.40
Clinical Manager	1.00	0	1.00
Administrator	0.10	0	0.10
In-Service	0.10	0	0.10
Clerical	0.75	0	0.75
Chief Technician	0.10	0	0.10
Equipment Technician	0.67	0	0.67
Total	10.52	1.25	11.77

The applicant provides projected direct care staff in OY2 in Section H.7, page 36.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, page 35, the applicant describes the methods used to recruit personnel or fill new positions and its existing training and continuing education programs. In Exhibits H.1 and H.2, the applicant provides supporting documentation. In Section I.3, page 38, the applicant identifies the current medical director as Dr. Eric Raasch. In Exhibit I.5, the applicant provides a letter from Dr. Raasch indicating an interest in continuing to serve in that capacity following the addition of two stations.

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.1, page 37, the applicant identifies the ancillary and support services necessary for the proposed services, as shown below in the table.

FMC TAR RIVER ANCILLARY AND SUPPORT SERVICES	
Services	Provider
In-center dialysis/maintenance	BMA
Self-care training (in-center)	BMA
Home training Hemodialysis Peritoneal Dialysis Accessible follow-up program	BMA
Psychological counseling	Keys to Recovery Counseling Service, LLC & Carolina Partners
Isolation – hepatitis	BMA
Nutritional counseling	BMA
Social Work services	BMA
Acute dialysis in an acute care setting	UNC Rex Hospital, Raleigh
Emergency care	BMA & Wake Medical Center
Blood bank services	UNC Rex Hospital
Diagnostic and evaluation services	UNC Rex Hospital
X-ray services	UNC Rex Hospital
Laboratory services	Spectra Labs
Pediatric nephrology	UNC Hospital
Vascular surgery	Raleigh Access Center, Triangle Access Center, Rex Vascular
Transplantation services	Duke
Vocational rehabilitation & counseling	Vocational Rehabilitation of Franklin County
Transportation	KARTS

Although, the applicant list UNC Rex as the hospital affiliate that will provide blood bank, diagnostic, evaluation and X-ray services on page 37, Exhibit I.3, contains a service agreement with Wake Medical Center. The applicant provides additional supporting documentation in Exhibit I concerning its other service agreements.

In Section I, pages 38-39, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.3 and I.4.

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

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space nor renovate any existing space, since the facility currently has space for the additional stations proposed in this application. Therefore, Criterion (12) is not applicable to this review.

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

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

C

In Section L.7, page 51, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown below in the table.

FMC Tar River CY2018 Payor Mix	
PAYOR CATEGORY	SERVICES AS PERCENT OF TOTAL
Self-Pay / Indigent / Charity	1.65%
Medicare	57.32%
Medicaid	4.64%
Commercial	7.16%
Medicare Commercial	26.80%
Miscellaneous (Includes VA)	2.43%
Total	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Franklin	16%	50%	37%	15%	11%	13%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

**Excludes "White alone, not Hispanic or Latino" **"Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."*

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

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities 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.3(e), page 49, the applicant states:

"BMA North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

facility will be responsible to 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.6, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

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.1(b), page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

FMC TAR RIVER PROJECTED PAYOR MIX - PY2	
PAYOR CATEGORY	SERVICES AS PERCENT OF TOTAL
Self-Pay / Indigent / Charity	3.1%
Medicare	56.3%
Medicaid	6.3%
Commercial	6.3%
Medicare Commercial	26.6%
Miscellaneous (Includes VA)	1.6%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.1% of total services will be provided to self-pay/indigent/charity patients, 82.9% to Medicare patients and 6.3% to Medicaid patients.

On page 48, 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 applicant states that the historical payor mix for FMC Tar River from January 1, 2018 to December 31, 2018 is the basis for the projected payor mix. With regards to the increase in the self-pay/indigent/charity projected payor mix, the applicant states in supplemental information that, *“the historical payor mix for this project is based off of the 2018 Fiscal Year and the projected payor mix is based off of a rolling 13 month average. Any changes in the patient population outside of 2018 would have impacted the payor mix.”*

The projected payor mix is reasonable and adequately supported for the reasons stated above.

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.4, page 50, 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.1.

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 FMC Tar River for a total of no more than 14 dialysis stations upon project completion.

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

Currently, there are three existing and approved dialysis facilities in Franklin County, one of which is owned and operated by BMA. The other two facilities are owned and operated by DaVita, one of which is approved but not yet operational, as shown in the following table:

FRANKLIN COUNTY DIALYSIS FACILITIES				
FACILITY	OWNER	LOCATION	# CERTIFIED STATIONS AS OF 6/30/18	UTILIZATION AS OF 6/30/18
Bunn Dialysis	DaVita	Bunn	10*	
Dialysis Care of Franklin County	DaVita	Louisburg	27	52.78%
FMC Tar River	FMC	Louisburg	10	92.50%

Source: Table B, January 2018 SDR. *Certificate of need approved, not developed as of June 1, 2018; the SDR cut-off date.

As shown in the table above, only one of the two operational dialysis facilities operated with a utilization at 90% or higher. Dialysis Care of Franklin County operated with 52.78% utilization and the stations to be located at Bunn Dialysis are currently under development.

In Section N, page 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 53, the applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Franklin County. ... The projected patient population for the ... facility begins with patients currently served by BMA, and a growth of that patient population using a growth rate of 10%, consistent with the facility [sic] historical performance.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O.3, page 58, the applicant states there are more than 100 Fresenius related dialysis facilities and more than 10,200 dialysis patients located in North Carolina. The applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that resulted in an Immediate Jeopardy in any of these

facilities. See Exhibit O.2 which contains a letter from CMS stating that FMC Tar River meets the Conditions for Coverage for ESRD facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius 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

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, pages 13 and 15, the applicant projects to serve 47 in-center patients by the end of OY1 (CY2020) for a utilization rate of 83.9% or 3.36 patients per station per week (47 patients / 14 stations = 3.357; 3.357 / 4 = 0.8392 or 83.92%). 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 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.