

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 28, 2016

Findings Date: October 28, 2016

Project Analyst: Gloria C. Hale

Team Leader: Lisa Pittman

Project ID #: E-11209-16

Facility: Fresenius Kidney Care Newton

FID #: 160340

County: Catawba

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

Project: Develop a new 12-station dialysis facility by relocating six stations from FMC Hickory and six stations from FMC of Catawba Valley

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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) proposes to develop a new 12-station dialysis facility, Fresenius Kidney Care Newton (FKC Newton) by relocating six existing certified dialysis stations from Fresenius Medical Care of Hickory (FMC Hickory) and six existing certified dialysis stations from Fresenius Medical Care of Catawba Valley (FMC Catawba Valley). All three facilities are located in Catawba County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of the project, FKC Newton will be certified for 12 dialysis stations, FMC Hickory will be certified for 29 stations (35-6), and FMC Catawba Valley will be certified for 19 stations (25-6).

Need Determination

The applicant proposes to relocate existing dialysis stations within Catawba County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 39 of the 2016 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 33 of the 2016 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS 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 contiguous counties shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous [sic] county is currently serving residents of that contiguous [sic] 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.”*

The applicant proposes to develop a new 12-station dialysis facility, FKC Newton, in Catawba County, by relocating 12 existing Catawba County dialysis stations: six from FMC Hickory and six from FMC Catawba Valley. Because all three facilities are located in Catawba County, there is no change in the total dialysis station inventory in Catawba County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (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, BMA, proposes to develop FKC Newton, a new 12-station Catawba County dialysis facility, by relocating six existing certified dialysis stations from FMC Hickory and six existing certified dialysis stations from FMC Catawba Valley. All three facilities are located in Catawba County.

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the 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 will be a new facility in Catawba County, therefore it has no existing patient origin.

In Section C.1, page 20, the applicant provides the projected patient origin for FKC Newton for in-center (IC) patients for the first two years of operation following completion of the project, Calendar Year 2018 (CY2018) and CY2019, as follows:

**FKC Newton
 Projected Patient Origin**

County	Operating Year 1 (OY1) CY2018	Operating Year 2 (OY2) CY2019	County Patients as Percent of Total	
	IC	IC	OY1	OY2
Catawba	42.8	45.7	100.0%	100.0%
Total*	42.0	45.0	100.0%	100.0%

*“Rounded down to the whole patient.”

In Section C.1, pages 20-22, and Section C.2, pages 22-23, the applicant provides the assumptions and data utilized to project patient origin, including a summary of 43 [42] in-center (IC) patient letters of support indicating their willingness to transfer to FKC Newton. See Exhibit C-1 for patients’ letters of support.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, pages 22-23, the applicant discusses the need to develop a new 12-station dialysis facility, FKC Newton, by relocating six stations from FMC Hickory and six stations from FMC Catawba Valley. The applicant states, in Section C.2, page 22, that patients living in proximity of the site of the proposed facility have stated in their letters of support that they would be willing to consider transferring to the proposed facility because it is more convenient and closer to their homes. In addition, the applicant states in Section C.2, page 23, that there is not another dialysis facility in the immediate area and that the next closest dialysis facility is more than five miles from the proposed site.

Projected Utilization for IC Patients

In Section C.1, pages 20-22, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

1. Forty-three [forty-two] letters of support were received from dialysis patients residing in close proximity to the site of the proposed facility who indicated their willingness to consider transferring their care to FKC Newton. Thirteen patient letters of support were received from patients dialyzing at FMC Hickory and 30 [29] were received from patients dialyzing at FMC Catawba Valley. Both facilities are in Catawba County and all of these patients reside in close proximity to the proposed FKC Newton site. See Exhibit C-1 for letters of support.
2. The applicant projects that 40 of the IC patients who provided letters of support will transfer to the proposed facility upon completion of the project, 12 from FMC Hickory and 28 from FMC Catawba Valley.
3. The project is scheduled to be completed on December 31, 2017. Operating Year 1 (OY1) is Calendar Year 2018 (CY2018) and Operating Year 2 (OY2) is Calendar Year 2019 (CY2019).
4. The applicant assumes the Catawba County IC dialysis patients transferring to the proposed FKC Newton facility are a part of the Catawba County ESRD patient population as a whole, and that this population will increase at the Catawba County Five Year Average Annual Change Rate (AACR) of 6.9%, as published in the July 2016 SDR.

Projected Utilization for In-Center Patients

In Section C.1, page 22, the applicant provides the calculations used to project IC patient census for FKC Newton for OY1 and OY2, as follows:

FKC Newton	In-Center Patients
Begin the facility census with 40 IC dialysis patients from Catawba County who indicated their willingness to consider transferring upon certification of FKC Newton, December 31, 2017	40
Project growth of the census of Catawba County patients by applying the Catawba County Five Year Average Annual Change Rate (AACR) of 6.9% for 12 months to December 31, 2017 [2018]. This is the end of OY 1.	$(40 \times .069) + 40 = 42.8$
Project growth of the census of Catawba County patients by applying the Catawba County Five Year Average Annual Change Rate (AACR) of 6.9% for 12 months to December 31, 2018 [2019]. This is the end of OY 2.	$(42.8 \times .069) + 42.8 = 45.7$

In Section VII.7, page 26, the applicant rounds down its projected in-center patients to 42 for OY1 (CY2018) and 45 to OY2 (CY2019), respectively.

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

- OY1: 3.5 patients per station per week, or 87.5% (42 patients/ 12 stations = 3.5/4 = .875 or 87.5%)
- OY2: 3.75 patients per station per week, or 93.75% (45 patients/ 12 stations = 3.75/4 = .9375 or 93.75%)

The projected utilization of 3.5 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

Projected utilization of in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

The applicant adequately identifies the population to be served and adequately demonstrates the need for a new, 12-station dialysis facility.

Access to Services

In Section C.3, page 23, the applicant states that Fresenius Medical Care Holdings, Inc. (FMC), the parent company to BMA, serves patients with low incomes, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons in its 100+ dialysis facilities in the state. On page 23, the applicant states that underserved persons will continue to have access to all Fresenius-related services. In Section L.1, page 71, the

applicant states that the projected payor mix for FKC Newton for project year two is based on “a weighted in-center payor mix based upon the FMC of Hickory and FMC Catawba Valley facilities...” On page 71, the applicant projects that 90.3% of patients receiving dialysis at FKC Newton will have their care covered by Medicare or Medicaid.

The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed 12-station facility, and demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

BMA proposes to develop a new 12-station dialysis facility, FKC Newton, by relocating six existing certified dialysis stations from FMC Hickory and six existing certified dialysis stations from FMC Catawba Valley. All three facilities are located in Catawba County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Upon completion of this project, FMC Hickory will be certified for 29 dialysis stations (35-6 = 29) and FMC Catawba Valley will be certified for 19 dialysis stations (25-6 = 19). In Section D.1, pages 32-38, the applicant discusses how the needs of dialysis patients at FMC Hickory and FMC Catawba Valley will continue to be met after the relocation of stations to the proposed FKC Newton dialysis facility.

FMC Hickory

In Section D.1, pages 32-35, the applicant provides the assumptions used to project utilization for FMC Hickory for December 31, 2017, the date when FKC Newton is to be operational. The assumptions are summarized as follows:

- FMC Hickory is certified for 35 dialysis stations as reported in the July 2016 Semiannual Dialysis Report (SDR). Six dialysis stations will be relocated to FKC Newton, leaving 29 dialysis stations at FMC Hickory.

- The applicant projects that 12 patients from FMC Hickory will transfer their care to FKC Newton. These transfers are expected to take place December 31, 2017, when FKC Newton becomes operational.
- The patient population of FMC Hickory is projected forward two years from December 31, 2015.
- As of December 31, 2015 there were 125 patients dialyzing at FMC Hickory and 107 of them were from Catawba County. BMA projects the Catawba County population forward 12 months by applying the Catawba County Five Year AACR of 6.9%, and does this again to project the Catawba County population forward another 12 months.
- The 11 [12] Catawba County patients who will transfer their care to FKC Newton are subtracted.
- The remaining patients from outside Catawba County are added at the end of the calculations.

Based on the above assumptions, the applicant projects utilization at FMC Hickory as follows:

FMC Hickory	
BMA begins with the Catawba County ESRD patient population of FMC Hickory as of December 31, 2015.	107
BMA projects this population forward 12 months to December 31, 2016, applying the Catawba County Five Year AACR of 6.9%.	$(107 \times 0.069) + 107 = 114.4$
BMA projects the population forward 12 months to December 31, 2017, applying the Catawba County Five Year AACR of 6.9%.	$(114.4 \times 0.069) + 114.4 = 122.3$
BMA subtracts 11 [12] Catawba County patients projected to transfer to FKC Newton.	$122.3 - 12 = 110.3$
BMA adds the 18 patients from counties outside of Catawba County for the ending census for December 31, 2017, the date FKC Newton is projected to be certified.	$110.3 + 18 = 128.3$

Thus, the applicant states, in Section D.1, page 33, that as of December 31, 2017 FMC Hickory is projected to have 128 in-center dialysis patients dialyzing on 29 stations for a utilization rate of 4.41 patients per station per week, or 110.34% ($128/29 = 4.41$; $4.41/4 = 1.1034$ or 110.34%).

The applicant states, on page 33, that four patients were dialyzing on a third shift at FMC Hickory as of June 30, 2016, and states,

“Assuming the third shift continues to operate with four patients, the effective utilization at FMC Hickory on December 31, 2017 would be a function of 124

patients dialyzing on 29 stations. This equates to a utilization rate of 4.28 patients per station, or 106.90%” [124/29 = 4.28; 4.28/4 = 1.07 or 107%].

The applicant states, on page 33, that BMA will apply to add six dialysis stations at FMC Hickory in response to a County Need Determination for Catawba County as published in the July 2016 SDR. The Project Analyst notes that the Agency has received BMA’s application, Project I.D. #E-011234-16, in response to the County Need Determination for Catawba County for the CON review beginning October 1, 2016. The applicant states that if it is approved for the six dialysis stations, and assuming this application, Project I.D. #E-11209-16, is approved, FMC Hickory would have a total of 35 dialysis stations at completion of both projects (29 + 6 = 35). This would result in 128 patients dialyzing on 35 stations for a utilization rate of 3.66 patients per station per week, or 91.43% [91.5%] utilization (128/35 = 3.66; 3.66/4 = 91.5%).

The applicant further states, on page 34, that if BMA’s application to add six dialysis stations to FMC Hickory is denied in response to the County Need Determination for Catawba County, BMA qualifies to add five stations to FMC Hickory using the Facility Need Methodology and will submit its application for the April 2017 CON review cycle. The applicant demonstrates, in Section D.1, page 34, that it qualifies to add five dialysis stations to FMC Hickory by using the Facility Need Methodology. If the application is approved, FMC Hickory would have a total of 34 dialysis stations at the completion of the project and the completion of this project, Project I.D. #E-11209-16 (29 + 5 = 34). This would result in 128 patients dialyzing on 34 stations for a utilization rate of 3.76 patients per station per week, or 94.1% utilization (128/34 = 3.76; 3.76/4 = 94.1%).

The applicant demonstrates that the needs of the population presently served at FMC Hickory will continue to be adequately met following the proposed relocation of six dialysis stations from FMC Hickory to FKC Newton.

FMC Catawba Valley

In Section D.1, pages 35-38, the applicant provides the assumptions used to project utilization for FMC Catawba Valley for December 31, 2017, the date which FKC Newton is projected to be operational. The assumptions are summarized as follows:

- FMC Catawba Valley is certified for 25 dialysis stations as reported in the July 2016 SDR.
- Eighty-eight of the 91 patients dialyzing at FMC Catawba Valley are residents of Catawba County. The applicant projects growth of the FMC Catawba Valley patient population for two years, beginning on December 31, 2015, applying the Catawba County Six Year AACR of 6.9%, as published in the July 2016 SDR, for each year.
- Twenty-eight patients will transfer from FMC Catawba Valley to FKC Newton on December 31, 2017, when FKC Newton is projected to be certified.

- BMA adds the three patients from outside of Catawba County at the end of its calculations.

Based on the above assumptions, in Section D.1, page 36, the applicant calculates the in-center patient census for FMC Catawba Valley starting December 31, 2015 through December 31, 2017, illustrated as follows:

FMC Catawba Valley	
BMA begins with the 88 Catawba County ESRD patients receiving dialysis care at FMC Catawba Valley as of December 31, 2015.	88
BMA projects this population forward for 12 months to December 31, 2016, applying the Catawba County Five Year AACR of 6.9%.	$(88 \times 0.069) + 88 = 94.1$
BMA projects this population forward for 12 months to December 31, 2017, applying the Catawba County Five Year AACR of 6.9%.	$(94.1 \times 0.069) + 94.1 = 100.6$
BMA subtracts the 28 Catawba County patients projected to transfer to the proposed FKC Newton facility.	$100.6 - 28 = 72.6$
BMA adds the three patients from outside Catawba County. This is the projected census for December 31, 2017.	$72.6 + 3 = 75.6$

The applicant states, in Section D.1, page 36, that as of December 31, 2017 FMC Catawba Valley will have 76 patients, rounded up, dialyzing on 19 stations for a utilization rate of 4.00 patients per station, or 100% utilization. The applicant states, on page 36, that FMC Catawba Valley does not currently offer a third shift, but states that it could if admissions increase. The applicant states that BMA will apply to add four dialysis stations in response to a County Need Determination for Catawba County as published in the July 2016 SDR. The Project Analyst notes that the Agency has received BMA's application, Project I.D. #E-011238-16, in response to the County Need Determination for Catawba County for the CON review beginning October 1, 2016. The applicant states that if it is approved for the four dialysis stations, and assuming this application, Project I.D. #E-11209-16, is approved, FMC Catawba County would have a total of 23 dialysis stations at completion of both projects ($19 + 4 = 23$). This would result in 75 patients, rounded down, dialyzing on 23 stations for a utilization rate of 3.26 patients per station per week, or 81.52% utilization ($75/23 = 3.26$; $3.26/4 = 81.52\%$).

The applicant further states, on page 36, that if BMA's application to add four dialysis stations to FMC Catawba Valley is denied in response to the County Need Determination for Catawba County, BMA qualifies to add three stations to FMC Catawba Valley using the Facility Need Methodology and will submit its application for the April 2017 CON review cycle. The applicant demonstrates, in Section D.1, page 37, that it qualifies to add three dialysis stations to FMC Catawba Valley by using the Facility Need Methodology. If the application is approved, FMC Catawba Valley would have a total of 22 dialysis stations at the completion of the project and the completion of this project, Project I.D. #E-11209-16 ($19 + 3 = 22$). This would result in 75 patients dialyzing on 22 stations for a utilization

rate of 3.41 patients per station per week, or 85.2% utilization ($75/22 = 3.41$; $3.41/4 = 85.2\%$).

The applicant demonstrates that the needs of the population presently served at FMC Catawba Valley will continue to be adequately met following the proposed relocation of six dialysis stations from FMC Catawba Valley to FKC Newton.

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Hickory and FMC Catawba Valley will continue to be adequately met following the proposed relocation of six dialysis stations from FMC Hickory and six dialysis stations from FMC Catawba Valley to FKC Newton and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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.

C

In Section E, page 39, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintaining the status quo – the applicant states that both of BMA’s two dialysis facilities in Catawba County are at physical plant capacity and, therefore, cannot be further expanded to meet the need. Therefore, this is not an effective alternative.
- Develop a facility in another area of Catawba County - the applicant states that it evaluated existing and projected populations served by BMA, concluding that the population in the Newton area would be better served by a new facility. Therefore, this is not an effective alternative.
- Develop a larger facility – the applicant states that it considered applying for more stations at the proposed FKC Newton facility but concluded that the 12-station facility will meet the needs of the projected patients who will transfer their care to the proposed facility upon certification, and will also meet the performance standard of 10A NCAC 14C .2203. Therefore, this is not an effective alternative.
- Develop a 10-station dialysis facility – the applicant states that it could have delayed its application and instead applied for a 10-station dialysis facility in response to the County Need Determination for Catawba County reported in the July 2016 SDR. However, the applicant states that it has demonstrated the need for 12 stations based on the projected population to be served, therefore 10 stations would be too limiting. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at FKC Newton and the physical plant constraints of existing BMA facilities in the county, the proposed project is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Newton shall materially comply with all representations made in the certificate of need application.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Newton shall relocate no more than six dialysis stations from Fresenius Medical Care Hickory and no more than six dialysis stations from Fresenius Medical Care of Catawba Valley.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Newton shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify six dialysis stations at Fresenius Medical Care Hickory for a total of no more than 29 dialysis stations at Fresenius Medical Care Hickory upon completion of this project.**
 - 5. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify six dialysis stations at Fresenius Medical Care of Catawba Valley for a total of no more than 19 dialysis stations at Fresenius Medical Care of Catawba Valley upon completion of this project.**
 - 6. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Newton 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 develop a new 12-station dialysis facility in Catawba County, FKC Newton, by relocating six stations from FMC Hickory and six stations from FMC Catawba Valley.

Capital and Working Capital Costs

In Section F.1, page 42, the applicant projects \$1,546,951 in capital costs to develop the proposed project, summarized as follows:

**FKC Newton
Capital Costs**

Category	Cost
Construction	\$1,036,629
Miscellaneous Project Costs	
(RO) Water Equipment	\$210,000
Other Equipment and Furniture	\$150,529
Architect/Engineering Fees	\$93,294
Contingency	\$56,496
Subtotal Miscellaneous	\$510,322
Total Project Capital Costs	\$1,546,951

In Section F.10, page 45, the applicant states that it will have \$152,304 in start-up expenses and in Section F.11, page 46, it states it will have eight months of initial operating expenses of \$1,936,402. The total estimated working capital for the project will be \$2,088,706.

Availability of Funds

In Section F.2, page 43, and Section F.13, page 47, the applicant states it will finance the capital costs and working capital costs with accumulated reserves of FMC. Exhibit F-1 contains a letter dated July 15, 2016, from the Senior Vice President & Treasurer of FMC, authorizing and committing \$1,546,951 in capital costs for the project. In addition, the letter in Exhibit F-1 states, *“I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location.”*

Exhibit F-2 contains the Consolidated Financial Statements for FMC and Subsidiaries for the years ending December 31, 2015 and December 31, 2014. These statements indicate that as of December 31, 2015, FMC and Subsidiaries had \$249.3 million in cash and cash equivalents, \$19,332,539 in total assets and \$10,144,288 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In Form B of the pro forma financial statements, 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
 Projected Revenues and Operating Expenses**

	Operating Year (OY) 1 CY2018	Operating Year (OY) 2 CY2019
Gross Patient Revenue	\$24,231,088	\$26,005,748
Deductions from Gross Patient Revenue	\$19,618,669	\$21,055,520
Net Patient Revenue	\$4,612,419	\$4,950,228
Total Operating Expenses	\$2,904,603	\$3,082,372
Net Income	\$1,707,816	\$1,867,856

The applicant states in its assumptions for Form C of the pro formas that it uses the average number of patients for OY1 and OY2 to calculate revenues for each of the operating years. In Section H.1, page 54, the applicant provides projected staffing and salaries. Form A of the pro formas shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference. The assumptions used by the applicant in preparation of the pro forma financial statements, including projected utilization, costs and charges, are reasonable and adequately supported. See Section R, the financial section 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 that the financial feasibility of the project is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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, BMA, proposes to develop a new 12-station dialysis facility in Catawba County, FKC Newton, by relocating six stations from FMC Hickory and six stations from FMC Catawba Valley.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the 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 also serve residents of counties not included in their service area.

According to the July 2016 SDR, there are two facilities offering in-center dialysis and one facility offering only peritoneal dialysis training and support in Catawba County. BMA owns and operates all three of these facilities. The table below summarizes information on the two BMA dialysis facilities providing in-center dialysis:

**Catawba County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2015**

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
FMC Hickory	BMA	Hickory	35	89.29%
FMC Catawba Valley	BMA	Conover	25	91.00%

As shown in the table above, both BMA’s dialysis facilities are operating above 80% utilization (3.2 patients per station). The applicant provides 43 [42] patient letters of support in Exhibit C-1 from in-center patients at BMA facilities in Catawba County indicating that the proposed facility, in southern Catawba County, would be closer to their homes, and therefore, more convenient.

The applicant is not increasing the number of dialysis stations in Catawba County, rather it is relocating 12 of them to develop a new facility that is closer to patients living in or near the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

The applicant adequately demonstrates the need to relocate stations to develop a new dialysis facility in Catawba County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at FMC Hickory and FMC Catawba Valley, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 54, the applicant provides the proposed staffing for the new facility, which includes 11.85 full-time equivalent (FTE) employee positions, summarized as follows:

Position	Projected # of FTE Positions
Medical Director*	
RN	2.00
Patient Care Technician	6.00
Clinical Manager	1.00
Administrator	0.15
Dietitian	0.50
Social Worker	0.50
Chief Technician	0.15
Equipment Technician	0.60
In-Service	0.15
Clerical	0.80
Total FTE Positions	11.85

*The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, page 55, the applicant describes its experience and process for recruiting and retaining staff.

In Section H.7, page 57, the applicant provides the projected Direct Care Staff Hours for OY2, illustrated as follows:

Projected Direct Care Staff Hours – OY2

Direct Care Positions	# FTEs [a]	Hours / Year / FTE** [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
Nurse*	2.0	2,080	4,160	3,120	1.33
Patient Care Technician	6.0	2,080	12,480	3,120	4.00
Total**	8.0	4,160 [2,080]	16,640	3,120	5.33

*The applicant states, in Section H.7, page 62, that the Nurse position does not include the RN Clinical Manager.

**Correction made by the Project Analyst is in brackets.

Exhibit I-6 contains a copy of a letter signed by David Harvey, M.D., dated June 21, 2016, stating that he has agreed to serve as Medical Director of FKC Newton.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (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 58, the applicant includes a list of providers of the necessary ancillary and support services that will be provided to patients receiving dialysis services at FKC Newton. Exhibits I-3, 4 and 5 contain documentation regarding the availability of laboratory, hospital, and kidney transplant services, respectively. Exhibit I-6 contains a letter from the physician willing to serve as Medical Director of the facility expressing his support and the support of Piedmont Nephrology for the proposed project. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 60-61. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

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

C

The applicant proposes to construct a 2,927 square foot building to house the proposed services which will be located in Newton in southern Catawba County. In Section F.1, page 42, the applicant lists the project costs, including \$1,036,629 for construction, \$510,322 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,546,951. In Section K.1, pages 63-64, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application, pages 90-93. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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.1, page 70, the applicant states that BMA has a long history of providing dialysis services to the underserved populations of North Carolina and that it is its policy to provide services to all patients regardless of income, racial/ethnic origin, age, or any other patient classified as underserved.

The applicant provides the historical payor mix for FMC Hickory in Section L.7, page 74. Six dialysis stations will be relocated from FMC Hickory to the proposed

facility and some patients will transfer to FKC Newton (See Exhibit C-1 for patients' letters of support.) The historical payor mix is as follows:

**FMC Hickory
Historical Payor Mix
CY2015**

Payor Type	Percent of In-Center Patients
Private Pay	2.69%
Commercial Insurance	6.87%
Medicare	70.34%
Medicaid	1.69%
Misc. (includes VA)	1.86%
Other Medicare Commercial	16.56%
Total	100.00%

As illustrated in the table above, 88.59% of FMC Hickory's patients were Medicare or Medicaid recipients.

Similarly, the applicant provides the historical payor mix for FMC Catawba Valley in Section L.7, page 75. Six dialysis stations will be relocated from FMC Catawba Valley to the proposed facility and some patients will transfer to FKC Newton (See Exhibit C-1 for patients' letters of support.) The historical payor mix is as follows:

**FMC Catawba Valley
Historical Payor Mix
CY2015**

Payor Type	Percent of In-Center Patients
Private Pay	2.97%
Commercial Insurance	4.32%
Medicare	77.85%
Medicaid	3.39%
Misc. (includes VA)	0.62%
Other Medicare Commercial	10.85%
Total	100.00%

As illustrated in the table above, 92.09% of FMC Catawba Valley' patients were Medicare or Medicaid recipients.

In addition, the applicant describes its admission and financial policies in Section L.3, pages 72-73, and provides a copy of its admission policy in Exhibit L-1 which states that patients will be "*admitted and treated without regard to race, creed or religion, color, age, sex, disability, national origin, and or sexual orientation.*"

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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Catawba	16%	51%	23%	16%	9%	18%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates.

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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report¹* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3, page 73, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service. However, the applicant states that it will treat all patients the same and that it is obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.

In Section L.6, page 74, the applicant states there have been no civil rights complaints filed against any BMA North Carolina facilities within the past five years. Therefore, 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 71, the applicant provides the projected payor mix for the proposed project for the second operating year, (CY2019). The applicant states, on page 71, the projected payor mix for FKC Newton is based on the weighted in-center payor mix at FMC Hickory and FMC Catawba Valley. Therefore, it is reasonable to assume that the projected payor mix for FKC Newton is reasonable, illustrated as follows:

**FKC Newton
Project Year Two**

Payment Source	Percent of In-Center Patients
Self Pay/Indigent/Charity	2.83%
Medicare	74.09%
Medicaid	2.54%
Commercial Insurance	5.59%
Medicare/Commercial Insurance	13.71%
VA	1.24%
Total	100.00%

As illustrated in the table above, the applicant projects that 90.34% of all of the patients receiving dialysis services at FKC Newton in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FKC Newton. Therefore, 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 73, the applicant describes the range of means by which a person will have access to the dialysis services at FKC Newton. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from other nephrologists, other physicians, or hospital emergency rooms. In addition, the applicant states that any nephrologist who applies for and receives medical staff privileges may admit patients to the facility. In Exhibit I-6, the applicant provides a letter signed by David Harvey, M.D., of Piedmont Nephrology and Hypertension Associates, P.A., indicating that the practice is providing care for a significant number of ESRD patients in the southern part of Catawba County and does medical rounds at the existing dialysis facilities in the county. Furthermore, the letter states confidence in the practice's ability to meet the needs of ESRD patients at FKC Newton. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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 76, the applicant states that the facility is available to all health-related education and training programs to receive instruction and to observe operations. Exhibit M-1 contains a copy of correspondence to Catawba Valley Community College inviting the school to do clinical rotations for nursing students at its proposed facility. The information provided is reasonable and adequately supports a determination that 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 develop a new 12-station dialysis facility, FKC Newton in Catawba County by relocating six stations from FMC Hickory and six stations from FMC Catawba Valley.

On page 369, the 2016 SMFP defines the service area for dialysis stations as *“the 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.

**Catawba County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2015**

Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2015
FMC Hickory	BMA	Hickory	35	89.29%
FMC Catawba Valley	BMA	Conover	25	91.00%

As shown in the table above, both of the dialysis facilities in Catawba County are owned and operated by BMA and both are operating above 80% utilization (3.2 patients per station).

In Section N.1, page 77, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 90% of the In-center treatments will be reimbursed at government payors (Medicare / Medicaid / VA) rates. The facility must capitalize upon every opportunity for efficiency.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

See also Sections A, B, C, K, L, N, and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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 lists the kidney disease treatment centers located in North Carolina that are owned and operated by the applicant or an affiliated company. In Section O.3, pages 83-84, the applicant identifies three of its 100+ Fresenius affiliated North Carolina facilities, BMA Lumberton, BMA East Charlotte, and RAI West College-Warsaw, as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(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.*
- C- In Section C.1, page 22, the applicant adequately demonstrates that FKC Newton will serve at least 42 in-center patients on 12 dialysis stations at the end of the first operating year, which is 3.5 patients per station per week, or a utilization rate of 87.5% ($42/12 = 3.5$; $3.5/4 = .875$ or 87.5%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- .2203(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.

- NA- The applicant is seeking to develop a new 12-station dialysis facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 26-27, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.