

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 27, 2019

Findings Date: March 27, 2019

Project Analyst: Ena Lightbourne

Assistant Chief: Lisa Pittman

Project ID #: E-11649-19

Facility: FKC Newton

FID #: 160340

County: Catawba

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

Project: Change of scope for Project ID# E-11209-16 (develop a new 12-station dialysis facility), Project ID# E-11390-17 (add five stations) and Project ID# E-11480-18 (add one station). The applicant proposes to relocate three dialysis stations from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FKC Newton proposes a change of scope (COS) for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of

Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

Need Determination

The county and facility need methodologies in the January 2019 Semiannual Dialysis Report (SDR) and the 2019 State Medical Facilities Plan (SMFP) are not applicable to this review.

Policies

There is one policy in the 2019 SMFP applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*, on page 25.

Policy ESRD-2

Policy ESRD-2 states:

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

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

FKC Newton and FMC of Catawba Valley are both located in Catawba County. Therefore, the proposed project is in compliance with Policy ESRD-2.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy ESRD-2. The three dialysis stations are being relocated from FMC of Catawba Valley to FKC Newton. Both facilities are in the same county, Catawba County.

- (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 a COS for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as, “A dialysis station’s service area is 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.

FKC Newton dialysis facility is an approved facility not yet operational, therefore, there is no current patient origin. In Section C, page 14, the applicant provides the projected patient origin from the previously approved application, Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley) and the projected patient origin for the proposed project, as illustrated in the tables below.

**FKC Newton (Project ID# 11209-16)
 Projected Patient Origin**

| County | Operating Year 1 (CY2020) | Operating Year 2 (CY2021) | % of Total | |
|---------|------------------------------|------------------------------|------------|--------|
| | In-Center | In-Center | Year 1 | Year 2 |
| Catawba | 42.8 | 45.7 | 100.0% | 100.0% |
| Total | 42 | 45 | 100.0% | 100.0% |

Source: Section C, page 14

**FKC Newton
 Projected Patient Origin**

| County | Operating Year 1 (CY2020) | Operating Year 2 (CY2021) | % of Total | |
|---------|------------------------------|------------------------------|------------|--------|
| | In-Center | In-Center | Year 1 | Year 2 |
| Catawba | 51.2 | 55.8 | 100.0% | 100.0% |
| Total | 51 | 58 | 100.0% | 100.0% |

Source: Section C, page 14

In Section C, pages 13-15, the applicant provides the assumptions and methodology it used to project patient origin. The applicant projects the patient origin for the proposed project using the projected patient census from Project ID# E-11209-16 and adding the three dialysis patients who have signed letters of support of the proposed project. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, pages 15-16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 15, the applicant states:

“The project is necessary due to the growing census of dialysis patients in Catawba County who reside near the Newton area, and who have indicated that FKC Newton would be more convenient for their dialysis care. This application will not reduce or increase the station count in Catawba County, but will re-distribute [three stations] to a location central to a significant number of dialysis patients.”

In Section C, pages 13-15, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- The applicant projects the first two full operating years of the project will be January 1, 2020-December 31, 2020 (CY2020) and January 1, 2021-December 31, 2021 (CY2021).
- In Section C, page 20, of the previously approved application for Project ID# 11209-16, the applicant projected a census of 42 in-center patients by the end of Operating

Year 1, using the Catawba County Five Year Average Change Rate (AACR), as published in the July 2016 SDR. For Project ID# 11209-16, the applicant provided documentation that these patients support the FKC Newton Facility. The applicant assumes these patients will continue to support the proposed project and transfer their dialysis care to FKC Newton. For this application, the applicant will begin projections with a patient census of 42 in-center patients.

- The applicant applies the Catawba County AACR of 9.1%, as published in the January 2019 SDR, to project the patient population forward.
- The applicant added three dialysis patients who indicated support for the proposed project in this application to the patient census at the appropriate point in time.
- Assuming the dialysis patients from Project ID# 11209-16 will continue to support the project and transfer their care to FKC Newton upon certification of the facility, the applicant projects a patient census of 51 in-center patients by the end of Operating Year 1.

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

- The applicant begins utilization projections using the projected patient census from the approved application, Project ID# 11209-16.
- The applicant applies the Catawba County Five Year Annual Change Rate (AACR) to project patient census population forward.

Projected Utilization

In Section C, pages 13-15, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the table below.

| FKC Newton In-Center Patients | |
|--|----------------------------|
| BMA begins June 30, 2019, with the 42 patients who have signed letters of support for the original application and were projected to transfer upon certification of the facility. These are Catawba County patients who have indicated their support for the project by letter of support. | 42 |
| Using one half of the annual Growth Rate of 9.1%, BMA projects this census forward for six months to December 31, 2019. | $42 \times 1.0455 = 43.9$ |
| Add three patients who have signed letters of support for this proposal. This is the starting census for this project. | $43.9 + 3 = 46.9$ |
| BMA projects the patient population forward for 12 months to December 31, 2020. This is the end of Operating Year 1. | $46.9 \times 1.091 = 51.2$ |
| BMA projects the patient population forward for 12 months to December 31, 2020 [2021]. This is the end of Operating Year 2. | $51.2 \times 1.091 = 55.8$ |

Source: Section C, page 15

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 51 in-center patients and at the end of OY2 (CY2021) the facility is projected to serve 55 in-center patients.

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

- OY1: 3.4 patients per station per week 80.95% ($51 \text{ patients} / 15 \text{ stations} = 3.4/4 = 0.8500$ or 85.00%)
- OY2: 3.6666 patients per station per week or 85.71% ($55 \text{ patients} / 15 \text{ stations} = 3.6666/4 = 0.9166$ or 91.66%)

The projected utilization of 3.4 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).

Projected utilization for all patients at FKC Newton is reasonable and adequately supported for the following reasons:

- The applicant begins its utilization projections with the projected patient census from the previously approved application, Project ID# 11209-16. The applicant assumes these patients will continue to support the project and transfer their care to FKC Newton.
- The applicant uses the Catawba County AACR of 9.1%, as published in the January 2019 SDR, to project the patient population forward.

- The applicant adequately demonstrates the need for three additional dialysis stations at FKC Newton because 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 16, the applicant states, “*It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient underserved.*”

In Section L, page 52, the applicant projects the following payor mix during the Second calendar year of operation following completion of the project, as illustrated in the following table.

**FKC Newton
Projected Payor Mix CY 2021**

| Payment Source | Percent of Total Patients |
|-----------------------------|----------------------------------|
| Self Pay/ Indigent/ Charity | 2.84% |
| Medicare | 66.62% |
| Medicaid | 4.39% |
| Commercial Insurance | 5.47% |
| Medicare / Commercial | 16.18% |
| Misc. (VA) | 4.50% |
| Total | 100.00% |

Source: Section L, page 52

On page 55, the applicant states its assumption for projecting payor mix. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

C

The applicant, proposes a change of scope (COS) for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

The following tables show the projected relocation of stations from FMC of Catawba Valley to the FKC Newton facility.

| FKC Newton | | |
|-------------------|---|---------------------|
| Stations | Description | Project ID # |
| 3 | # of stations to be added as part of this project | |
| 12 | # of stations previously approved to be added but not yet certified | E-11209-16 |
| 15 | Total # of stations upon completion of all facility projects | |

Source: Section A, page 4

| FMC of Catawba Valley | | |
|------------------------------|---|--------------------------|
| Stations | Description | Project ID # |
| 25 | Total # of existing certified stations as of the most recent SDR | |
| 3 | # of stations to be deleted as part of this project | E-11649-19 |
| 5 | # of stations previously approved to be added but not yet certified | E-11390-17 E-11480-18 |
| 6 | # of stations previously approved to be deleted but not yet certified | E-11209-16 |
| 22 | Total # of stations upon completion of all facility projects | |

Source: Section A, page 4

In Section D, pages 22-24, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or related will be adequately met following completion of the project. On pages 22-24, the applicant states:

- According to ESRD Data Collection forms submitted to DHSR, as of December 31, 2018, FMC of Catawba Valley patient census was 96 Catawba County in-center patients on 25 stations. FMC of Catawba Valley does not have a home training program. FMC of Catawba Valley will net 22 stations upon completion of this project and Project ID# E-11209-16, E-11390-17 and E-11480-18.
- As previously stated in Project ID# E-11209-16, the applicant projected 28 Catawba County patients will transfer from FMC of Catawba Valley to FKC Newton upon completion of Project ID# E-11209-16.
- The applicant projects FMC of Catawba Valley’s patient census by using the Catawba County Five-Year AACR of 9.1%, as published in the January 2019 SDR.
- The applicant projects the future utilization at FMC of Catawba Valley as a 22-station facility for years 2019 through 2021 will exceed 85.00%. The applicant projects as of December 31, 2019, 76 in-center patients dialyzing at FMC of Catawba Valley on 22 certified dialysis stations for a utilization rate of 86.37%, or 3.45 patients per station per week ($76/22 = 3.4545/4 = 0.8637$ [0.8636] or 86.37 [86.36] as illustrated in the table below.

| FMC of Catawba Valley, as a 22 Station Facility | | | |
|--|--------|--------|---------|
| December 31 | 2019 | 2020 | 2021 |
| Projected Census | 76 | 83 | 91 |
| Utilization | 86.37% | 94.32% | 103.41% |
| Patients/Stations | 3.4545 | 3.7727 | 4.1364 |

Source: Section D, page 23

- Although FMC of Catawba County facility’s utilization exceeds 100%, the applicant states that the facility’s utilization rate was 104.00%, with 104 in-center patients on 25 stations as of June 30, 2018. The facility is eligible to apply for additional stations in the April 2019 application cycle. Based on the Facility Need Methodology, the facility qualifies to apply for up to three stations.

In Section D, page 23, the applicant provided projected utilization as illustrated in the following table.

| FMC of Catawba Valley In-Center Patients | |
|--|------------------------------------|
| | In-Center |
| BMA begins with the Catawba County patient census as of December 31, 2018. | 96 |
| BMA projects this census forward for six months to June 30, 2019 using one half of the Catawba County Five Year Average Annual Change Rate | $96 \times 1.0455 = 100.4$ |
| Subtract 28 Catawba County patients projected to transfer to FKC Newton. | $100.4 - 28 = 72.4$ |
| BMA projects this census forward for six months to December 31, 2019. | $71.4 [72.4] \times 1.0455 = 75.7$ |
| BMA projects this census forward for six months to December 31, 2020. | $75.7 \times 1.091 = 82.5$ |
| BMA projects this census forward for twelve months to December 31, 2021. | $82.5 \times 1.091 = 90.1$ |

Source: Section D, page 23

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

- The applicant begins its utilization projections with the existing in-center patient census of FMC of Catawba Valley as of December 31, 2018.
- The applicant uses the Catawba County Five Year AACR of 9.1% as published in the January 2019 SDR, to project growth of in-center patients dialyzing at FMC of Catawba Valley as a 22-station facility.
- The applicant projects a utilization rate of 86.37% as of December 31, 2019, however, the utilization rate for FMC of Catawba Valley was 104.00% as of June 30, 2018. The facility qualifies to apply for additional stations based on Facility Need Methodology.

In Section D, page 25, the applicant states:

“This location of stations will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care. Patients needing dialysis services will continue to have access to dialysis at either their current dialysis facility, or in a BMA facility closer to their residence location. This application will not have any effect upon access to care for any patient.”

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 and adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

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

CA

The applicant proposes a COS for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

In Section E, page 26, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the COS proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states that this is not the most effective alternative because of the growing need of patients residing in the area and who would benefit from having additional dialysis services closer to their residence.
- Relocate Stations from FMC Hickory in Catawba County - The applicant states all of the BMA facilities in Catawba County are well utilized, however, the FMC Catawba County qualifies to apply for additional stations based on the Facility Need Methodology.
- Relocation of Stations to another Location – The applicant states the growth in the areas around the new FKC Newton warrants additional stations at this location.

In Section E, page 26, the applicant states that its proposal is the most cost effective alternative because of its modest capital expenditure.

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 the representations in this application and the representations made in Project ID# E-11209-16. Where representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than three dialysis stations from FMC of Catawba Valley to FKC Newton for a total of no more than 15 certified stations upon completion of this project and Project ID# E-11209-16 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 three dialysis stations, which shall include any isolation stations.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at FMC of Catawba Valley for a total of no more than 22 dialysis stations at FMC of Catawba Valley.**
 - 5. 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.

The applicant proposes a COS for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

Capital and Working Capital Costs

In Section F.1, page 28, the applicant projects the total capital cost of the project to be \$11,250, with \$2,250 for water treatment equipment and \$9,000 for equipment/furniture.

In Section F, page 32, the applicant provides the assumptions used to project the capital cost.

Applicant provided start-up and initial operating costs in Section F, pages 45-46, of the approved application for Project ID# E-11209-16. In Section F, page 31, of this application, the applicant states there will be no additional start-up or initial operating expenses associated with the proposed project.

Availability of Funds

In Section F.2, page 29, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

| Type | BMA | Total |
|---------------------------------|------------|--------------|
| Accumulated reserves or OE * | \$11,250 | \$11,250 |
| Total Financing | \$11,250 | \$11,250 |

* OE = Owner's Equity

Exhibit F-1 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 contains a copy of the Consolidated Balance Sheets from Fresenius Medical Care Holdings, Inc., which showed that as of December 31, 2017 Fresenius Medical Care Holdings, Inc. had \$569,818,000 in cash and equivalents, \$19,822,127,000 in total assets and \$10,542,494,000 in net assets (total assets less total liabilities).

Financial Feasibility

In Section R of the previously approved application for Project I.D's # E-11209-16, the applicant provided pro forma financial statements for the first two years of the project. The

applicant projected that revenues would exceed operating expenses in the first two operating years of this project. The applicant includes that information in the current COS application.

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

| FKC Newton | Operating Year 1 FY2020 | Operating Year 2 FY2021 |
|---|------------------------------------|------------------------------------|
| Total Treatments | 7261 | 7854 |
| Total Gross Revenues (Charges) | \$28,956,868 | \$31,321,752 |
| Total Net Revenue | \$2,188,062 | \$2,366,760 |
| Average Net Revenue per Treatment | \$301.44 | \$301.34 |
| Total Operating Expenses (Costs) | \$1,953,883 | \$2,040,701 |
| Average Operating Expense per Treatment | \$269.09 | \$259.82 |
| Net Income | \$234,180 | \$326,059 |

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 for the following reasons:

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

The applicant proposes a COS for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

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

According to the January 2019 SDR there are five existing and approved dialysis facilities in Catawba County as shown below.

| Facility Name | Provider | Location | # of Stations | Percent Utilization |
|-------------------------------|-----------------|-----------------|----------------------|----------------------------|
| FMC Hickory Home Program | FMC | Hickory | 0 | 0.00% |
| FMC of Catawba Valley | FMC | Conover | 25 | 104.00% |
| FMC of Hickory | FMC | Hickory | 35 | 90.71% |
| Fresenius Kidney Care Newton* | FMC | Newton | 0 | 0.00% |
| Catawba County Dialysis | DaVita | Hickory | 10 | 0.00% |

Source: January 2019 SDR, Table B

*Received CON approval but facility is not operational yet.

In Section G.2, page 36, 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:

“Relocating existing dialysis stations will not duplicate those stations. BMA seeks to improve access to care and reduce patient travel time to dialysis by increasing the number of stations at FKC Newton”

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

- The proposal will not result in an increase in the number of dialysis stations in Catawba County. It involves the transfer of existing stations from one FMC facility in

Catawba County to another FMC facility in Catawba County and thus does not duplicate any existing or approved dialysis services in Catawba County.

- The applicant adequately demonstrates that the proposed stations are needed at FKC Newton.

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

The applicant proposes a COS for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

In Section H.1, page 37, the applicant provides the proposed staffing for the facility, and states that FKC Newton is projected to have a staff of 10.30 FTEs upon project completion. In addition, the applicant provides projected direct care staff in Operating Year 2 in Section H.7, page 39.

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, Section R. In Exhibits H-1 and H-2, the applicant provides an outline of its training program and continuing education programs. In Section I.3, page 42, the applicant identifies the current medical director for the facility. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in serving 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.1, page 40, the applicant identifies the ancillary and support services necessary for the proposed services.

| BMA Kings Mountain – Ancillary and Support Services | | |
|--|--------------------|---|
| Services | To be added | Provider |
| In-center dialysis/maintenance | X | BMA on site |
| Self-care training (in-center) | | BMA-Referral to FMC or FMC Home Program |
| Home training HH PD Accessible follow-up program | | BMA- FMC Hickory FMC Hickory Home Program FMC Hickory or FMC Home Program |
| Psychological counseling | | Catawba County Behavioral Health-Referral |
| Isolation – hepatitis | X | BMA on site |
| Nutritional counseling | X | BMA on site |
| Social Work services | X | BMA on site |
| Acute dialysis in an acute care setting | | Catawba Valley Medical Center or Frye Regional Medical Center-Referral |
| Emergency care | | BMA-Ambulance transport to hospital |
| Blood bank services | | Catawba Valley Medical Center or Frye Regional Medical Center-Referral |
| Diagnostic and evaluation services | | Catawba Valley Medical Center or Frye Regional Medical Center-Referral |
| X-ray services | | Catawba Valley Medical Center or Frye Regional Medical Center-Referral |
| Laboratory services | X | 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. of Health and Human Services, Vocational Rehabilitation and Independent living services-Referral |
| Transportation | | DSS OF Catawba County, Greenway Transportation, Premier Medical Transportation, Specialty Transport |

The applicant provides supporting documentation for its ancillary and support services in Exhibits I-1 through I-4.

In Section I, pages 41-42, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

NA

The applicant does not propose to make more than minor renovations to 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

FKC Newton is an approved facility, not yet operational. Therefore, there is no historical payor mix to report. The applicant states the majority of the patients transferring to FKC Newton are currently dialyzing at FMC of Catawba Valley. However, the applicant provides the historical payor mix for CY 2018 at FMC of Catawba Valley, as shown in the table below.

| FMC of Catawba Valley Historical payor Mix CY 2018 | |
|---|----------------------------------|
| Payment Source | Percent of Total Patients |
| Self Pay/ Indigent/ Charity | 2.84% |
| Medicare | 66.62% |
| Medicaid | 4.39% |
| Commercial Insurance | 5.47% |
| Medicare / Commercial | 16.18% |
| Misc. (VA) | 4.50% |
| Total | 100.0% |

Source: Section L, page 55

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.

The Agency reviewed the:

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

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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 53, the applicant states,

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The 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.6, page 54, the applicant states there have been no civil rights complaints lodged against any BMA North Carolina facilities in the past three years.

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.1, page 52, 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.

**FKC Newton
Projected Payor Mix CY 2021**

| Payment Source | Percent of Total Patients |
|------------------------------|----------------------------------|
| Self- Pay/ Indigent/ Charity | 2.84% |
| Medicare | 66.62% |
| Medicaid | 4.39% |
| Commercial Insurance | 5.47% |
| Medicare / Commercial | 16.18% |
| Misc. (VA) | 4.50% |
| Total | 100.00% |

Note: Totals may not foot due to rounding

As shown in the table above, during the second year of operation, the applicant projects that 2.84% of total services will be provided to self-pay/indigent/charity patients, 99% to Medicare patients (includes Medicare and Medicare/Commercial), and 4.4% to Medicaid patients.

On page 52, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix.

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.4, page 54, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 56, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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 a COS for Project ID# E-11209-16 (develop a new 12-station dialysis facility by relocating six stations from FMC of Hickory and six stations from FMC of Catawba Valley), Project ID# E-11390-17 (add five stations to FMC of Catawba Valley) and Project ID# E-11480-18 (add one station to FMC of Catawba Valley). The applicant proposes to relocate three dialysis station from FMC of Catawba Valley. Upon completion of this project, Project ID# E-11209-16, Project ID# E-11390-17 and Project ID# E-11480-18, FKC Newton will be certified for a total of 15 stations and FMC of Catawba Valley will be certified for a total of 22 stations.

On page 369, the 2019 SMFP defines the service area for dialysis stations as, “A *dialysis station’s service area is 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.

According to the January 2019 SDR there are five existing and approved dialysis facilities in Catawba County as shown below.

| Facility Name | Provider | Location | # of Stations | Percent Utilization |
|-------------------------------|----------|----------|---------------|---------------------|
| FMC Hickory Home Program | FMC | Hickory | 0 | 0.00% |
| FMC of Catawba Valley | FMC | Conover | 25 | 104.00% |
| FMC of Hickory | FMC | Hickory | 35 | 90.71% |
| Fresenius Kidney Care Newton* | FMC | Newton | 0 | 0.00% |
| Catawba County Dialysis | DaVita | Hickory | 10 | 0.00% |

Source: January 2019 SDR, Table B

*Received CON approval but facility is not operational yet.

In Section N, page 57, 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 57, the applicant states:

“FKC Newton does not expect this proposal to have effect on the competitive climate in Catawba County. DaVita has recently opened a new facility in Hickory. BMA does not project to serve dialysis patients currently being served by another provider in Catawba County. The projected patient population begins with the patients currently served by BMA, and a growth of that patient population using a [five] year average annual change rate of 9.1% for the Catawba County 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 B and 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 a total of 114 of this type of facility located in North Carolina.

In Section O, page 61, 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 with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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- The applicant is not proposing to establish a new End Stage Renal Disease 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 15, the applicant projects that FKC Newton will serve 51 in-center patients on 15 stations, or a rate of 3.4 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 13-16, 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.