

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 29, 2018

Findings Date: June 29, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria C. Hale

Assistant Chief: Lisa Pittman

Project ID #: K-11478-18

Facility: Fresenius Medical Care Tar River

FID #: 170323

County: Franklin

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

Project: Relocate two dialysis stations from FMC Northern Wake to FMC Tar River for a total of 12 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care Tar River (FMC Tar River) proposes to relocate two existing dialysis stations from FMC Northern Wake for a total of 12 dialysis stations at FMC Tar River and 14 dialysis stations at FMC Northern Wake upon project completion.

Need Determination

The applicant is proposing to relocate two existing dialysis stations from Wake County to Franklin County, therefore there are no need methodologies in the 2018 State Medical Facilities Plan (2018 SMFP) applicable to this review.

Policies

Policy ESRD-2 is applicable to this review. Policy ESRD-2 on page 27 of the 2018 SMFP states:

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

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

FMC Tar River is located in Franklin County and FMC Northern Wake is located in Wake County. The applicant proposes to relocate existing dialysis stations between contiguous counties. In Section B.3, page 6, the applicant states that the January 2018 Semiannual Dialysis Report (SDR) indicated that there is a surplus of 11 dialysis stations in Wake County. The same SDR indicates a deficit of two stations in Franklin County. The proposed relocation of two stations from Wake County to Franklin County would reduce the surplus of stations in Wake County to a surplus of 9 stations (11-2=9) and eliminate the deficit of stations in Franklin County. Additionally, in Section D.1, page 20, the applicant states that the patients residing in Franklin County, but dialyzing at FMC Northern Wake are projected to transfer their care to the FMC Tar River facility. In Exhibit C.1, the applicant provides copies of support letters from patients currently dialyzing FMC Northern Wake, Eastern Wake and one patient from Zebulon Kidney Center who have expressed a willingness to consider transferring their care to the FMC Tar River facility. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

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

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

C

The applicant proposes to relocate two existing dialysis stations from FMC Northern Wake to FMC Tar River for a total of 12 dialysis stations at FMC Tar River and 14 dialysis stations at FMC Northern Wake upon project completion.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Franklin County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 12, and Section C.8, page 17, the applicant provides the projected and historical patient origin for FMC Tar River, as illustrated in the table below.

County	FMC Tar River											
	Current As Of 3/15/2018				Operating Year 1 CY 2019				Operating Year 2 CY 2020			
	In-Center	HHD	PD	% of Total	In-Center	HHD	PD	% of Total	In-Center	HHD	PD	% of Total
Franklin	34	2	2	100%	39.2	2	2	100%	39.3	2	2	100%
Total*	34	2	2	100%	39	2	2	100%	39	2	2	100%

*Rounded down to the whole patient

In Section C, pages 12-14, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 12-14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, page 5, the applicant states,

“BMA notes that the reported utilization for FMC Tar River was 42.50% for the period ended June 30, 2017. The NC SMFP, Chapter 14, End-Stage Renal Dialysis Facilities, Basic Principle # 6 includes the following language:

‘No existing facility may expand unless its utilization is 80 percent or greater.’

The FMC Tar River census at December 31, 2017 was 30 patients, with a utilization rate of 75.00%. The census on March 15, 2018 was 34 patients and utilization was 85.0% [34/10=3.4; 3.4/4=0.85 or 85%]”

On pages 12-13, the applicant provides the following assumptions:

- The applicant begins the projections for the future patient population of FMC Tar River by using the in-center patient census of 34 patients, as of March 15, 2018.
- The applicant states that the census at FMC Tar River is growing at a rate faster than the Franklin County Five-Year Average Annual Change Rate. However, the applicant states that it will “*conservatively*” use the Franklin County Five-Year Average Annual Change Rate (AACR), which is 3.0%, to project the Franklin County patient population forward.
- The applicant provides letters from five patients currently dialyzing at other BMA facilities (one patient from BMA Zebulon, two patients from FMC Eastern Wake and two patients from FMC Northern Wake) who have expressed a willingness to consider transferring their care to FMC Tar River.
- Operating Year 1 (OY1) = Calendar Year (CY) 2019
Operating Year 2 (OY2) = Calendar Year (CY) 2020

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

- the applicant begins its projections of the patient population to be served with the existing patient census of FMC Tar River on March 15, 2018;
- the applicant grows the Franklin County patient population by the January 2018 SDR Franklin County five-year AACR of 3.0%, and,
- the applicant demonstrates a willingness of other dialysis patients dialyzing at other BMA facilities to transfer their care to FMC Tar River.

Projected Utilization

In Section C, page 12, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

FMC Tar River	
Begin with Franklin County patients dialyzing at FMC Tar River as of March 15, 2018.	34
Project the Franklin County patient population forward nine months (April 1 to December 31, 2018) using the Five-Year Average Annual Change Rate for Franklin County of 3.0%	$34 \times 1.00225 = 34.07$
Add in the five patients projected to transfer their care from other BMA facilities to FMC Tar River. This is the starting census for the project.	$34.07 + 5 = 39.7$
OY1: Project the Franklin County population forward one year to December 31, 2019 using the Five-Year Average Annual Change Rate for Franklin County of 3.0%. This is the ending census for OY1.	$39.07 \times 1.003 = 39.19$
OY2: Project the Franklin County population forward one year to December 31, 2020 using the Five-Year Average Annual Change Rate for Franklin County of 3.0%. This is the ending census for OY2.	$39.19 \times 1.003 = 39.30$

The applicant provides the assumptions for the projected in-center utilization on pages 12-14, as summarized below:

- The applicant begins its methodology using FMC Tar River’s beginning census, based on the applicant’s internal census, as of March 15, 2018.
- OY1 is the period from January 1 through December 31, 2019.
- OY2 is the period from January 1 through December 31, 2020.
- The 34 in-center patients from Franklin County will continue to dialyze at FMC Tar River.
- Five patients provided letters of support stating their willingness to transfer their care from other BMA operated facilities to FMC Tar River.
- The Franklin County patient census will grow at the Franklin County AACR of 3.0%, as reported in the January 2018 SDR.

In Section C.2, page 14, the applicant states:

“In this application, BMA has projected a patient population of 39.2 rounded down to 39 in-center patients, to be dialyzing at the FMC Tar River facility at the end of the first year. Failure to add these stations will lead to higher utilization rates at the facility. Utilization by 39 patients on 12 dialysis stations is calculated to be 3.25 patients per station, or 81.25% utilization.”

The applicant rounds down to the nearest whole number. Therefore, the applicant projects to serve 39 in-center patients or 3.25 patients per station per week ($39/12 = 3.25$) by the end of OY1 and OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Home Hemodialysis and Peritoneal Dialysis

The applicant currently provides services for home hemodialysis (HHD) and peritoneal dialysis (PD) patients. The applicant provides service for two HHD patients and two PD patients. In Section C.5, page 13, the applicant provides its methodology for projecting utilization for HHD and PD patients using the Franklin County AACR of 3.0%. However, due to rounding, the applicant does not project a change in the number of patients receiving those services.

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

- the applicant begins its utilization with the existing patients of FMC Tar River,
- the grows the Franklin County patient population by the January 2018 SDR Franklin County AACR and holds the patient population from outside Franklin County constant, and
- the resulting utilization rate at FMC Tar River by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Access

In Section C, page 15, the applicant states,

“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.”

In Section L.1(a), pages 46-47, the applicant states that each of BMA’s 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons regardless of their ability to pay. In Section L.1(b), page 47, the applicant provides the projected payor mix for OY2 calendar year (CY) 2020 for FMC Tar River, as illustrated below.

Payment Source	Percent of Total Patients	Percent of In-Center	Percent of HHD	Percent of PD
Self Pay/ Indigent/ Charity	2.27%	1.40%	0.00%	0.00%
Medicare	45.45%	44.88%	93.98%	93.98%
Medicaid	0.00%	0.96%	0.00%	0.00%
Commercial Insurance	18.18%	20.07%	0.00%	0.00%
Medicare / Commercial	31.82%	31.40%	6.02%	6.02%
Misc. (VA)	2.27%	1.30%	0.00%	0.00%
Total*	100.0%	100.0%	100.0%	100.0%

*Totals may not foot due to rounding

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate two existing dialysis stations from FMC Northern Wake to FMC Tar River for a total of 12 dialysis stations at FMC Tar River upon project completion. Upon completion of this project, FMC Northern Wake will be certified for 14 dialysis stations (16 - 2 = 14).

In Section D.1, page 20, the applicant states it assumes that the number of in-center patients at FMC Northern Wake who live in Wake County will increase at 5.6% per year based on the Five Year AACR for Wake County, as reported in Table D of the January 2018 SDR. The applicant does not expect patients from South Carolina or other states to continue to dialyze at FMC Northern Wake because the applicant believes those patients to be transient. The applicant does not project growth with its Franklin County patients because those patients have expressed a willingness to transfer their care to the FMC Tar River Dialysis facility. In Section D.1, page 20, the applicant calculates the in-center patient census for FMC Northern Wake beginning with the December 31, 2017 inpatient census, summarized as follows:

FMC Northern Wake	
BMA begins with the Wake County patient census as of December 31, 2017.	37
Project the census forward for 12 months using the Wake County Five Year Average Change Rate to December 31, 2018.	$37 \times 1.056 = 39.07$

On page 21, the applicant states on December 31, 2018 FMC Northern Wake projects to relocate two stations to FMC Tar River. The applicant rounds the patient population of 39.07 down to 39 in-center patients for a utilization of 69.6% or 2.79 patients per station, per week. This is based on 39 in-center patients dialyzing on 14 certified dialysis stations ($39 / 14 = 2.7857$; $2.7857 / 4 = 0.6964$ or 69.64%).

Project utilization is reasonable and adequately supported based on the following:

- The applicant projects the patient census for FMC Northern Wake based on existing patients who reside in Wake County, and those patients from Franklin County who have signed letters expressing their willingness to consider transferring their care to FMC Tar River.
- The applicant's growth projections are based on an assumption that the Wake County patient census will increase at an annual rate of 5.6%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Wake County, as reported in Table D of the January 2018 SDR

On page 21, the applicant states, *"This relocation of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care. Patients needing dialysis services will continue to have access to dialysis at either their current dialysis facility, or in a BMA facility closer to their residence location."*

FMC Northern Wake has a history of underutilization as reported in the January and July 2017 SDR. As of the July 2017 SDR, the facility had a utilization of 39.06% with 1.525 patients per station per week based on 25 in-center patients dialyzing on 16 stations [$25/16 = 1.5625 / 4 = 0.39.06$ or 39.06%]. Additionally, as of the January 2017 SDR the facility had a 35.94% utilization with 1.45375 patients per station per week which is based on 23 in-center patients dialyzing on 16 stations [$23/16 = 1.4375 / 4 = 0.35937$ or 35.94%].

Thus, the applicant states that the proposed relocation of stations and transfer of patients will not have an adverse impact 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E, page 22, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in the 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 because of the number of people currently dialyzing at a FMC Tar River. The applicant states that failure to expand the facility could result in a lack of capacity and the ability to accept patients for admission. Therefore, this alternative was rejected.
- Relocate stations from another BMA facility in Wake County – BMA operates 12 of the 13 facilities in Wake County. The applicant reports that of the four BMA Wake County facilities serving Franklin County residents, FMC Northern Wake is the only underutilized facility and has been underutilized since opening. Thus, it was the best choice to relocate stations from to accommodate the growing need for additional stations at FMC Tar River. Therefore, this alternative was rejected.
- Relocate stations from a facility in a contiguous county – The applicant states that FMS Oxford in Granville County and FMC Spring Hope in Nash County both serve one patient from Franklin County. However, FMS Oxford has an increasing in-center patient population and Nash County has a deficit of two dialysis stations as reported in the January 2018 SDR. Thus, stations could not be relocated from either of those facilities. Therefore, this alternative was rejected.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because, *“Given the residence location of the existing patients, the number of patients projected to be served at FMC Tar River, and the growth of the ESRD population dialyzing with BMA, BMA believes it is most appropriate to apply for this relocation of four [sic] stations.”* (See page 22)

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

- the applicant adequately demonstrates a need for additional stations at the facility,
- maintaining the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions, and
- there are no other BMA facilities in Wake County or contiguous counties that could relocate stations.

Conclusion

The Agency reviewed the:

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Tar River shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than two dialysis stations from Fresenius Medical Care Northern Wake for a total of no more than twelve dialysis stations at Fresenius Medical Care Tar River.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Tar River shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify two dialysis stations Fresenius Medical Care Northern Wake for a total of no more than fourteen dialysis stations at Fresenius Medical Care Northern Wake.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Tar River 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

The applicant proposes to relocate two existing dialysis stations from FMC Northern Wake to FMC Tar River for a total of 12 dialysis stations at FMC Tar River and a total of 14 dialysis stations at FMC Northern Wake upon project completion.

Capital and Working Capital Costs

In Section F.1, page 24, 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 Capital Cost	\$7,500

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

In Section F, page 27, the applicant projects that there will be no start-up or initial operating costs associated with the proposed project as FMC Tar River is an existing facility.

Availability of Funds

In Section F.2, page 25, 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	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, 2018, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company of BMA, which states,

“BMA is submitting a Certificate of Need Application to relocate two dialysis stations from its FMC Northern Wake dialysis facility (Wake County) to the FMC Tar River facility. The project does call for a capital expenditure of \$7,500 on behalf of BMA.

...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.2 contains the Subsidiaries Consolidated Financial Statements for FMCH which indicates that it had \$357.9 million in cash and cash equivalents as of December 31, 2016,

\$20.1 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, should there be a need.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	5,779	5,779
Total Gross Revenues (Charges)	\$25,407,548	\$25,407,548
Total Net Revenue	\$2,891,485	\$2,891,485
Average Net Revenue per Treatment	\$500.34	\$500.34
Total Operating Expenses (Costs)	\$2,390,213	\$2,416,818
Average Operating Expense per Treatment	\$413.60	\$418.21
Net Income	\$501,271	\$474,667

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

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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

The applicant proposes to relocate two existing dialysis stations from FMC Northern Wake to FMC Tar River for a total of 12 dialysis stations at FMC Tar River and a total of 14 dialysis stations at FMC Northern Wake upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Franklin County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently two operational dialysis facilities and one facility under development in Franklin County, as illustrated below.

FRANKLIN COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility/Owner	Certified Stations 6/30/17	# In-center Patients	Percent Utilization	Patients per Station
Bunn Dialysis (DaVita)*	10	0	0	0
Dialysis Care of Franklin County (DaVita)	27	68	62.96%	2.5185
FMC Tar River (BMA)	10	17	42.50%	1.7000
Totals**	47	85	57.43%	2.2972

Source: January 2018 SDR.

*New Facility

**Only the operational facilities are included in the total for percent of utilization and patients per station

As shown in the table above, one facility is currently under development which will be operated by DaVita. Of the two operational facilities, BMA operated one facility, FMC Tar River. In Section G, page 32, the applicant states that as of December 31, 2017, FMC Tar River had a utilization of 75%. On page 32, the applicant further states that FMC Tar River had 34 patients as of March 15, 2018 for a utilization rate of 85% ($34/10 = 3.4$; $3.4/4 = 0.85$ or 85%). On page 32 the applicant states,

“The FMC Tar River facility is convenient to a large segment of the ESRD patient population of the county and is prepared to serve all patients regardless of residence location. FMC Tar River will serve patients across the county.”

The January 2018 SDR reports a deficit of two dialysis stations in Franklin County and a surplus of 11 dialysis station in Wake County. Therefore, the relocation of two dialysis stations from FMC Northern Wake in Wake County to FMC Tar River in Franklin County will eliminate the deficit of dialysis stations in Franklin County and reduce the surplus of dialysis stations in Wake County to nine dialysis 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 proposal will eliminate the deficit of dialysis stations in Franklin County and decrease the surplus of dialysis stations in Wake County.
- the applicant adequately demonstrates that the proposed addition of two dialysis stations at FMC Tar River is needed in addition to the existing or approved dialysis 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 reasons stated above.

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

C

In Section H, page 33, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

POSITION	CURRENT # FTES	PROJECTED # FTES OY2
Registered Nurse	1.25	1.50
Home Training Nurse	1.00	1.00
Technician (PCT))	3.50	4.00
Dietician	0.25	0.35
Social Worker	0.25	0.35
Clinical Manager	1.00	1.00
Admin. (FMC Dir. Ops)	0.15	0.15
In-Service	0.15	0.15
Clerical	0.50	0.75
Chief Tech	0.15	0.15
Equipment Tech	0.30	0.40
Total	8.50	9.80

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 61, which is found in Section R. In Section H, pages 33-34, the applicant describes the methods used to recruit or fill new positions and its existing training

and continuing education programs. In Exhibit I.5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of FMC Tar River. In Exhibit H, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section I, page 36, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

FMC Tar River Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	FMC Tar River (on site)
Self-care training (in-center)	FMC Tar River (on site)
Home training HH PD Accessible follow-up program	FMC Tar River (on site)
Psychological counseling	Keys to Recovery Counseling Service, PLLC; Carolina Partners
Isolation – hepatitis	FMC Tar River (on site)
Nutritional counseling	FMC Tar River (on site)
Social Work services	FMC Tar River (on site)
Acute dialysis in an acute care setting	UNC Rex Hospital
Emergency care	BMA/Wake Memorial Hospital
Blood bank services	Rex Hospital, Raleigh
Diagnostic and evaluation services	Rex Hospital, Raleigh
X-ray services	Rex Hospital, Raleigh
Laboratory services	Spectra
Pediatric nephrology	UNC Hospitals
Vascular surgery	Raleigh Access Center, Triangle Access Center, Rex Vascular
Transplantation services	Duke University Med. Center
Vocational rehabilitation & counseling	Vocational Rehab. of Franklin County
Transportation	KARTS

The applicant provides supporting documentation for the necessary ancillary and support services in Exhibit I.2-4. Exhibits I-2 through I-4, respectively, contain copies of agreements for Spectra laboratories services, Wake Medical Center transfer agreement, and Duke University Medical Center for transplant services.

In Section I, pages 37-38, the applicant describes its existing and proposed relationships with other local healthcare and social service providers and provides supporting documentation in Exhibits I.3-I.6.

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

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct new space nor renovate the existing space. Therefore, Criterion (12) is not applicable to this review.

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

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

C

In Section L.7, page 50, the applicant provides the historical payor mix for FMC Tar River from January 1 to December 31, 2017 for CY 2017, as shown in the table below.

Payment Source	Percent of Total Patients	Percent of In-center Patients	Percent of HHD Patients	Percent of PD Patients
Self Pay/ Indigent/ Charity	2.27%	1.40%	0.00%	0.00%
Medicare	45.45%	44.88%	93.98%	93.98%
Medicaid	0.00%	0.96%	0.00%	0.00%
Commercial Insurance	18.18%	20.07%	0.00%	0.00%
Medicare / Commercial	31.82%	31.40%	6.02%	6.02%
Misc. (VA)	2.27%	1.30%	0.00%	0.00%
Total	100.0%	100.0%	100.0%	100.0%

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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Franklin	16%	50%	36%	16%	11%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

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

***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable... The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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, pages 48-49, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The 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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

In Section L, page 49, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section L, page 47, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix OY 2

Payment Source	Percent of Total Patients	Percent of In-center Patients	Percent of HHD Patients	Percent of PD Patients
Self Pay/ Indigent/ Charity	2.27%	1.40%	0.00%	0.00%
Medicare	45.45%	44.88%	93.98%	93.98%
Medicaid	0.00%	0.96%	0.00%	0.00%
Commercial Insurance	18.18%	20.07%	0.00%	0.00%
Medicare / Commercial	31.82%	31.40%	6.02%	6.02%
Misc. (VA)	2.27%	1.30%	0.00%	0.00%
Total	100.0%	100.0%	100.0%	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.27% of total services will be provided to self-pay/indigent/charity patients and 77.27% to Medicare patients (includes Medicare and Medicare/Commercial). The applicant further projects that 0.96% of its in-center patients will be to Medicaid patients.

On page 47, the applicant states the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project is based upon the recent facility performance throughout 2017. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at FMC Tar River.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section L.4, page 49, the applicant adequately describes the range of means by which the patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C

In Section M, page 51, 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
- Information which was publicly available during the review and used by the Agency.

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate two existing dialysis stations from FMC Northern Wake to FMC Tar River for a total of 12 dialysis stations at FMC Tar River and a total of 14 dialysis stations at FMC Northern Wake upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Franklin County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, there are currently two operational dialysis facilities and one facility under development in Franklin County, as illustrated below.

FRANKLIN COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2017				
Dialysis Facility/Owner	Certified Stations 6/30/17	# In-center Patients	Percent Utilization	Patients per Station
Bunn Dialysis (DaVita)*	10	0	0	0
Dialysis Care of Franklin County (DaVita)	27	68	62.96%	2.5185
FMC Tar River (BMA)	10	17	42.50%	1.7000
Totals**	47	85	57.43%	2.2972

Source: January 2018 SDR.

*New Facility

**Only the operational facilities are included in the total for percent of utilization and patients per station

In Section N.1, page 52, 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 cost-effectiveness, quality and access to the proposed services. On page 52, the applicant states,

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

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ...

BMA facilities have done an exceptional job of containing costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment. ”

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

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

Conclusion

The Agency reviewed the:

- Application

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

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

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

C

In Section A, page 11, page 14, the applicant states that BMA operates 112 facilities in North Carolina. In Section O.3, page 57, the applicant states, *“As of February 28, 2018, Fresenius related facilities were providing dialysis care and treatment for more than 9,800 dialysis patients receiving care in a North Carolina dialysis facility.”*

Of the more than 100 Fresenius related facilities in North Carolina, the applicant identifies BMA East Rocky Mount as the only BMA facility cited for an immediate jeopardy citation during the 18-months immediately preceding submission of the application. The applicant summarizes the deficiencies cited and the resolution in Section O.3 and provides documentation in Exhibit O-3(a) and (b). On page 57, the applicant states that BMA East Rocky Mount was back in full compliance with all CMS Guidelines upon the submittal of the application. After reviewing and considering the information provided by the applicant and considering the quality of care provided at all Fresenius facilities in North Carolina, the applicant provided sufficient evidence that quality care has been provided in the past.

The Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- FMC Tar River is an existing facility.

.2203(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, pages 12-14, the applicant demonstrates that FMC Tar River will serve a total of 39 in-center patients at the end of OY1 for a utilization rate of 81.25% or 3.25 patients per station per week (39 patients / 12 dialysis stations = 3.25 / 4 = 0.8125 or 81.25%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- In Section C, pages 12-14, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.