

CORRECTED

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 14, 2019

Findings Date: August 14, 2019

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: J-11707-19

Facility: Fresenius Medical Care Stallings Station

FID #: 030941

County: Johnston

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

Project: Relocate entire facility to new location for a total of no more than 18 stations upon completion of this project, Project I.D. #J-11435-17 (relocate 10 stations), and Project I.D. #J-11473-18 (add four stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (hereinafter known as “BMA” or “the applicant”) proposes to relocate an existing dialysis facility, Fresenius Medical Care Stallings Station (FMC Stallings Station) from 5420 Barber Mill Road in Clayton to leased space in an existing building located at 11618 US Highway 70 in Clayton.

Need Determination

The applicant is proposing to relocate existing dialysis stations within Johnston County. Neither the county nor facility need methodologies in the 2019 State Medical Facilities Plan (2019 SMFP) are applicable to this review.

Policies

There are two policies in the 2019 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy ESRD-2: Relocation of Dialysis Stations (page 25 of the 2019 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*
- 1. 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.”*

The applicant proposes to relocate existing dialysis stations within Johnston County; thus, there will be no change to the dialysis inventory of Johnston County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop

and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, pages 15-16, the applicant provides a written statement describing its plan to assure improved energy efficiency and water conservation. On page 15, the applicant states:

"Fresenius Medical Care is committed to ensuring the building will maximize improved energy efficiency. The building plumbing systems will be designed to ensure conservation of water. The exterior building envelope, consisting of roofing, wall, and glass systems meets current requirements for energy conservation."

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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 the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 and Policy GEN-4.

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

women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to relocate an existing dialysis facility, FMC Stallings Station, from 5420 Barber Mill Road in Clayton to leased space in an existing building located at 11618 US Highway 70 in Clayton, which is 1.8 miles and five minutes driving time from the current site. According the January 2019 Semiannual Dialysis Report (SDR), BMA was certified for 24 stations as of June 30, 2018. There are two projects, previously approved but not yet developed, which will affect the number of dialysis stations at FMC Stallings Station. Project I.D. #J-11435-17 will relocate 10 stations from FMC Stallings Station to develop Fresenius Kidney Care West Johnston and Project I.D. #J-11473-18 will add four stations to FMC Stallings Station pursuant to the facility need methodology. In Section C, page 19, the applicant states the relocated facility will have 18 certified dialysis stations.

FMC Stallings Station currently offers both home hemodialysis training (HH) and home peritoneal dialysis training (PD) and plans to continue to offer both HH and PD following completion of the proposed project.

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 is Johnston County. Facilities may serve residents of counties not included in their service area.

The following table shows current and projected patient origin.

| FMC Stallings Station Current (CY 2018) and Projected Patient Origin (OY 2 – CY 2022) | | | | | | | | |
|---|-------------------------------------|----------|-----------|-----------------------------|-----------|-----------|------------------|---------------|
| County | Last Full Operating Year CY 2018 | | | Operating Year 2 CY 2022 | | | Percent of Total | |
| | IC | HH | PD | IC | HH | PD | CY 2018 | CY 2022 |
| Johnston | 85 | 7 | 13 | 94 | 9 | 17 | 90.5% | 91.5% |
| Wake | 2 | 2 | 4 | 2 | 2 | 4 | 6.9% | 6.2% |
| Harnett | 0 | 0 | 1 | 0 | 0 | 1 | 0.9% | 0.8% |
| Nash | 0 | 0 | 1 | 0 | 0 | 1 | 0.9% | 0.8% |
| Wayne | 0 | 0 | 1 | 0 | 0 | 1 | 0.9% | 0.8% |
| Total | 87 | 9 | 20 | 96 | 11 | 24 | 100.0% | 100.0% |

Source: Section C, pages 18-19

In Section C, pages 19-21, 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 22-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The overall patient population at FMC Stallings Station has increased at an average annual growth rate of 10.8 percent between December 31, 2013 and December 31, 2018. The home dialysis patient population has increased at a higher rate than the in-center dialysis patient population.
- The existing lease for FMC Stallings Station expires at the end of 2020. There is currently limited space to expand the existing facility to accommodate growth of the home dialysis patient population’s needs (training and support).
- Relocating the entire facility is more cost effective than developing a freestanding home dialysis training program, and the proposed site of the relocation is close to the existing site, which maintains the proximity of the facility to its patient population.

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

- The applicant bases the need to relocate the facility on factors such as patient population growth and proximity to current patients.
- The applicant has considered options other than relocation and provides reasonable and adequately supported information to justify the choice to relocate the facility.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as shown in the table below.

| FMC Stallings Station – Historical and Projected Utilization – CY 2018-2022 | | | | | |
|--|-------------------|----------------|----------------|------------------|----------------|
| | Historical | Interim | | Projected | |
| | CY 2018 | CY 2019 | CY 2020 | CY 2021 | CY 2022 |
| In-Center Patients | 87 | 92 | 94 | 89 | 95 |
| HH Patients | 9 | 9 | 9 | 10 | 11 |
| PD Patients | 20 | 20 | 21 | 22 | 23 |
| Total Patients | 116 | 122 | 126 | 122 | 130 |

Note: Consistent with the applicant’s assumptions, the table shows the number of patients at the end of each year, rounded down to the nearest whole patient.

In Section Q, the applicant provides the assumptions and methodology it used to project in-center, HH, and PD patient utilization, which are summarized below.

In-Center

- The applicant begins its utilization projections by using its in-center patient facility census as of December 31, 2018.
- The applicant assumes the in-center patient population currently receiving treatment at FMC Stallings Station and who currently reside in Johnston County will increase annually at a rate of 6.6 percent, which is the Five Year Average Annual Change Rate (AACR) for Johnston County published in the January 2019 SDR.
- The applicant assumes no population growth for the in-center patients who utilize the facility and live in Wake County but assumes the patients will continue to dialyze at FMC Stallings Station and adds them to the calculations when appropriate.
- In its application for FKC Selma (Project I.D. #J-11372-17), the applicant projected four patients residing in Johnston County and dialyzing at FMC Stallings Station would transfer care to FKC Selma, and the applicant subtracts the four patients projected to transfer from the calculations on December 31, 2019 (when FKC Selma is projected to be certified).
- In its application for FKC West Johnston (Project I.D. #J-11435-17), the applicant projected 10 patients residing in Johnston County and dialyzing at FMC Stallings Station would transfer care to FKC West Johnston, and the applicant subtracts the 10 patients projected to transfer from the calculations on December 31, 2020 (when FKC West Johnston is projected to be certified).
- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

The applicant's calculations are summarized in the table below.

| FMC Stallings Station In-Center Projections | |
|--|------------------------------|
| Starting point of calculations is Johnston County patients dialyzing in-center at FMC Stallings Station on December 31, 2018. | 85 |
| Johnston County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (6.6%). | $85 \times 1.066 = 90.6$ |
| Four Johnston County patients, projected to transfer care to FKC Selma, are subtracted from the projected patient population. | $90.6 - 4 = 86.6$ |
| Johnston County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (6.6%). | $86.6 \times 1.066 = 92.3$ |
| 10 Johnston County patients, projected to transfer care to FKC West Johnston, are subtracted from the projected patient population. | $92.3 - 10 = 82.3$ |
| The patients from Wake County are added. This is the projected census on December 31, 2020 and the starting census for this project. | $82.3 + 2 = 84.3$ |
| Johnston County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (6.6%). | $82.3^* \times 1.066 = 87.7$ |
| The patients from Wake County are added. This is the projected census on December 31, 2021 (OY1). | $87.7 + 2 = 89.7$ |
| Johnston County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (6.6%). | $87.7 \times 1.066 = 93.6$ |
| The patients from Wake County are added. This is the projected census on December 31, 2022 (OY2). | $93.6 + 2 = 95.6$ |

*In the table in Section Q, the applicant appears to multiply all patients – including patients from other counties – by the Johnston County Five Year Average Annual Change Rate; however, the actual calculation reflects only Johnston County patients. ($82.3 \times 1.066 = 87.7$; $84.3 \times 1.066 = 89.9$)

The applicant rounds down and projects to serve 89 in-center patients on 18 stations, which is 4.94 patients per station per week ($89 \text{ patients} / 18 \text{ stations} = 4.94$), by the end of OY1 and 95 in-center patients on 18 stations, which is 5.28 patients per station per week ($95 \text{ patients} / 18 \text{ stations} = 5.28$), by the end of OY2. In Section Q, in the assumptions used to project staffing for Form H, the applicant states it will add a third shift at FMC Stallings Station when utilization approaches 100 percent (100 percent utilization is equivalent to four patients per station per week).

Home Hemodialysis Patients

- The applicant begins its utilization projections by using its HH patient census as of December 31, 2018.
- As discussed above under in-center patient utilization, the applicant projects the Johnston County HH population will grow at the Five Year AACR for Johnston County published in the January 2019 SDR (6.6 percent).
- The applicant assumes no population growth for the patients who utilize HH services at FMC Stallings Station and live in Wake County but adds the patients to the calculations when appropriate.

- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

The applicant's calculations are summarized in the table below.

| FMC Stallings Station HH Patients | |
|--|--------------------------|
| Starting point of calculations is Johnston County HH patients dialyzing at FMC Stallings Station on December 31, 2018. | 7 |
| Johnston County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (6.6%). | $7 \times 1.066 = 7.5$ |
| Johnston County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (6.6%). | $7.5 \times 1.066 = 8.0$ |
| The patients from Wake County are added. This is the projected census on December 31, 2020 and the starting census for this project. | $8.0 + 2 = 10.0$ |
| Johnston County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (6.6%). | $8.0 \times 1.066 = 8.5$ |
| The patients from Wake County are added. This is the projected census on December 31, 2021 (OY1). | $8.5 + 2 = 10.5$ |
| Johnston County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (6.6%). | $8.5 \times 1.066 = 9.0$ |
| The patients from Wake County are added. This is the projected census on December 31, 2022 (OY2). | $9.0 + 2 = 11.0$ |

Home Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its PD patient census as of December 31, 2018.
- As discussed above under in-center patient utilization, the applicant projects the Johnston County PD population will grow at the Five Year AACR for Johnston County published in the January 2019 SDR (6.6 percent).
- The applicant assumes no population growth for the patients who utilize PD services at FMC Stallings Station and live in other counties but adds the patients to the calculations when appropriate.
- The project is scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

The applicant's calculations are summarized in the table below.

| FMC Stallings Station PD Patients | |
|---|----------------------------|
| Starting point of calculations is Johnston County PD patients dialyzing at FMC Stallings Station on December 31, 2018. | 13 |
| Johnston County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (6.6%). | $13 \times 1.066 = 13.9$ |
| Johnston County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (6.6%). | $13.9 \times 1.066 = 14.8$ |
| The patients from other counties are added. This is the projected census on December 31, 2020 and the starting census for this project. | $14.8 + 7 = 21.8$ |
| Johnston County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (6.6%). | $14.8 \times 1.066 = 15.7$ |
| The patients from other counties are added. This is the projected census on December 31, 2021 (OY1). | $15.7 + 7 = 22.7$ |
| Johnston County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (6.6%). | $15.7 \times 1.066 = 16.8$ |
| The patients from other counties are added. This is the projected census on December 31, 2022 (OY2). | $16.8 + 7 = 23.8$ |

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

- The applicant projects future utilization based on historical utilization.
- The applicant uses the Five Year AACR for Johnston County as published in the January 2019 SDR to project growth of Johnston County residents.
- The applicant reasonably accounts for projected patient utilization by related projects under development.
- The applicant does not project growth for its patients who do not reside in Johnston County.
- While the Criteria and Standards for End Stage Renal Disease Services are not applicable to this review, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as promulgated in 10A NCAC 14C .2203(b).

Access

In Section C, page 26, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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

In Section L, page 54, the applicant projects the following payor mix during the second full year of operation following completion of the project, as illustrated in the following table.

| FMC Stallings Station Projected Payor Mix CY 2022 | | | |
|--|-----------------------------|----------------------|----------------------|
| Payment Source | % In-Center Patients | % HH Patients | % PD Patients |
| Self-Pay/Indigent/Charity | 0.57% | 0.73% | 0.73% |
| Insurance* | 6.19% | 11.84% | 11.84% |
| Medicare* | 68.82% | 72.67% | 72.67% |
| Medicaid* | 3.71% | 0.00% | 0.00% |
| Medicare/Commercial | 19.30% | 14.49% | 14.49% |
| Misc. (including VA) | 1.41% | 0.27% | 0.27% |
| Total | 100.00% | 100.00% | 100.00% |

*Including any managed care plans

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 (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

BMA proposes to relocate an existing dialysis facility, FMC Stallings Station, from 5420 Barber Mill Road in Clayton to leased space in an existing building located at 11618 US Highway 70 in Clayton, which is 1.8 miles and five minutes driving time from the current site. According to the January 2019 SDR, BMA was certified for 24 stations as of June 30, 2018. There are two projects, previously approved but not yet developed, which will affect the number of dialysis stations at FMC Stallings Station. Project I.D. #J-11435-17 will relocate 10 stations from FMC Stallings Station to develop Fresenius Kidney Care West Johnston and Project I.D. #J-11473-18 will add four stations to FMC Stallings Station pursuant to the facility need methodology. In Section C, page 19, the applicant states the relocated facility will have 18 certified dialysis stations.

In Section D, page 30, the applicant states it will relocate the entire dialysis facility to a new location and will no longer offer dialysis services at the current location.

In Section D, pages 30-31, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 30, the applicant states:

“The facility is planned to be relocated to a new location approximately one mile from the current facility. The patients will continue to have the same access to dialysis care and treatment.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The needs of the population currently using the services to be 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

BMA proposes to relocate an existing dialysis facility, FMC Stallings Station, from its existing location in Clayton to leased space in an existing building in Clayton 1.8 miles and five minutes driving time from the current site. The relocated facility will have 18 stations following completion of this project and associated projects.

In Section E, page 32, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: The applicant states this option would ultimately limit the number of home dialysis patients at FMC Stallings Station; therefore, this was not an effective alternative.
- Expand the Current Location: The applicant states expanding the current location would result in only a small increase in space and is not cost-effective; therefore, this was not an effective alternative.
- Develop a Freestanding Home Dialysis Facility: The applicant states this option would result in duplicative operating costs, require more staff, and result in staff inefficiencies caused by sharing staff between the two facilities; therefore, this was not the most effective alternative.

On page 32, the applicant states relocating the facility is the most cost-effective approach to account for patient population growth as well as increasing space for home dialysis patient training and support.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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. 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 18 stations from the existing location of Fresenius Medical Care Stallings Station to the proposed new site for a total of no more than 18 stations at FMC Stallings Station upon completion of this project, Project I.D. #J-11435-17 (relocate 10 stations to develop Fresenius Kidney Care West Johnston), and Project I.D. #J-11473-18 (add four stations).**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls of Fresenius Medical Care Stallings Station for no more than 18 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to relocate an existing dialysis facility, FMC Stallings Station, from its existing location in Clayton to leased space in an existing building in Clayton 1.8 miles and five minutes driving time from the current site. The relocated facility will have 18 stations following completion of this project and associated projects.

Capital and Working Capital Costs

In Section Q on Form F.1a, the applicant projects \$2,515,658 in capital costs to develop the proposed project as summarized below:

| | |
|-----------------------|--------------------|
| Construction Contract | \$1,727,576 |
| Medical Equipment | \$300,948 |
| Other Equipment | \$237,499 |
| Fees | \$155,482 |
| Contingency | \$94,153 |
| Total | \$2,515,658 |

In Section F, pages 35-36, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since it is an existing facility which is already operational.

Availability of Funds

In Section F, page 35, the applicant states funding for the capital expenses of the proposed project will be funded through accumulated reserves.

Exhibit F-2 contains a letter dated May 15, 2019 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. (FMCH), the parent company for BMA, authorizing and committing accumulated reserves of FMCH for the capital costs of the project. The letter further states:

“This project is to be funded through Fresenius Medical Care Holdings, Inc., accumulated reserves. Our 2017 Consolidated Balance Sheet reflects more than \$569 million in cash, and total assets exceeding \$19 billion. The 2018 Consolidated Balance Sheet is not yet available.”

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 on Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

| Projected Revenues and Operating Expenses | | |
|--|-------------------------------------|-------------------------------------|
| FMC Stallings Station | Operating Year 1 CY 2021 | Operating Year 2 CY 2022 |
| Total Treatments | 18,428 | 18,749 |
| Total Gross Revenues (Charges) | \$115,936,719 | \$117,949,995 |
| Total Net Revenue | \$5,836,051 | \$5,947,861 |
| Average Net Revenue per Treatment | \$317 | \$317 |
| Total Operating Expenses (Costs) | \$4,570,884 | \$4,838,655 |
| Average Operating Expense per Treatment | \$248 | \$258 |
| Net Income/Profit | \$1,265,167 | \$1,109,206 |

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

BMA proposes to relocate an existing dialysis facility, FMC Stallings Station, from its existing location in Clayton to leased space in an existing building in Clayton 1.8 miles and five minutes driving time from the current site. According to the January 2019 SDR, BMA was certified for 24 stations as of June 30, 2018. The relocated facility will have 18 stations following completion of this project, Project I.D. #J-11435-17 (relocate 10 stations to develop Fresenius Kidney Care West Johnston), and Project I.D. #J-11473-18 (add four 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 for this facility is Johnston County. Facilities may serve residents of counties not included in their service area.

The applicant operates three dialysis centers in Johnston County. BMA has also been approved to develop two additional facilities in Johnston County, FKC Selma and FKC West Johnston, but the facilities were not yet operational on December 31, 2018. There are no other providers of dialysis services in Johnston County. The existing and approved Johnston County dialysis facilities are shown below:

| Johnston County Dialysis Facilities and Utilization as of December 31, 2018 | | | | |
|--|--|-------------------------------------|--------------------------|---------------------------------|
| Dialysis Facility | Certified Stations 12/31/2018 | CON Issued Not Certified | % Utilization | Patients Per Station |
| FMC Four Oaks | 22 | -2 | 73.86% | 2.95 |
| FMC Stallings Station | 24 | -6 | 90.63% | 3.63 |
| Johnston Dialysis Center | 31 | 1 | 86.29% | 3.45 |
| FKC Selma | 0 | 10 | 0.00% | 0.00 |
| FKC West Johnston | 0 | 10 | 0.00% | 0.00 |

Source: Section G, page 40; July 2019 SDR, Table B

As shown in the table above, two of the three operational Johnston County dialysis facilities were operating above 80 percent utilization (3.2 patients per station) as of December 31, 2018.

In Section G, page 41, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Johnston County. The applicant states the stations to be relocated already exist and there will be no increase or decrease in the number of dialysis stations or facilities in Johnston County.

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

- The proposal would not result in an increase in the number of dialysis stations in Johnston County.
- The applicant adequately demonstrates that the proposed relocation of existing dialysis stations is needed in addition to the existing or approved dialysis stations in Johnston County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits in 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.

- (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 on Form H, the applicant provides its current and projected staffing in full-time equivalent positions (FTEs), as shown in the table below.

| FMC Stallings Station Current and Projected Staffing (FTEs) | | | |
|--|--------------------------------|-----------------------|-----------------------|
| Position | Current (as of 5/15/19) | OY 1 (CY 2021) | OY 2 (CY 2022) |
| Administrator | 1.00 | 1.00 | 1.00 |
| Registered Nurses | 3.00 | 3.75 | 4.50 |
| Licensed Practical Nurses | 1.00 | 1.00 | 1.00 |
| Home Training Nurses | 2.00 | 2.00 | 2.00 |
| Patient Care Technicians | 8.00 | 10.00 | 12.00 |
| Dietician | 1.00 | 1.00 | 1.00 |
| Social Worker | 1.00 | 1.00 | 1.00 |
| Maintenance | 0.80 | 0.80 | 0.80 |
| Business Office | 1.00 | 1.00 | 1.00 |
| FMC Director Operations | 0.20 | 0.20 | 0.20 |
| In-Service | 0.30 | 0.30 | 0.30 |
| Chief Technician | 0.30 | 0.30 | 0.30 |
| Total FTEs | 19.60 | 22.35 | 25.10 |

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3 in Section Q. In Section H, page 42, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-3.1 and H-3.2. In Section H, page 43, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I, pages 44-45, the applicant states that the following ancillary and support services are necessary for the proposed services:

| FMC Stallings Station Ancillary and Support Services | |
|--|-------------------------------------|
| Services | Provider |
| In-center dialysis/maintenance | FMC Stallings Station |
| Self-care training (in-center) | FMC Stallings Station |
| Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program | FMC Stallings Station |
| Psychological counseling | Johnston County Mental Health |
| Isolation – hepatitis | FMC Stallings Station |
| Nutritional counseling | FMC Stallings Station |
| Social Work services | FMC Stallings Station |
| Acute dialysis in an acute care setting | Johnston Health, WakeMed |
| Emergency care | FMC Stallings Station |
| Blood bank services | Johnston Health |
| Diagnostic and evaluation services | Johnston Health, WakeMed |
| X-ray services | Johnston Health, WakeMed |
| Laboratory services | Spectra Laboratory |
| Pediatric nephrology | UNC Healthcare |
| Vascular surgery | Raleigh Access Center, Rex Vascular |
| Transplantation services | UNC Healthcare |
| Vocational rehabilitation & counseling | Amedisys Home Health |
| Transportation | JCATS, Lyft, Uber |

On page 45, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.2, I-1.3, and I-1.4.

In Section I, page 45, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

C

In Section K, page 48, the applicant states that the project involves upfitting 10,948 square feet of leased space. Line drawings are provided in Exhibit K-2.

On page 48, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

On page 48, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 49-50, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 50-51, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The applicant provides supporting documentation in Exhibit K-4.

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.

- (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 53, the applicant provides the historical payor mix for CY 2018 at FMC Stallings Station, as shown in the table below.

| FMC Stallings Station Historical Payor Mix CY 2018 | | | |
|---|-----------------------------|----------------------|----------------------|
| Payment Source | % In-Center Patients | % HH Patients | % PD Patients |
| Self-Pay/Indigent/Charity | 0.57% | 0.73% | 0.73% |
| Insurance* | 6.19% | 11.84% | 11.84% |
| Medicare* | 68.82% | 72.67% | 72.67% |
| Medicaid* | 3.71% | 0.00% | 0.00% |
| Medicare/Commercial | 19.30% | 14.49% | 14.49% |
| Misc. (including VA) | 1.41% | 0.27% | 0.27% |
| Total | 100.00% | 100.00% | 100.00% |

*Including any managed care plans

In Section L, page 52, the applicant provides the following comparison.

| FMC Stallings Station | % of Total Patients Served during CY 2018 | % of the Population of Johnston County |
|-------------------------------------|--|---|
| Female | 35.0% | 51.0% |
| Male | 65.0% | 49.0% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 56.7% | 87.0% |
| 65 and Older | 43.3% | 13.0% |
| American Indian | 0.0% | 0.9% |
| Asian | 0.8% | 0.9% |
| Black or African-American | 55.9% | 16.5% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.1% |
| White or Caucasian | 37.3% | 67.9% |
| Other Race | 5.9% | 13.7% |
| Declined / Unavailable | 0.0% | 0.0% |

Sources: BMA internal data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 53, 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 applicant will treat all patients the same regardless of race or handicap status.”

In Section L, page 54, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 54, 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 Stallings Station Projected Payor Mix CY 2022 | | | |
|--|-----------------------------|----------------------|----------------------|
| Payment Source | % In-Center Patients | % HH Patients | % PD Patients |
| Self-Pay/Indigent/Charity | 0.57% | 0.73% | 0.73% |
| Insurance* | 6.19% | 11.84% | 11.84% |
| Medicare* | 68.82% | 72.67% | 72.67% |
| Medicaid* | 3.71% | 0.00% | 0.00% |
| Medicare/Commercial | 19.30% | 14.49% | 14.49% |
| Misc. (including VA) | 1.41% | 0.27% | 0.27% |
| Total | 100.00% | 100.00% | 100.00% |

*Including any managed care plans

As shown in the table above, during the second year of operation, the applicant projects that 0.57 percent of total services will be provided to self-pay, indigent, and charity

care patients, 88.12 percent to patients having some or all their services paid for by Medicare, and 3.71 percent to Medicaid patients.

On page 54, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for FMC Stallings Station.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 56, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

BMA proposes to relocate an existing dialysis facility, FMC Stallings Station, from its existing location in Clayton to leased space in an existing building in Clayton 1.8 miles and five minutes driving time from the current site. According to the January 2019 SDR, BMA was certified for 24 stations as of June 30, 2018. The relocated facility will have 18 stations following completion of this project, Project I.D. #J-11435-17 (relocate 10 stations to develop Fresenius Kidney Care West Johnston), and Project I.D. #J-11473-18 (add four 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 for this facility is Johnston County. Facilities may serve residents of counties not included in their service area.

The applicant operates three dialysis centers in Johnston County. BMA has also been approved to develop two additional facilities in Johnston County, FKC Selma and FKC West Johnston, but the facilities were not yet operational on December 31, 2018. There are no other providers of dialysis services in Johnston County. The existing and approved Johnston County dialysis facilities are shown below:

| Johnston County Dialysis Facilities and Utilization as of December 31, 2018 | | | | |
|--|--|-------------------------------------|--------------------------|---------------------------------|
| Dialysis Facility | Certified Stations 12/31/2018 | CON Issued Not Certified | % Utilization | Patients Per Station |
| FMC Four Oaks | 22 | -2 | 73.86% | 2.95 |
| FMC Stallings Station | 24 | -6 | 90.63% | 3.63 |
| Johnston Dialysis Center | 31 | 1 | 86.29% | 3.45 |
| FKC Selma | 0 | 10 | 0.00% | 0.00 |
| FKC West Johnston | 0 | 10 | 0.00% | 0.00 |

Source: Section G, page 40; July 2019 SDR, Table B

As shown in the table above, two of the three operational Johnston County dialysis facilities were operating above 80 percent utilization (3.2 patients per station) as of December 31, 2018.

In Section N, pages 57-59, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 52, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Johnston County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Stallings Station facility begins with patients currently served by the facility, and a growth of that patient population consistent [with] recent growth of the facility census at the Johnston County Five Year Average Annual Change Rate of 6.6%.”

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 Q 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 Sections C, D, and 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 Q on Form A, the applicant provides a list of the Fresenius-related dialysis facilities located in North Carolina. In Section C, page 26, the applicant states there are 128 Fresenius-related dialysis facilities in North Carolina.

In Section O, page 63, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents at any Fresenius-related facility resulting in an immediate jeopardy violation. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius-related facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

The applicant proposes to relocate its existing facility to leased space approximately one mile from its current location. The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review because the applicant does not propose to establish a new end stage renal disease facility or to add stations to an existing facility.