

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 18, 2020

Findings Date: February 18, 2020

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: K-11767-19

Facility: Fresenius Medical Care Tar River

FID #: 130122

County: Franklin

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

Project: Add no more than four dialysis stations for a total of no more than 18 stations upon completion of this project, and Project ID# K-11669-19 (add 2 stations)

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) d/b/a FMC Tar River proposes to add no more than four dialysis stations for a total of no more than 18 stations upon completion of this project and Project ID# K-11669-19 (add 2 stations).

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of two dialysis stations in Franklin County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per

week, or 80 percent. The utilization rate reported for FMC Tar River in the July 2019 SDR is 3.58 patients per station per week, or 89.58 percent, based on 43 in-center dialysis patients and 12 certified dialysis stations $[43/12 = 3.5833; 3.5833 / 4 = 0.8958 \text{ or } 89.58\%]$.

Below is a table that illustrates the facility need for additional dialysis stations at FMC Tar River.

October 1 Review Table (July SDR)

| | | Part A |
|--|---|---------------|
| Required SDR Utilization | | 80% |
| FMC Tar River | | |
| July 2019 SDR | | |
| Facility Utilization Rate (as of 12/31 of the previous year) | | 89.58% |
| | | Part B |
| # of Certified Stations | | 12 |
| # of Pending Stations | | 2 |
| Total Existing and Pending Stations | | 14 |
| In-Center Patients as of 12/31/18 - (July 2019 SDR) (SDR2) | | 43 |
| In-Center Patients as of 6/30/18 - (Jan. 2019 SDR) (SDR1) | | 37 |
| Step | Description | Result |
| (i) | Difference (SDR2 - SDR1) | 6 |
| | Multiply the difference by 2 for the projected net in-center change | 12 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients from SDR1 | 0.3243 |
| (ii) | Divide the result of Step (i) by 12 | 0.0270 |
| (iii) | Multiply the result of Step (ii) by 12 | 0.3243 |
| (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 | 56.9459 |
| (v) | Divide the result of Step (iv) by 3.2 patients per station | 17.7956 |
| | and subtract the number of certified and pending stations to determine the number of stations needed | 3.7956 |

Source: Table on page 9 of the application.

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four 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 four new stations; therefore, the application 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.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, page 11; Section N.2, page 53; Section O, pages 55-58, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 11-12; Section C.7, page 22; Section L, pages 47-50; Sections N.2, page 53, and referenced exhibits. The information provided by the applicant is reasonable and 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, pages 12-13; Section F, pages 31-34; Section K, page 43; Section N.2, page 53; Section Q, pages 73-85; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than four dialysis stations for a total of no more than 18 stations upon completion of this project and Project ID# K-11669-19 (add 2 stations).

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.

The following tables illustrate current and projected patient origin for in-center patients served by FMC Tar River.

| FMC Tar River Historical Patient Origin Last Full Operating Year-1/1/2018-12/31/2018 | | | | | | |
|---|----------------------|-------------------|--------------------------|-------------------|----------------------------|-------------------|
| County | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Franklin | 40 | 93.0% | 1 | 50.0% | 2 | 50.0% |
| Halifax | 1 | 2.3% | 0 | 0.0% | 0 | 0.0% |
| Nash | 0 | 0.0% | 0 | 0.0% | 1 | 25.0% |
| Vance | 1 | 2.3% | 1 | 50.0% | 0 | 0.0% |
| Wake | 1 | 2.3% | 0 | 0.0% | 0 | 0.0% |
| Virginia | 0 | 0.0% | 0 | 0.0% | 1 | 25.0% |
| Total | 43 | 100.0% | 2 | 100.0% | 4 | 100.0% |

Source: Section C, page 16

| FMC Tar River Projected Patient Origin Second Full Operating Year-1/1/2022-12/31/2022 | | | | | | |
|---|---------------|---------------|-------------------|---------------|---------------------|---------------|
| County | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Franklin | 56.99 | 90.50% | 1.24 | 100.0% | 4.96 | 83.2% |
| Halifax | 1.00 | 1.60% | 0.00 | 0.0% | 1.00 | 16.8% |
| Vance | 1.00 | 1.60% | 0.00 | 0.0% | 0.00 | 0.0% |
| Wake | 2.00 | 3.20% | 0.00 | 0.0% | 0.00 | 0.0% |
| Virginia | 2.00 | 3.20% | 0.00 | 0.0% | 0.00 | 0.0% |
| Total | 62.99 | 100.0% | 1.24 | 100.0% | 5.96 | 100.0% |

Source: Section C, page 17

In Section C, pages, 17-20, 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, page 20, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 20, the applicant states:

“Failure to receive dialysis care will ultimately lead to the patient’s demise. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. BMA has identified the population to be served as 59.6 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”

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

- The applicant demonstrates a facility need of four additional stations based on the facility need methodology, as published in the July 2019 SDR. The applicant is proposing to add four stations.
- The applicant projects 60 in-center patients on 18 stations at the end of the first operating year for a utilization rate of 3.33 patients per station per week (60/18=3.33) which exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected Utilization

In Section C, pages 18-19 and Section Q, pages 66-70, the applicant provides its projected utilization, as illustrated in the following tables.

In-Center

| FMC Tar River | In-Center Dialysis Patients |
|---|------------------------------------|
| BMA begins with the Franklin County patient population as of June 30, 2019. | 46 |
| Project the Franklin County patient population forward for six months to December 31, 2019 using half of the Franklin County Five-Year Average Annual Growth Rate (AACR) of 6.3%. | $46 \times 1.0315 = 47.4$ |
| Project the Franklin County patient population forward for one year to December 31, 2020 using the appropriate Five-Year AACR. | $47.4 \times 1.063 = 50.4$ |
| Add the patients from other counties and the State of Virginia. This is the projected beginning census for this project. | $50.4 + 6 = 56.4$ |
| Project the Franklin County patient population forward for one year to December 31, 2021 using the appropriate Five-Year AACR. | $50.4 \times 1.063 = 53.6$ |
| Add the patients from other counties and the State of Virginia. This is the projected ending census for Operating Year 1. | $53.6 + 6 = 59.6$ |
| Project the Franklin County patient population forward for one year to December 31, 2022 using the appropriate Five-Year AACR. | $53.6 \times 1.063 = 56.99$ |
| Add the patients from other counties and the State of Virginia. This is the projected ending census for Operating Year 2. | $56.99 + 6 = 62.99$ |

Source: Section Q, page 68

In Section Q, pages 67-68, the applicant provides the assumptions and methodology used to project utilization for in-center patients, which is summarized below.

- The applicant begins the projections by using the in-center patient census at FMC Tar River as of June 30, 2019, based on ESRD Data collection forms submitted to the Agency August 2019.
- The applicant projects that the Franklin County patient population will increase based on the Five-Year AACR of 6.3%, as published in the July 2019 SDR.
- As of June 30, 2019, FMC Tar River was serving one patient from Halifax County, one patient from Vance County, two from Wake County and two from the state of Virginia. The applicant does not project any increase in this population but projects that by choice they will continue to dialyze at this facility.
- The project is scheduled for completion on December 31, 2020.
- Operating Year 1 (OY1) = January 1, 2021 – December 31, 2021 (CY2021)
- Operating Year 2 (OY2) = January 1, 2022 – December 31, 2022 (CY2022)

Projected patients for OY1 and OY2 are rounded up to the nearest whole number. Therefore, at the end of OY1 (CY2021) the facility is projected to serve 60 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 63 in-center patients.

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

- OY1: 3.3 patients per station per week or 83.33% ($60 \text{ patients} / 18 \text{ stations} = 3.333/4 = 0.8333$ or 83.33%)
- OY2: 3.5 patients per station per week or 87.5% ($63 \text{ patients} / 18 \text{ stations} = 3.5/4 = 0.875$ or 87.5%)

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

The applicant based its projections on 18 stations at FMC Tar River. According to ESRD data collection forms submitted to the Agency for June 2019, FMC Tar river was certified for 14 stations. This includes two additional stations that were certified June 17, 2019 (Project ID# K-11669-19).

Home Hemodialysis (HH) and Peritoneal Dialysis (PD)

| FMC Tar River Home Therapies | HH | PD |
|--|----------------------------|----------------------------|
| BMA begins with the Franklin County patient population as of June 30, 2019. | 1 | 4 |
| Project the Franklin County patient population forward for six months to December 31, 2019 using half of the Franklin County Five-Year AACR of 6.3%. | $1 \times 1.0315 = 1.03$ | $4 \times 1.0315 = 4.13$ |
| Project the Franklin County patient population forward for one year to December 31, 2020 using the appropriate Five-Year AACR. | $1.03 \times 1.063 = 1.10$ | $4.13 \times 1.063 = 4.39$ |
| Add the patient from Halifax County. This is the projected beginning census for this project. | $1.10 + 0 = 1.10$ | $4.39 + 1 = 5.39$ |
| Project the Franklin County patient population forward for one year to December 31, 2021 using the appropriate Five-Year AACR. | $1.10 \times 1.063 = 1.17$ | $4.39 \times 1.063 = 4.66$ |
| Add the patient from Halifax County. This is the projected ending census for Operating Year 1. | $1.17 + 0 = 1.17$ | $4.66 + 1 = 5.66$ |
| Project the Franklin County patient population forward for one year to December 31, 2022 using the appropriate Five-Year AACR. | $1.17 \times 1.063 = 1.24$ | $4.66 \times 1.063 = 4.96$ |
| Add the patient from Halifax County. This is the projected ending census for Operating Year 2. | $1.24 + 0 = 1.24$ | $4.96 + 1 = 5.96$ |

Source: Section Q, page 69

Projected HH patients for OY1 and OY2 are rounded down to the nearest whole number. Projected PD patients for OY1 and OY2 are rounded up to the nearest whole number. Therefore, at the end of OY1 (CY2021) the facility is projected to serve one HH patient and five PD patients. At the end of OY2 (CY2022) the facility is projected to serve one HH patient and six PD patients.

In Section Q, pages 68-70, the applicant provides the assumptions and methodology used to project utilization for in HH and PD patients, which is summarized below.

- The applicant begins the projections by using the HH and PD patient census at FMC Tar River as of June 30, 2019, based on ESRD Data collection forms submitted to the Agency August 2019.
- The applicant projects the Franklin County patient population will increase based on the Five-Year AACR of 6.3%, as published in the July 2019 SDR.
- As of June 30, 2019, FMC Tar River was serving one home PD patient from Halifax County. The applicant does not project any increase in this population but assumes that by choice they will continue at this facility.
- The project is scheduled for completion on December 31, 2020.
- Operating Year 1 (OY1) = January 1, 2021 – December 31, 2021 (CY2021)
- Operating Year 2 (OY2) = January 1, 2022 – December 31, 2022 (CY2022)

Projected utilization for all patients at FMC Tar River is reasonable and adequately supported for the following reasons:

- The applicant demonstrates a facility need of four additional stations based on the facility need methodology, as published in the July 2019 SDR. The applicant is proposing to add four stations.
- The applicant projects future utilization based on historical utilization.
- The applicant assumes a projected annual growth rate of 6.3 percent for Franklin County patient census at FMC Tar River which is equal to the Franklin County Five-Year AACR as published in the July 2019 SDR.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 22, 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.3, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

| FMC Tar River Projected Payor Mix Second Full Operating Year-1/1/2022-12/31/2022 | | | | | | |
|--|---------------|----------------|-------------------|----------------|---------------------|----------------|
| Payor Source | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Self-Pay | 1.72 | 2.73% | 0.00 | 0.00% | 0.00 | 0.00% |
| Insurance** | 5.39 | 8.56% | 0.07 | 5.51% | 0.33 | 5.47% |
| Medicare** | 33.68 | 53.47% | 1.12 | 90.20% | 3.28 | 55.13% |
| Medicaid** | 3.02 | 4.79% | 0.00 | 0.00% | 1.17 | 19.57% |
| Other: Medicare/Commercial | 17.88 | 28.38% | 0.00 | 0.00% | 1.18 | 19.83% |
| Other: Misc. (includes VA) | 1.30 | 2.06% | 0.05 | 4.29% | 0.00 | 0.00% |
| Total | 62.99 | 100.00% | 1.24 | 100.00% | 5.96 | 100.00% |

** Including any managed care plans

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

- The applicant projects the payor mix based on FMC Tar River’s recent history of actual treatment volumes of the facility.
- The applicant does not project any change in the payor mix.

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 or 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

The applicant proposes to add no more than four dialysis stations for a total of no more than 18 stations upon completion of this project, and Project ID# K-11669-19 (add 2 stations).

In Section E, pages 28-29, the applicant describes the alternatives it considered and explains why the alternatives not chosen are either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo-The applicant states that this was not effective due to the growth in patient population in the area of the facility. The applicant states that failure to add stations will result in higher utilization rates and fewer opportunities for admission.
- Apply for Less than Four Stations-The applicant states this was not an effective alternative because it does not meet the needs of the projected patient population for this facility. The applicant states the growth of the facility has exceeded the Franklin County Five-Year AACR, as published in the July 2019 SDR.

In Section E.2, Page 29, the applicant states that its proposal is the most effective alternative because it is a cost-effective approach to meeting the needs of the patient population projected to be served.

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 growth has exceeded the Franklin County Five-Year AACR, as published in the July 2019 SDR.
- The applicant utilizes the facility need methodology to show the need for additional stations.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than four additional dialysis stations for a total of no more than 18 certified stations at FMC Tar River upon completion of this project, and Project ID# K-11669-19 (add 2 stations), 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

The applicant proposes to add no more than four dialysis stations for a total of no more than 18 stations upon completion of this project and Project ID# K-11669-19 (add 2 stations).

Capital and Working Capital Costs

In Section Q, page 74, the applicant projects the capital cost for the proposed project will be \$15,000; \$3,000 for water treatment equipment and furniture and \$12,000 for patient TVs and dialysis chairs. In Section F, pages 31-32 the applicant states that there are no projected start-up or initial operating expenses because FMC Tar River is an existing facility that is already operational.

Availability of Funds

In Section F, page 30, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

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

* OE = Owner's Equity

Exhibit F-2 contains a letter from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. The letter states that the 2018 consolidated balance sheet for Fresenius Medical Care Holdings, Inc. reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, page 76, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

| Projected Revenues and Operating Expenses | | |
|--|-------------------------------------|-------------------------------------|
| FMC Tar River | Operating Year 1 CY 2021 | Operating Year 2 CY 2022 |
| Total Treatments | 9,572.97 | 10,110.80 |
| Total Gross Revenues (Charges) | \$60,223,538 | \$63,607,020 |
| Total Net Revenue | \$2,730,746 | \$2,884,292 |
| Average Net Revenue per Treatment | \$285.26 | \$285.27 |
| Total Operating Expenses (Costs) | \$2,548,174 | \$2,643,812 |
| Average Operating Expenses per Treatment | \$266.18 | \$261.48 |
| Net Income/Profit | \$182,572 | \$240,480 |

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. 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than four dialysis stations for a total of no more than 18 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 is Franklin County. Facilities may serve residents of counties not included in their service area.

The following table shows the existing and approved dialysis facilities in Franklin County. The applicant has one operating facility in Franklin County. DaVita operates Dialysis Care of Franklin County and owns Bunn Dialysis which is not yet operational. As of December 31, 2018, the average in-center utilization for FMC Tar River was 89.58% or 3.58 patients per station, as published in the July 2019 SDR.

| Facility Name | Certified stations as of 12/31/2018 | # of In-Center Patients as of 12/31/2018 | Utilization by percent as of 12/31/2018 | Patients per Station |
|----------------------------------|-------------------------------------|--|---|----------------------|
| FMC Tar River | 12 | 43 | 89.58% | 3.5833 |
| Dialysis Care of Franklin County | 27 | 52 | 48.15% | 1.9259 |
| Bunn Dialysis | 0 | 0 | NA | NA |
| Total | 39 | 95 | NA | NA |

Source: Table B, July 2019 SDR, page 44

In Section G, page 36, 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 the following:

“BMA is not proposing to duplicate services, but to ensure a sufficient number of stations remain available for the patients of the area. The July 2019 SDR reports a deficit of two stations for Franklin County. Adding stations at FMC Tar River will not duplicate services.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing and approved dialysis stations.

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 reason stated above.

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

C

In Section Q, page 84, the applicant provides current and projected staffing in full time equivalents (FTEs) for the proposed services as illustrated in the following table. In Section Q, page 85, the applicant states that the medical director is not a FTE position, but is a contracted position.

| FMC Tar River Staffing | | |
|-------------------------------|----------------------------|-------------------------|
| Position | Current # FTEs | Projected # FTEs |
| | As of June 30, 2019 | OY2 (CY2022) |
| Administrator | 1.00 | 1.00 |
| Registered Nurse | 2.00 | 2.50 |
| Home Training RN | 0.25 | 0.50 |
| Patient Care Technician | 5.00 | 6.00 |
| Dietitian | 0.50 | 0.50 |
| Social Worker | 0.50 | 0.50 |
| Maintenance | 0.50 | 0.50 |
| Administration | 1.00 | 1.00 |
| FMC Director of Operations | 0.15 | 0.15 |
| Other: In-Service | 0.15 | 0.15 |
| Chief Tech | 0.15 | 0.15 |
| Total | 11.20 | 12.95 |

The assumptions and methodology used to project staffing are provided in Section Q, page 85. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3.1 and H-3.2, 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

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.

In Section I, page 40, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how each ancillary and support service is made available.

| FMC Tar River Necessary Ancillary and Support Services | |
|---|--|
| Services | Provider |
| Self-care training (in-center) | On site |
| Home training: HH PD Accessible follow-up program | |
| Isolation – hepatitis | |
| Nutritional counseling | On site |
| Social Work services | On site |
| Laboratory Services | On Site |
| Vascular surgery | Referral to Rex Vascular; Raleigh Access Center; Wake Med Vascular |
| Pediatric nephrology | Referral to UNC HealthCare |
| Acute dialysis in an acute care setting | Referral to Wake Med, Rex or Duke Health Raleigh |
| Transplantation services | Referral to UNC Healthcare |
| Emergency care | Provided by facility staff until Ambulance arrival |
| Blood bank services | Referral to Rex Hospital |
| X-ray, Diagnostic and evaluation services | Referral to Wake Radiology, Wake Med, Rex Hospital |
| Psychological Counseling | Referral to Carolina Partners |
| Vocational rehabilitation & counseling services | Vocational Rehabilitation Services Franklin County |
| Transportation | KARTS Transportation |

Source: Section I, page 40

In Section I, page 40, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

As stated in Section K, page 43, the applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the

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

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

C

In Section L, page 48, the applicant provides the historical payor mix during Calendar Year 2018 (CY 2018) for its existing services, as shown in the table below.

| FMC Tar River Historical Payor Mix Last Full Operating Year-1/1/2018-12/31/2018 | | | | | | |
|---|---------------|----------------|-------------------|----------------|---------------------|----------------|
| Payor Source | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Self-Pay | 1.18 | 2.73% | 0.00 | 0.00% | 0.00 | 0.00% |
| Insurance** | 3.68 | 8.56% | 0.11 | 5.51% | 0.22 | 5.47% |
| Medicare** | 22.99 | 53.47% | 1.80 | 90.20% | 2.21 | 55.13% |
| Medicaid** | 2.06 | 4.79% | 0.00 | 0.00% | 0.78 | 19.57% |
| Other: Medicare/Commercial | 12.20 | 28.38% | 0.00 | 0.00% | 0.79 | 19.83% |
| Other: Misc. (includes VA) | 0.89 | 2.06% | 0.09 | 4.29% | 0.00 | 0.00% |
| Total | 43.00 | 100.00% | 2.00 | 100.00% | 4.00 | 100.00% |

**Including any managed care plans

In Section L.1(a), page 46, the applicant provides a comparison of the demographical information on FMC Tar River patients and the service area population during CY2018, as summarized below.

| FMC Tar River | Percentage of Total Patients Served during the Last Full OY | Percentage of the Population of the Service Area* |
|-------------------------------------|---|---|
| Female | 36.2% | 50.6% |
| Male | 63.8% | 49.4% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 50.0% | 83.2% |
| 65 and Older | 50.0% | 16.8% |
| American Indian | 0.0% | 0.9% |
| Asian | 0.0% | 0.7% |
| Black or African-American | 79.3% | 26.0% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.1% |
| White or Caucasian | 19.0% | 63.5% |
| Other Race | 1.7% | 8.8% |
| Declined / Unavailable | 0.0% | 0.0% |

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the 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 applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 48, the applicant states,

“BMA does not have any obligations under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.”

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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 49, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

| FMC Tar River Projected Payor Mix Second Full Operating Year-1/1/2022-12/31/2022 | | | | | | |
|---|----------------------|-------------------|--------------------------|-------------------|----------------------------|-------------------|
| Payor Source | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Self-Pay | 1.72 | 2.73% | 0.00 | 0.00% | 0.00 | 0.00% |
| Insurance** | 5.39 | 8.56% | 0.07 | 5.51% | 0.33 | 5.47% |
| Medicare** | 33.68 | 53.47% | 1.12 | 90.20% | 3.28 | 55.13% |
| Medicaid** | 3.02 | 4.79% | 0.00 | 0.00% | 1.17 | 19.57% |
| Other: Medicare/Commercial | 17.88 | 28.38% | 0.00 | 0.00% | 1.18 | 19.83% |
| Other: Misc. (includes VA) | 1.30 | 2.06% | 0.05 | 4.29% | 0.00 | 0.00% |
| Total | 62.99 | 100.00% | 1.24 | 100.00% | 5.96 | 100.00% |

**Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3% of total services will be provided to self-pay in center patients, 82% to Medicare in-center patients (includes Medicare and Medicare/Commercial) and 5% to Medicaid in-center patients.

On pages 49-50, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 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-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to add no more than four dialysis stations for a total of no more than 18 stations upon completion of this project and Project ID# K-11669-19 (add 2 stations).

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

The following table shows the existing and approved dialysis facilities in Franklin County. The applicant has one operating facility in Franklin County. DaVita operates Dialysis Care of Franklin County and owns Bunn Dialysis which is not yet operational. As of December 31, 2018, the average in-center utilization for FMC Tar River was 89.58% or 3.58 patients per station, as published in the July 2019 SDR.

| Facility Name | Certified stations as of 12/31/2018 | # of In-Center Patients as of 12/31/2018 | Utilization by percent as of 12/31/2018 | Patients per Station |
|----------------------------------|-------------------------------------|--|---|----------------------|
| FMC Tar River | 12 | 43 | 89.58% | 3.5833 |
| Dialysis Care of Franklin County | 27 | 52 | 48.15% | 1.9259 |
| Bunn Dialysis | 0 | 0 | NA | NA |
| Total | 39 | 95 | NA | NA |

Source: Table B, July 2019 SDR, page 44

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 52, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the Fresenius Medical Care Tar River facility begins with the current patient population.

...

There are currently two dialysis facilities within Franklin County (DaVita also has their Bunn Dialysis project under development). With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at Fresenius Medical Care Tar River.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 53, the applicant states:

“Approval of this application will allow the Fresenius Medical Tar River facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment.”

Regarding the impact of the proposal on quality, in Section N, page 53, the applicant states:

“Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality to every patient at every treatment.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 53, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section Q, pages 61-65, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 127 of this type of facility located in North Carolina.

In Section O, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 127 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

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- FMC Tar River is an existing 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, pages 17-20, the applicant documents the need for the project and demonstrates that it will serve a total of 60 in-center patients on 18 stations at the end of the first operating year, which is 3.33 patients per station per week or a utilization rate of 83.33 percent. The discussion regarding analysis of need 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 17-19, and in Section Q, page 67-70, 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.