

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 17, 2019

Findings Date: January 17, 2019

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: E-11570-18

Facility: FMC of Hickory

FID #: 955790

County: Catawba

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

Project: Add two stations for a total of 35 stations upon completion of this project, Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Hickory proposes to add two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton).

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of two dialysis stations in Catawba County. Therefore, the July 2018 SDR does not

indicate a need for additional stations in Catawba County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for FMC of Hickory in the July 2018 SDR is 3.74 patients per station per week, or 93.57 percent, based on 131 in-center dialysis patients and 35 certified dialysis stations [$131/35 = 3.74$; $3.74 / 4 = 0.9357$ or 93.57%].

Below is a table that illustrates the facility need for additional dialysis stations at FMC Hickory:

| October 1 Review-JULY SDR | | |
|--|---|--------------------------------------|
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 12/31/17 | | 93.57% |
| Certified Stations | | 35 |
| Pending Stations | | 4 |
| Total Existing and Pending Stations | | 39 |
| In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2) | | 131 |
| In-Center Patients as of 6/30/17 (January 2018 SDR) (SDR1) | | 122 |
| Step | Description | Result |
| | Difference (SDR2 - SDR1) | 9 |
| (i) | 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 6/30/17 | 0.1475 |
| (ii) | Divide the result of Step (i) by 12 | 0.0123 |
| (iii) | Multiply the result of Step (ii) by 12 | 0.1475 |
| (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 | 150.3279 |
| (v) | Divide the result of Step (iv) by 3.2 patients per station and subtract the number of certified and pending stations to determine the number of stations needed | 46.9775 7.9775 8 |

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

Policies

There is one policy in the 2018 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on page 33 of the 2018 SMFP, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4 (a and d), pages 8 and 10-11; Section K.1(g), page 44; Section N.1, page 53; Section O, pages 55-58, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4 (b and d), pages 9-11; Section C.3, page 18; 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 would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4 (c and d), pages 10-11; Section C, pages 14-17; Section F, pages 25-32; Section K, pages 42-44; 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 would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton).

Patient Origin

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

In Section C.8, page 20, the applicant provides a table showing the historical patient origin for in-center (IC), home peritoneal dialysis (PD), and home hemodialysis (HHD) patients served by FMC of Hickory, as shown below.

| FMC of Hickory Patients by County – 6/30/2018 | | | |
|--|-------------------------|--------------------------|-------------------------|
| County | # of IC Patients | # of HHD Patients | # of PD Patients |
| Catawba | 112 | 6 | 0 |
| Alexander | 1 | 0 | 0 |
| Burke | 5 | 1 | 0 |
| Caldwell | 7 | 1 | 0 |
| Lincoln | 2 | 0 | 0 |
| Gaston | 0 | 1 | 0 |
| Total | 127 | 9 | 0 |

In Section C.1, page 14, the applicant provides the projected patient origin for FMC of Hickory for IC patients, PD patients, and HHD patients for the first two operating years (OY) following completion of the project, as shown in the table below.

| FMC of Hickory Patients by County – Operating Years 1 & 2 | | | | | | | | |
|--|-------------------------------------|------------|-----------|-------------------------------------|------------|-----------|--|---------------|
| County | Operating Year 1 CY 2020 | | | Operating Year 2 CY 2021 | | | County Patients as % of Total | |
| | IC | HHD | PD | IC | HHD | PD | OY 1 | OY 2 |
| Catawba | 125.1 | 7.5 | 0 | 136.5 | 8.1 | 0 | 88.0% | 88.9% |
| Alexander | 1.0 | 0.0 | 0 | 1.0 | 0.0 | 0 | 0.7% | 0.6% |
| Burke | 5 | 1.0 | 0 | 5.0 | 1 | 0 | 4.0% | 3.7% |
| Caldwell | 7 | 1.0 | 0 | 7.0 | 1 | 0 | 5.3% | 4.9% |
| Lincoln | 2 | 0.0 | 0 | 2.0 | 0 | 0 | 1.3% | 1.2% |
| Gaston | 0 | 1.0 | 0 | 0.0 | 1 | 0 | 0.6% | 0.6% |
| Total | 140 | 10 | 0 | 151 | 11 | 0 | 100.0% | 100.0% |

Note: Tables may not foot due to rounding.

*Rounded down to the whole patient.

The applicant provides the assumptions and methodology used to project patient origin on pages 14-16. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, pages 6-8, the applicant states that the application is filed pursuant to the facility need methodology in the 2018 SMFP, utilizing the data from the July 2018 SDR. The applicant proposes to add two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton). In Section C, pages 17-18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 14-16, the applicant describes its assumptions for projecting utilization of the proposed services as follows:

- The applicant begins the projections by using the IC and HHD patient census at the facility as of June 30, 2018.
- The applicant assumes that the dialysis patient population residing in Catawba County, and dialyzing at FMC of Hickory will increase at a rate of 9.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Catawba County published in the July 2018 SDR.
- The applicant projects that 12 patients residing in Catawba County and dialyzing at FMC of Hickory would transfer their care to the new FKC Newton facility upon completion of that project. The applicant will subtract these patients from projections of future patient populations effective December 31, 2018.
- The applicant is not projecting any increase in patients residing outside of Catawba County, but will add the patients at appropriate points in time.

- The project is scheduled for completion on December 31, 2019.
- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 Calendar Year (CY2020)
- Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 Calendar Year (CY2021)

Projected Utilization

In Section C, pages 15-16, the applicant provides the methodology used to project utilization during the first two years of operation following project completion.

In-Center

| FMC of Hickory | In-Center Dialysis |
|--|------------------------------|
| Begin with 112 Catawba County ESRD patients dialyzing at the center on June 30, 2018. | 112 |
| BMA projects this population forward for 6 months to December 31, 2018. | $112 \times 1.0455 = 117.1$ |
| BMA subtracts 12 Catawba County residents projected to transfer their care to the new FKC Newton facility. | $117.1 - 12 = 105.1$ |
| BMA projects the Catawba County patient population forward for 12 months to December 31, 2019. | $105.1 \times 1.091 = 114.7$ |
| Add the 15 patients residing in other counties. This is the beginning census for Operating Year 1. | $114.7 + 15 = 129.7$ |
| BMA projects the Catawba patient population forward for 12 months to December 31, 2020. | $114.7 \times 1.091 = 125.1$ |
| Add the 15 patients residing in other counties. This is the ending census for Operating Year 1. | $125.1 + 15 = 140.1$ |
| *BMA projects growth of the Catawba County patients for one year to December 31, 2021. | $125.1 \times 1.091 = 136.5$ |
| Add the 15 patients residing in other counties. This is the ending census for Operating Year 2. | $136.5 + 15 = 151.5$ |

Source: Section C, page 15

*Note: The applicant incorrectly references the wrong number of patients; 140 instead of 125.1; however the calculation is correct, thus the Project Analyst assumes that this error is just a typo. The Project Analyst uses the correct number in the table above.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2020) the facility is projected to serve 140 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 151 in-center patients.

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

- OY1: 4.0000 patients per station per week or 100% ($140 \text{ patients} / 35 \text{ stations} = 4.0000/4 = 1.0000$ or 100%)
- OY2: 1.07855 patients per station per week or 107.78% ($151 \text{ patients} / 35 \text{ stations} = 4.3142/4 = 1.07855$ or 107.78%)

The project utilization of 4 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Home Hemodialysis

- The applicant begins its utilization projections by using its HHD patient census as of June 30, 2018.
- The applicant assumes home hemodialysis patients residing in Catawba County, and dialyzing at FMC of Hickory will increase at a rate of 9.1 percent, which is the Five Year Average Annual Change Rate (AACR) for Catawba County published in the July 2018 SDR.
- The applicant assumes no growth for patients living outside Catawba County.
- Operating Year 1 (OY1) = January 1, 2020 – December 31, 2020 (CY2020)
 Operating Year 2 (OY2) = January 1, 2021 – December 31, 2021 (CY2021)

In Section C.1, pages 16-17, the applicant provides the methodology used to arrive at the projected HHD patient census for OY1 and OY2, as summarized in the table below.

| FMC of Hickory | HHD |
|---|--------------------------|
| Begin with 6 Catawba County ESRD patients dialyzing at the center on June 30, 2018. | 6 |
| BMA projects this population forward for 6 months to December 31, 2018. | $6 \times 1.0455 = 6.3$ |
| BMA projects the Catawba County patient population forward for 12 months to December 31, 2019. | $6.3 \times 1.091 = 6.8$ |
| Add the 3 patients residing in other counties. This is the beginning census for Operating Year 1. | $6.8 + 3 = 9.8$ |
| BMA projects the Catawba patient population forward for 12 months to December 31, 2020. | $6.8 \times 1.091 = 7.5$ |
| *Add the 3 patients residing in other counties. This is the ending census for Operating Year 1. | $7.5 + 3 = 10.5$ |
| BMA projects growth of the Catawba County patients for one year to December 31, 2021. | $7.5 \times 1.091 = 8.1$ |
| *Add the 3 patients residing in other counties. This is the ending census for Operating Year 2. | $8.1 + 3 = 11.1$ |

Source: Table from Section C, page 16

*Note: The applicant incorrectly references the wrong number of patients; 15 instead of 3; however the calculation is correct, thus the Project Analyst assumes that this error is just a typo. The Project Analyst uses the correct number in the table above.

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

- The applicant begins its utilization projections with the existing patient census for the facility.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Catawba County which is 9.1% to project the Catawba County patient population forward.
- The applicant assumes no growth for patients living outside Catawba County.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 18, the applicant states that all of Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population in North Carolina.

In Section L.1, 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 of Hickory Projected Payor Mix Project Year 2, CY 2021 | | | | |
|---|-------------------------|----------------------|-----------------------|----------------------|
| Payment Source | % Total Patients | % IC Patients | % HHD Patients | % PD Patients |
| Self-Pay/Indigent/Charity | 0.62% | 0.21% | 0.20% | 0.00% |
| Medicare | 65.43% | 65.12% | 73.19% | 0.00% |
| Medicaid | 5.56% | 6.00% | 0.00% | 0.00% |
| Commercial Insurance | 5.56% | 4.42% | 15.59% | 0.00% |
| Medicare/Commercial | 17.90% | 19.14% | 0.00% | 0.00% |
| Misc. (including VA) | 5.56% | 5.12% | 11.03% | 0.00% |
| Total | 100.00% | 100.00% | 100.00% | 100.00% |

Note: Totals may not foot due to rounding.
 Source: Section L, page 48

As shown in the table above, during the second year of operation, the applicant projects that 83% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 6% to Medicaid patients.

Conclusion

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose to reduce or eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton).

In Section E, page 24, the applicant describes the alternatives it considered prior to submitting this application for the proposed project. The applicant explains why the 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 that this alternative was dismissed because additional stations are needed at FMC Hickory to assure continuous access to dialysis care.

- Apply for fewer Stations-The applicant states that this alternative was considered, however, the projected utilization rate would force patients to a third or evening dialysis shift.
- Relocate Stations from FMC Catawba Valley-The applicant states this was not a viable alternative because the stations are needed at the FMC Catawba Valley facility. The facility is well utilized with a utilization rate of 4.16 patients per station.

The applicant states that due to the high utilization and the projected population to be served, adding additional stations is the most appropriate alternative to meet the need as identified by the applicant. The applicant states applying for additional stations is also the most cost effective alternative because the project does not require any capital expense.

After considering the alternatives above, the applicant states the proposed project represented in the application is the most effective alternative to meet the identified need for two additional stations at FMC of Hickory.

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

- The facility is operating at over 80% capacity as of the July 2018 SDR.
- The applicant utilizes the facility need methodology to show the need for additional stations.
- The applicant's projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant adequately demonstrates that maintaining the status quo is not the most effective alternative to meet the need for additional dialysis stations at FMC of Hickory because of the growth of the patient population dialyzing at the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Information which was publicly available during the review and used by the Agency
Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**

2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than two additional dialysis stations for a total of no more than 35 certified stations at FMC of Hickory upon completion of this project, Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton), which shall include any home hemodialysis training or isolation stations.
 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than two dialysis stations which shall include any isolation 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

The applicant proposes to add two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton).

Capital and Working Capital Costs

In Section F.1, page 25, the applicant states that BMA is not projecting any capital costs for this project. The proposed additional stations are intended to replace two of the six dialysis planned for relocation to the FKC Newton facility. The space already exists and the dialysis equipment will be leased.

In Sections F.10 and F. 11, page 28, the applicant states that FKC of Hickory is an existing facility, this the project will not involve start-up or initial operating expenses.

Financial Feasibility

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

| Projected Revenues and Operating Expenses | | |
|--|-------------------------------------|-------------------------------------|
| FKC of Hickory | Operating Year 1 CY 2020 | Operating Year 2 CY 2021 |
| Total Treatments | 21,340 | 22,971 |
| Total Gross Revenues (Charges) | \$85,103,920 | \$91,608,348 |
| Total Net Revenue | \$5,968,838 | \$6,420,619 |
| Average Net Revenue per Treatment | \$280 | \$280 |
| Total Operating Expenses (Costs) | \$5,169,956 | \$5,436,605 |
| Average Operating Expenses per Treatment | \$242 | \$237 |
| Net Income/Profit | \$798,882 | \$984,014 |

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. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton).

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

The applicant operates four facilities in Catawba County. This includes one proposed facility and one Home Hemodialysis program. The only other facility in Catawba County is operated by Davita. The applicant states that the two existing facilities are operating above 90% utilization.

| Facility Name | Provider Name | Location | # of Stations | Utilization |
|--------------------------|------------------------|----------|---------------|-------------|
| FMC of Hickory | Fresenius Medical Care | Hickory | 35 | 93.75% |
| FMC of Catawba Valley | Fresenius Medical Care | Conover | 25 | 99.00% |
| FKC Newton | Fresenius Medical Care | Newton | 12 | N/A |
| Catawba County Dialysis | DaVita | Hickory | 10 | N/A |
| FMC Hickory Home Program | Fresenius Medical Care | Hickory | 0 | N/A |

Source: July 2018 SDR

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

“BMA is not creating unnecessary duplication of existing or approved health services. Rather this application seeks to ensure that adequate dialysis resources are available for the patient population choosing to dialyze at the FMC of Hickory facility.”

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H, pages 34 and 37, the applicant provides current and projected staffing in full time equivalents (FTEs) for FMC of Hickory as demonstrated in the chart below. The applicant

does not project an increase in direct staffing in Operating Year 2. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

| FMC of Hickory facility staffing | | |
|---|-----------------------|---------------------|
| Position | Current # FTEs | Projected |
| | CY 2018 | OY1 (CY2021) |
| Registered Nurse | 6.00 | 6.00 |
| Home Training Nurse | 0.75 | 0.75 |
| Patient Care Technician | 14.00 | 14.00 |
| Dietitian | 1.00 | 1.00 |
| Social Worker | 1.00 | 1.00 |
| Clinical Manager | 1.00 | 1.00 |
| Administration | 0.15 | 0.15 |
| In-Service | 0.25 | 0.25 |
| Clerical | 2.00 | 2.00 |
| Chief Tech | 0.25 | 0.25 |
| Equipment Tech | 1.20 | 1.20 |
| Total | 27.60 | 27.60 |

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 35, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit H-1 and H-2, the applicant provides supporting documentation. In Section I, page 39, the applicant identifies the current medical director. In Exhibit I-6, the applicant provides a letter from the current medical director indicating an 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
- 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, page 38, 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 of Hickory – Necessary Ancillary and Support Services | |
|--|---|
| Services | Provider |
| In-center dialysis/maintenance | Bio-Medical Applications on site |
| Self-care training (in-center) | FMC Hickory Home Program |
| HH | Bio-Medical Applications-on site |
| PD | FMC Hickory Home Program |
| Accessible follow-up program | FMC Hickory Home Program |
| Psychological counseling | Catawba County Behavioral Health-Referral |
| Isolation – hepatitis | Bio-Medical Applications on site |
| Nutritional counseling | Bio-Medical Applications on site |
| Social Work services | Bio-Medical Applications on site |
| Acute dialysis in an acute care setting | Catawba Valley Medical Center, or Frye Regional Medical Center |
| Emergency care | All BMA staff trained to respond and full stocked crash cart available; Ambulance transport to hospital |
| Blood bank services | Catawba Valley Medical Center, or Frye Regional Medical Center |
| Diagnostic and evaluation services | Catawba Valley Medical Center, or Frye Regional Medical Center |
| X-ray services | Catawba Valley Medical Center, or Frye Regional Medical Center |
| Laboratory services | Spectra |
| Pediatric nephrology | NC Baptist Hospital-Referral |
| Vascular surgery | Horizon Surgical Center, Dr. Randal Bast-Referral |
| Transplantation services | Wake Forest Baptist Hospital-Referral |
| Vocational rehabilitation & counseling | NC Dept. Health and Human Services, Vocational Rehabilitation and Independent Living Services-Referral |
| Transportation | DSS of Catawba County; Greenway Transportation; Premier Medical Transportation; Specialty Transport |

Source: Section I, page 38

In Section I, pages 39-40, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 through I-5.

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 Calendar Year 2017 (CY 2017) for its existing services, as shown in the table below.

| FMC of Hickory Historical Payor Mix CY 2017 | |
|--|-------------------------|
| Payment Source | % Total Patients |
| Self-Pay/Indigent/Charity | 0.22% |
| Medicare | 69.66% |
| Medicaid | 4.82% |
| Commercial Insurance | 4.10% |
| Medicare/Commercial | 16.69% |
| Misc. (including VA) | 4.52% |
| Total | 100.00% |

Source: Section L, page, 51

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 |
| Catawba | 17% | 51% | 25% | 13% | 10% | 13% |
| Statewide | 16% | 51% | 37% | 15% | 10% | 12% |

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

*Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other 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 service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

- (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 50, the applicant states,

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicapped status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

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 of Hickory Projected Payor Mix Project Year 2, CY 2021 | | | | |
|---|-------------------------|----------------------|-----------------------|----------------------|
| Payment Source | % Total Patients | % IC Patients | % HHD Patients | % PD Patients |
| Self-Pay/Indigent/Charity | 0.62% | 0.21% | 0.20% | 0.00% |
| Medicare | 65.43% | 65.12% | 73.19% | 0.00% |
| Medicaid | 5.56% | 6.00% | 0.00% | 0.00% |
| Commercial Insurance | 5.56% | 4.42% | 15.59% | 0.00% |
| Medicare/Commercial | 17.90% | 19.14% | 0.00% | 0.00% |
| Misc. (including VA) | 5.56% | 5.12% | 11.03% | 0.00% |
| Total | 100.00% | 100.00% | 100.00% | 100.00% |

Note: Totals may not foot due to rounding
 Source: Section L, page 48

As shown in the table above, during the second year of operation, the applicant projects that 83% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 6% 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 for the following reasons:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M.1, page 52, 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-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 two dialysis stations to the existing facility for a total of 35 stations upon completion of this project and the following projects: Project ID # E-11485-18 (add 4 stations) and Project ID # E-11209-16 (relocate 6 stations to FKC Newton).

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

The applicant operates four facilities in Catawba County. This includes one proposed facility and one Home Hemodialysis program. The only other facility in Catawba County is operated by Davita. The applicant states that the existing facilities are operating above 90% utilization.

| Facility Name | Provider Name | Location | # of Stations | Utilization |
|--------------------------|------------------------|----------|---------------|-------------|
| FMC of Hickory | Fresenius Medical Care | Hickory | 35 | 93.75% |
| FMC of Catawba Valley | Fresenius Medical Care | Conover | 25 | 99.00% |
| FKC Newton | Fresenius Medical Care | Newton | 12 | N/A |
| Catawba County Dialysis | DaVita | Hickory | 10 | N/A |
| FMC Hickory Home Program | Fresenius Medical Care | Hickory | 0 | N/A |

Source: July 2018 SDR

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

“The applicant does not expect this proposal to have effect on the competitive climate in Catawba County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for FMC of Hickory facility begins with the patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Catawba County five year average annual change rate of 9.1% as published within the July 2018 SDR.

The facility also has added value stemming from the strength of our relationship with Piedmont Nephrology and Hypertension Associates, P.A.

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

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).
- (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 a total of 114 of this type of facility located in North Carolina.

In Section O, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific criteria are discussed below.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station*

per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

- NA- FMC of Hickory is an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C pages 14-18, the applicant documents the need for the project and demonstrates that it will serve a total of 140 in-center patients on 35 stations at the end of the first operating year, which is 4 patients per station per week or a utilization rate of 100 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.