

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 14, 2019

Findings Date: June 14, 2019

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: M-11662-19

Facility: FMC Services of West Fayetteville

FID #: 011019

County: Cumberland

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

Project: Add no more than one dialysis station for a total of no more than 40 stations upon completion of this project and Project ID #M-11650-19 (relocate one station)

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. (the applicant) proposes to add one dialysis station to FMC Services of West Fayetteville (FMC West Fayetteville), an existing facility, for a total of 40 dialysis stations upon completion of this project and Project ID #M-11650-19 (relocate one station).

By way of explanation, the following projects are historically relevant to this application:

1. Project ID #M-11286-17 (FKC Rockfish): Develop a new 10-station dialysis facility by relocating five stations from FCM South Ramsey and five stations from FMC West Fayetteville. The CON was effective on May 23, 2017.
2. Project ID #M-11314-17 (FMC West Fayetteville): Add five stations. The CON was effective on August 8, 2017.

3. Project ID #M-11650-19: Relocate one dialysis station from FMC West Fayetteville for a total of 21 stations at FKC Rockfish.

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 Table D in the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 11 stations in Cumberland County, but no need determination. Therefore, the applicant cannot apply to add any additional stations based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations in its existing facility 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%. The utilization rate reported for FMC West Fayetteville in the January 2019 SDR is 3.9 patients per station per week, or 97.50%, based on 156 in-center dialysis patients and 40 certified dialysis stations [$156 / 40 = 3.9$; $3.9 / 4 = 0.9750$ or 97.50%].

Application of the facility need methodology indicates up to one additional station is needed at this facility, as illustrated in the following the table:

| FMC West Fayetteville | | |
|--|---|-----------|
| APRIL 1 REVIEW-JANUARY SDR | | |
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 6/30/18 | | 97.50% |
| Certified Stations | | 40 |
| Pending Stations | | 5 |
| Total Existing and Pending Stations | | 45 |
| In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2) | | 156 |
| In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1) | | 165 |
| Step | Description | Result |
| (i) | Difference (SDR2 - SDR1) | -9 |
| | Multiply the difference by 2 for the projected net in-center change | -18 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17 | -0.1091 |
| (ii) | Divide the result of step (i) by 12 | -0.0091 |
| (iii) | Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18) | -0.0545 |
| (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 | 147.4909 |
| (v) | Divide the result of step (iv) by 3.2 patients per station | 46.0909 |
| | and subtract the number of certified and pending stations to determine the number of stations needed | 1 |

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC West Fayetteville is one, based on rounding allowed in Step (v). 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 one new station; 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 will promote safety and quality in Section B.4 (a and d), pages 8 and 10 - 11, respectively; Section N.1, page 53; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.4 (b and d), pages 9 - 11; Section C.3, page 16; Section L, pages 47 - 51; Section N.1, page 53; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.4 (c and d), pages 10 - 11; Section F, page 25; Section K, pages 42 - 46; Section N.1, page 53; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of 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 one dialysis station to FMC Services of West Fayetteville (FMC West Fayetteville), an existing facility, for a total of 40 dialysis stations upon completion of this project and Project ID #M-11650-19 (relocate one station).

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

In Section C.8, page 18, the applicant provides the patient origin for FMC West Fayetteville patients as of December 31, 2018, as shown in the table below.

**FMC West Fayetteville
 Historical Patient Origin**

| COUNTY | # OF PATIENTS |
|----------------|---------------|
| Cumberland | 150 |
| Bladen | 1 |
| Hoke | 16 |
| Johnston | 1 |
| Mecklenburg | 1 |
| Robeson | 3 |
| South Carolina | 1 |
| Virginia | 1 |
| Other States | 3 |
| Total | 177 |

The following table illustrates projected patient origin for the first two years of operation following project completion, as provided in Section C, page 13.

**FMC West Fayetteville
 Projected Patient Origin**

| COUNTY | OPERATING YEAR 1 CY 2021 | | OPERATING YEAR 2 CY 2022 | |
|--------------|-----------------------------|---------------|-----------------------------|---------------|
| | # PTS. | % OF TOTAL | # PTS. | % OF TOTAL |
| Cumberland | 129.1 | 91.4% | 133.3 | 91.74% |
| Bladen | 1 | 0.71% | 1 | 0.69% |
| Hoke | 10 | 7.09% | 10 | 6.88% |
| Robeson | 1 | 0.71% | 1 | 0.69% |
| Total | 141 | 100.0% | 145 | 100.0% |

In Section C, pages 13 - 15, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to add one dialysis station to the existing FMC West Fayetteville, for a total of 40 dialysis stations upon completion of this project and Project ID#M-11650-19 (add one station). In Section C.1, pages 13 - 15, the applicant describes its need methodology and assumptions for projecting utilization of the proposed facility, summarized as follows:

- The applicant assumes the Cumberland County patient population who dialyze at FMC West Fayetteville will increase at a rate equal to the 3.3% Cumberland County Five Year Average Annual Change Rate (AACR) published in the January 2019 SDR.
- As part of Project ID #M-11286-17, the applicant proposed to relocate five stations from FMC West Fayetteville to develop a new facility, FKC Rockfish. Also as part of that project, the applicant projected that 22 Cumberland County and six Hoke County residents

would transfer their care to FKC Rockfish. The applicant affirms those assumptions in this application.

- In Project ID #M-11344-17, the applicant proposed to develop a new facility, FKC Hope Mills. Also as part of that project, the applicant projected that 2 Cumberland County and eight Robeson County residents would transfer their care to FKC Hope Mills. The applicant affirms those assumptions in this application.
- In Project ID #M-11502-18, the applicant was approved for a change of scope (COS) application which effectively merged Project ID #M-11286-17 and Project ID#M-11344-17 to develop one 20-station facility, FKC Rockfish.
- The applicant states FKC Rockfish is projected to be complete at the end of 2019.
- The applicant projects the following number of patients currently dialyzing at FMC West Fayetteville to transfer their care to FKC Rockfish at the end of 2019, when that facility is complete:

FMC West Fayetteville Patients to Transfer to FCK Rockfish

| COUNTY OF RESIDENCE | FKC ROCKFISH M-11286-17 | FKC HOPE MILLS M-11344-17 | FKC ROCKFISH (COS) M-11502-18 |
|---------------------|-------------------------|---------------------------|-------------------------------|
| Cumberland | 22 | 8 | 30 |
| Hoke | 6 | 0 | 6 |
| Robeson | 0 | 2 | 2 |
| Total | 28 | 10 | 38 |

- As shown above, the applicant projects that 28 patients currently dialyzing at FMC West Fayetteville will transfer their care to FKC Rockfish effective December 31, 2019.
- The applicant states as of December 31, 2018, the following number of patients were dialyzing at FMC West Fayetteville:

| COUNTY | # PATIENTS |
|----------------|------------|
| Cumberland | 150 |
| Bladen | 1 |
| Hoke | 16 |
| Johnston | 1 |
| Mecklenburg | 1 |
| Robeson | 3 |
| South Carolina | 1 |
| Virginia | 1 |
| Other states | 3 |
| Total | 177 |

- The applicant assumes the patients from Mecklenburg and Johnston counties and other states are transient patients; therefore, the applicant does not include those patients in projections of future patient populations for FMC West Fayetteville.
- The applicant will not project growth in the patients residing in Bladen, Hoke or Robeson counties; however, it will add those patients at the end of the growth projections, less any patients projected to transfer to FKC Rockfish.
- The applicant projects this project to be complete by December 31, 2019.
- The first Operating Year (OY) for this project is thus calendar year (CY) 2020, January 1, 2020 – December 31, 2020. The second OY is CY 2021, January 1, 2021 – December 31, 2021.

Projected Utilization

In Section C, page 15, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the following table.

| FMC WEST FAYETTEVILLE IN-CENTER PATIENTS | |
|--|------------------------------|
| Begin with facility census of Cumberland County patients as of December 31, 2018. | 150 |
| Project this population forward one year to December 31, 2019, using the Cumberland County Five Year AACR of 3.3%. | $150 \times 1.033 = 154.95$ |
| Subtract 30 patients projected to transfer to FKC Rockfish (22 from M-11286-17 and 8 from M-11344-17). | $155 - 22 = 30 = 125$ |
| Add patients from Bladen, Hoke and Robeson Counties projected to continue to dialyze at FMC West Fayetteville. | $125 + 12 = 137$ |
| Project Cumberland County patients forward one year to December 31, 2020, using the Cumberland County Five Year AACR of 3.3%. | $125 \times 1.033 = 129.1$ |
| Add patients from Bladen, Hoke and Robeson Counties projected to continue to dialyze at FMC West Fayetteville. This is the ending census for OY 1. | $129.1 + 12 = 141.1$ |
| Project Cumberland County patients forward one year to December 31, 2021, using the Cumberland County Five Year AACR of 3.3%. | $129.1 \times 1.033 = 133.3$ |
| Add patients from Bladen, Hoke and Robeson Counties projected to continue to dialyze at FMC West Fayetteville. This is the ending census for OY 2. | $133.3 + 12 = 145.3$ |

Source: Table in Section C, page 15

Projected patients for OY 1 and OY 2 are rounded down to the nearest whole number. Therefore, at the end of OY 1 (CY 2020) FMC West Fayetteville is projected to serve 141 in-center patients on 40 stations; and at the end of OY 2 (CY 2021) the facility is projected to serve 145 in-center patients on 40 stations.

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

- OY 1: 3.53 patients per station per week, or 88.1% utilization [$141 / 40 = 3.525$; $3.53 / 4 = 0.88125$].

- OY 2: 3.63 patients per station per week, or 90.6% utilization [145 patients / 40 stations = 3.625; 3.625 / 4 = 0.90625%].

The projected utilization of 3.53 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- FMC West Fayetteville was operating at 97.5% capacity as of June 30, 2018, as reported in the January 2019 SDR.
- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the patient population using the Cumberland County Five Year AACR of 3.3%, as published in the January 2019 SDR.
- Projected utilization at the end of OY 1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 16, 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 undeserved persons.

...

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 undeserved person.”

In Section L, page 48, 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 West Fayetteville
 Projected Payor Mix CY 2022**

| Payment Source | % of Total |
|---------------------------|-------------------|
| Self-pay/Indigent/Charity | 0.32% |
| Medicare | 74.45% |
| Medicaid | 5.27% |
| Commercial Insurance | 3.82% |
| Medicare/Commercial | 13.29% |
| Miscellaneous (incl. VA) | 2.85% |
| Total | 100.00% |

Note: numbers may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

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 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 a service, 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 one dialysis station to FMC Services of West Fayetteville (FMC West Fayetteville), an existing facility, for a total of 40 dialysis stations upon completion of this project and Project ID #M-11650-19 (relocate one station).

In Section E, page 22, the applicant states it considered two alternatives, though its choices were limited, since this application is filed pursuant to the Facility Need Methodology which is unique to this facility. The two alternatives considered were:

1. Maintain the status quo – the applicant states this was not a reasonable alternative because it ignores the growth of the Cumberland County ESRD patient population and the stated deficit in the 2019 SDR. Adding one station decreases the county deficit by only one station.
2. Relocate a station from FMC North Ramsey – the applicant states the utilization of FMC North Ramsey, as of December 31, 2018, when the data for the ESRD Data Collection Form was submitted, was 96.88 % based on 155 patients and 40 stations. The applicant states it would be inappropriate to remove stations from this facility under these circumstances.

In Section E, page 22, the applicant states that its proposal is the most cost-effective alternative because it requires no capital expenditure and serves to meet the growing needs of patients choosing to dialyze at FMC West Fayetteville.

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 provided credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

1. **Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
2. **Pursuant to the facility need determination in the January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station at FMC Services of West Fayetteville for a total of no more than 40 certified stations upon completion of this project and Project ID #M-11650-18 (relocate one station from FMC Services of West Fayetteville), 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

Bio-Medical Applications of North Carolina, Inc. (the applicant) proposes to add one dialysis station to FMC Services of West Fayetteville (FMC West Fayetteville), an existing facility, for a total of 40 dialysis stations upon completion of this project and Project ID #M-11650-19 (relocate one station).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant states there is no capital cost associated with this project.

In Sections F.10 and F.11, page 26, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Financial Feasibility

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

FMC West Fayetteville Projected Revenue and Operating Expenses

| | OY 1 CY 2020 | OY 2 CY 2021 |
|---|-------------------------|-------------------------|
| Total Treatments | 20,599 | 21,192 |
| Total Gross Revenue (charges) | \$82,148,812 | \$84,513,696 |
| Total Net Revenue | \$5,145,242 | \$5,293,362 |
| Average Net Revenue per Treatment | \$249.78 | \$249.78 |
| Total Operating Expenses (costs) | \$4,907,290 | \$5,040,115 |
| Average Operating Expense per Treatment | \$238.23 | \$237.83 |
| Net Income / Profit | \$237,952 | \$253,248 |

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because 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 one dialysis station to FMC West Fayetteville, an existing facility, for a total of 40 dialysis stations upon completion of this project and Project ID #M-11650-19 (relocate one station).

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

The applicant is the only provider of dialysis services in Cumberland County. Currently there are four existing and one approved but not yet developed facilities, all of which are located in the greater Fayetteville area, where the applicant states is close proximity to the larger number of dialysis patients. See the following table that shows the existing and approved dialysis facilities in Cumberland County, from Table B of the January 2019 SDR:

| FACILITY | PROVIDER | LOCATION | # STATIONS | UTILIZATION |
|----------------------------|------------------------|-----------------|-------------------|--------------------|
| Fayetteville Kidney Center | Fresenius Medical Care | Fayetteville | 50 | 86.00% |
| FMC North Ramsey | Fresenius Medical Care | Fayetteville | 40 | 76.25% |
| FMC South Ramsey | Fresenius Medical Care | Fayetteville | 51 | 81.37% |
| FMC West Fayetteville | Fresenius Medical Care | Fayetteville | 40 | 97.50% |
| FKC Rockfish* | Fresenius Medical Care | Fayetteville | 20 | 0.00% |

*FKC Rockfish was approved pursuant to Project ID#M-11502-18 to combine two previously approved projects (Project ID #M-11286-17 and M-11344-17) into one 20-station facility.

In Section G, page 31, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

“The January 2019 SDR reports a deficit of 11 dialysis stations in Cumberland County. This is an application to add one station which will serve to reduce that deficit. Approval of this application will obviously not completely resolve the deficit situation. Cumberland County has the fourth largest ESRD patient population in NC, following Mecklenburg, Wake and Guilford counties. More stations are needed within the county in order to meet the growing patient population.”

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

- There is a facility need determination at FMC West Fayetteville, as calculated using the methodology in the January 2019 SDR, for the proposed additional dialysis station.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 33, the applicant provides a table illustrating current staffing in full time equivalents (FTEs) for FMC West Fayetteville. The applicant does not propose to add any FTE equivalent positions as part of this project. The assumptions and methodology used to project existing staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Exhibit H-2, the applicant provides an outline of its continuing education programs. In Section I.3, page 38, the applicant identifies the current medical director for the facility. In Exhibit I-

5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the application and supporting exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section I, page 37, 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 ANSON COUNTY – ANCILLARY AND SUPPORT SERVICES | |
|---|--|
| SERVICES | PROVIDER |
| In-center dialysis/maintenance | BMA Fayetteville |
| Self-care training (in-center) | Referral to BMA Fayetteville |
| Home training HH PD Accessible follow-up program | Referral to BMA Fayetteville |
| Psychological counseling | Cumberland County Mental Health |
| Isolation – hepatitis | BMA on site |
| Nutritional counseling | BMA on site |
| Social Work services | BMA on site |
| Acute dialysis in an acute care setting | Cape Fear Valley Hospital |
| Emergency care | BMA staff; transport to hospital |
| Blood bank services | Cape Fear Valley Hospital / Imaging Center / Valley Radiology |
| Diagnostic and evaluation services | |
| X-ray services | |
| Laboratory services | Spectra |
| Pediatric nephrology | UNC Pediatric Nephrology |
| Vascular surgery | Carolina Kidney Care Vascular Access Center; Village Surgical; various nephrologists; patient choice |
| Transplantation services | UNC / Pitt County Memorial Hospital |
| Vocational rehabilitation & counseling | Vocational Rehabilitation Services of Fayetteville |
| Transportation | Cumberland County Department of Social Services; Fayetteville Area Transit System |

Source: Table in Section I, page 37

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I-1, I-3 through I-4, the applicant provides supporting documentation for other established relationships with local health care 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

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 51, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

**FMC West Fayetteville
Historical Payor Mix CY 2018**

| Payment Source | % of Total |
|---------------------------|-------------------|
| Self-pay/Indigent/Charity | 0.69% |
| Medicare | 75.28% |
| Medicaid | 5.19% |
| Commercial Insurance | 3.11% |
| Medicare/Commercial | 13.01% |
| Miscellaneous (Incl. VA) | 2.72% |
| Total | 100.00% |

Note: numbers may not sum due to rounding

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

| Percent of Population | | | | | | |
|-----------------------|---------------|---------------|-------------------------------|------------------------|------------------------------|--|
| County | % 65+ | % Female | % Racial and Ethnic Minority* | % Persons in Poverty** | % < Age 65 with a Disability | % < Age 65 without Health Insurance ** |
| 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate | 2017 Estimate |
| Cumberland | 12% | 50% | 57% | 19% | 12% | 11% |
| Bladen | 21% | 52% | 46% | 26% | 17% | 17% |
| Hoke | 10% | 51% | 60% | 20% | 11% | 16% |
| Robeson | 15% | 52% | 75% | 28% | 12% | 18% |
| Statewide | 16% | 51% | 37% | 15% | 10% | 12% |

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

*Excludes "White alone, not Hispanic or Latino"

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

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

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant’s

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

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, the applicant states in Section L, page 50, that it has no obligation in any of its facilities to provide uncompensated care or community service under any federal regulations.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

**FMC West Fayetteville
Projected Payor Mix CY 2021**

| Payment Source | % of Total |
|---------------------------|-------------------|
| Self-pay/Indigent/Charity | 0.32% |
| Medicare | 74.45% |
| Medicaid | 5.27% |
| Commercial Insurance | 3.82% |
| Medicare/Commercial | 13.29% |
| Miscellaneous (Incl. VA) | 2.85% |
| Total | 100.00% |

Note: numbers may not sum due to rounding

As shown in the table above, during the second year of operation, the applicant projects that 0.32% of total services will be provided to self-pay/indigent/charity patients, 87.74% to Medicare patients (includes Medicare and Medicare/Commercial), and 5.27% to Medicaid patients.

On page 48, 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 because the projected payor mix is based on the historical payor mix of FMC West Fayetteville.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 52, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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 one dialysis station to FMC West Fayetteville, an existing facility, for a total of 40 dialysis stations upon completion of this project and Project ID #M-11650-19 (relocate one station).

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

The applicant is the only provider of dialysis services in Cumberland County. Currently there are four existing and one approved but not yet developed facilities, all of which are located in the greater Fayetteville area, where the applicant states is close proximity to the larger number of dialysis patients. See the following table that shows the existing and approved dialysis facilities in Cumberland County, from Table B of the January 2019 SDR:

| FACILITY | PROVIDER | LOCATION | # STATIONS | UTILIZATION |
|----------------------------|------------------------|--------------|------------|-------------|
| Fayetteville Kidney Center | Fresenius Medical Care | Fayetteville | 50 | 86.00% |
| FMC North Ramsey | Fresenius Medical Care | Fayetteville | 40 | 76.25% |
| FMC South Ramsey | Fresenius Medical Care | Fayetteville | 51 | 81.37% |
| FMC West Fayetteville | Fresenius Medical Care | Fayetteville | 40 | 97.50% |
| FKC Rockfish* | Fresenius Medical Care | Fayetteville | 20 | 0.00% |

*FKC Rockfish was approved pursuant to Project ID#M-11502-18 to combine two previously approved projects (Project ID #M-11286-17 and M-11344-17) into one 20-station facility.

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

“BMA does not expect this proposal to have effect on the competitive climate in Cumberland County. All of the dialysis facilities in Cumberland County are operated by Fresenius Medical Care, parent to BMA. BMA does not project to serve dialysis patients currently served by another provider in a contiguous county. The projected patient population for the facility begins with patients currently served by BMA, and a growth of that patient population using a five year average annual change rate of 3.3% for the Cumberland County patients.

...

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

BMA facilities have done an exceptional job of containing operation costs while continuing to provide outstanding care and treatment to patients.”

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

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

- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Exhibit A-4, 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 more than 100 dialysis facilities owned, operated, or managed by the applicant or a related entity 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 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 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 West Fayetteville 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, page 13, the applicant projects that FMC West Fayetteville will serve 141 in-center patients on 40 stations, or a rate of 3.53 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13 - 15, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.