

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

CORRECTED

Decision Date: March 29, 2017

Findings Date: March 29, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: F-11266-16

Facility: Fresenius Kidney Care North Gaston

FID #: 160496

County: Gaston

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

Project: Develop a new 12-station dialysis facility by relocating 12 dialysis stations from FMC Gastonia and offer home training and support for home hemodialysis and peritoneal dialysis patients

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to develop a new 12-station dialysis facility, Fresenius Kidney Care North Gaston (FKC North Gaston) by relocating 12 existing certified dialysis stations from FMC Gastonia. In addition, the proposed facility will offer home training and support for home hemodialysis (HH) and peritoneal dialysis (PD). Both the existing and proposed facilities will be located in Gaston County. The proposed facility will be located at 1508 Lower Dallas Highway in Dallas. 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 North Gaston will be certified for 12 dialysis stations and FMC Gastonia will be certified for 27 stations (39-12 = 27).

Need Determination

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

Policies

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 a contiguous county 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 North Gaston, in Gaston County, by relocating 12 existing Gaston County dialysis stations from FMC Gastonia. Because both facilities will be located in Gaston County, there will be no change in the total dialysis station inventory in Gaston 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 North Gaston, a new 12-station Gaston County dialysis facility, by relocating 12 existing certified dialysis stations from FMC Gastonia. In addition, the proposed facility will offer home training and support for home hemodialysis (HH) and peritoneal dialysis (PD). Both the existing and proposed facilities will be located in Gaston County.

Patient Origin

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

FKC North Gaston will be a new facility in Gaston County, therefore it has no existing patient origin.

In Section C-1, page 17, the applicant identifies the patient population it proposes to serve for FKC North Gaston for the first two years of operation following project completion for in-center (IC), HH and PD patients for the first two years of operation following completion of the project, Calendar Year (CY) 2019 and CY2020, as follows:

FKC NORTH GASTON PROJECTED PATIENT ORIGIN								
County	Operating Year 1 (OY1) CY2019			Operating Year 2 (OY2) CY2020			County Patients as Percent of Total**	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Gaston	40.8	3.1	3.1	41.6	4.4	4.4	100.0%	100.0%
Total*	40	3	3	41	4	4	100.0%	100.0%

***Rounded down to the whole patient.” **Totals may not foot due to rounding.*

In Section C-1, pages 17-19, the applicant provides the assumptions and methodology used to project patient origin, including a summary of the patient support letters in Exhibit C-1. As shown above, the applicant identifies only patients from Gaston County in its projected patient origin. However, in Exhibit C-1, the project analyst counted four letters from home therapy patients from Gaston County (one), Lincoln County (two) and Cleveland County (one). Nevertheless, the applicant projects 40 IC patients by the end of the first operating year and has the majority of its letters from Gaston County patients (48) to meet the minimum standard as required by 10A NCAC 14C .2203(b) (3.2 patients per station at the end of the first operating year).

The applicant adequately identifies the population to be served.

Analysis of Need

Although the applicant does not submit the application based upon a need determination in the 2016 SMFP, the applicant states in Section B-4, page 11, the following about the need to develop a new 12-station dialysis facility - FKC North Gaston by relocating 12 dialysis stations from FMC Gastonia.

“This development will promote safety and quality by delivering needed dialysis care and treatment to the patient population of northern Gaston County and Dallas in a very convenient, easily accessible location. . . . Patient quality of life will be enhanced with time returned to the patient rather than time spent in transit to and from dialysis treatment.”

In Section C-2, page 20, the applicant states that it identified a number of IC, HH, and PD dialysis patients receiving care at BMA dialysis facilities who reside in northern Gaston County and who would be closer to the site of the proposed facility. The applicant further states that the BMA dialysis facilities where these patients are currently receiving dialysis are not the most convenient locations for the patients, requiring more travel time and more travel expense. The applicant states in Section C-1, page 17, that it received 48 letters of support from IC patients residing in close proximity to the proposed facility who are currently receiving dialysis care and treatment at BMA dialysis facilities in Gaston County or Lincoln County. In addition, four letters of support were received from HH and PD patients residing in close proximity to the proposed facility. Each of these patients’ letters state their willingness to consider transferring their care to the proposed facility because it would be closer than where they are currently dialyzing, more convenient and resulting in less travel time. Moreover, on page 20, the applicant states that there are no other dialysis facilities located in the area proposed for the new facility.

Projected Utilization for IC Patients

In Section C-1, pages 17-19, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

1. Fifty-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 North Gaston. Forty-eight of the letters of support are from IC patients. The applicant projects that 40 IC patients will transfer to the proposed facility based on their expressed support. The applicant states that each of these patients could be better served by a dialysis facility in Dallas (a suburb of both Gastonia (Gaston County) and Charlotte (Mecklenburg County)). See the map in Section G-2, page 47 and Exhibit C-1 for letters of support.
2. The 48 letters received from IC patients indicate that they all reside in Gaston County. The applicant assumes the Gaston County IC dialysis patients transferring to the proposed FKC North Gaston facility are a part of the Gaston County ESRD

patient population as a whole, and that this population will increase at the Gaston County Five Year Average Annual Change Rate (AACR) of 6.9%, as published in the July 2016 Semiannual Dialysis Report (SDR).

3. FKC North Gaston will offer home therapies. Four letters of support were received from home therapy patients; two HH and two PD. In addition to these four home therapy patients projected to transfer their care to the new facility, the applicant projects that two patients in the first two operating years will change from IC dialysis to home dialysis. BMA assumes that one patient per year to choose HH and one patient per year to choose PD.
4. The project is scheduled for occupancy December 31, 2018. Operating Year 1 (OY1) is CY2019 and OY2 is CY2020.

In Section C-1, page 19, the applicant provides the assumptions and methodology used to project in-center patient utilization for FKC North Gaston for Operating Years 1 and 2, as follows:

FKC NORTH GASTON	In-Center Patients
Begin with 40 Gaston County patients who indicated their willingness to consider transferring to FKC North Gaston.	40
Project growth of Gaston County patients by applying the Gaston County Five Year Average Annual Change Rate (AACR) of 6.9% forward 12 months to December 31, 2019.	$(40 \times .069) + 40 = 42.8$
Subtract 2 patients projected to change to home dialysis. End of OY1.	$42.8 - 2 = 40.8$
Project growth of the Gaston County patients for one year to December 31, 2020 by applying the appropriate Five Year AACR.	$(40.8 \times .069) + 40.8 = 43.6$
Subtract 2 patients projected to change to home dialysis. End of OY2.	$43.6 - 2 = 41.6$

The applicant rounds down its projected in-center patients to 40 for OY1 (CY2019) and 41 to OY2 (CY2020), respectively.

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

- OY1: 3.3 patients per station per week, or 83.3% (40 patients/ 12 stations = $3.3/4 = .833$ or 83.3%)
- OY2: 3.4 patients per station per week, or 85.4% (41patients/ 12 stations = $3.4/4 = .854$ or 85.4%)

The projected utilization of 3.3 patients per station per week at the end of OY1 exceeds 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.

Projected Utilization for Home Hemodialysis and Home Peritoneal Dialysis Patients

In Section C-1, page 17, the applicant states that both HH and PD will be provided at FKC North Gaston. Four letters of support were provided from home dialysis patients indicating their willingness to transfer their care to the proposed facility's home training program. All four of the home dialysis patients, two HH patients and two PD patients, indicated in their letters that the proposed facility would be more convenient because it would be closer to their homes. See Exhibit C-1 for letters of support from home dialysis patients.

In Section C-1, page 19, the applicant provides the assumptions and methodology used to project HH and PD patient utilization for FKC North Gaston for OYs 1 and 2, as follows:

FKC NORTH GASTON	HH	PD
Begin with 2 HH patients and 2 PD patients from Gaston County, beginning December 31, 2018.	2	2
Project census growth of the Gaston County home patients using the County Five Year AACR of 6.9% forward to December 31, 2019.	$(2 \times .069) + 2 = 2.1$	$(2 \times .069) + 2 = 2.1$
Add 1 HH and 1 PD patient projected to change to home dialysis. Ends OY 1.	$2.1 + 1 = 3.1$	$2.1 + 1 = 3.1$
Project census growth of the Gaston County home patients using the County Five Year AACR of 6.9% forward to December 31, 2020.	$(3.1 \times 0.69) + 3.1 = 3.4$	$(3.1 \times 0.69) + 3.1 = 3.4$
Add 1 HH and 1 PD patient projected to change to home dialysis. Ends OY 2.	$3.4 + 1 = 4.4$	$3.4 + 1 = 4.4$

The applicant states it will serve three HH patients and three PD patients in OY1, and four HH patients and four PD patients in OY2, therefore, the applicant rounds down to the nearest whole.

The applicant's projected utilization of HH and PD 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 to include home training and support for HH and PD dialysis patients.

Access to Services

In Section C-3, page 21, the applicant states that Fresenius Medical Care Holdings, Inc., 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. Also, on page 25, the applicant states that underserved persons will continue to have access to all Fresenius-related services. In Section L-1, page 65, the applicant provides the projected payor mix for FKC North Gaston and states that its projected payor mix is based on the historical payor mix at the FMC Gastonia dialysis facility.

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 to include a home training program, 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 North Gaston, by relocating 12 existing certified dialysis stations from FMC Gastonia. In addition, the proposed facility will offer home training and support for HH and PD patients. Both the existing and proposed facilities will be located in Gaston 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 Gastonia will be certified for 27 dialysis stations ($39 - 12 = 27$).

In Section D-1, pages 30-33, the applicant discusses how the needs of dialysis patients at FMC Gastonia will continue to be met after the relocation of 12 stations to the proposed FKC North Gaston dialysis facility.

FMC Gastonia

In Section D-1, pages 30-32, the applicant provides the assumptions used to project utilization for FMC Gastonia for December 31, 2018, the date when FKC North Gaston is to be operational. The assumptions are summarized as follows:

- FMC Gastonia is certified for 39 dialysis stations as reported in the July 2016 SDR. The number of stations at FMC Gastonia will remain the same until the proposed

project is completed; unless other projects come on line to impact the number of certified dialysis stations.

- The applicant projects that 24 patients from FMC Gastonia will transfer their care to FKC North Gaston, based on 48 letters of support. These transfers are expected to take place December 31, 2018.
- As of June 30, 2016 there were 142 patients dialyzing at FMC Gastonia and 136 of them were from Gaston County. BMA projects the Gaston County population forward six months by applying the Gaston County Five Year AACR of 6.9%.
- The six remaining patients from outside Gaston County are added at the end of the calculations.

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

FMC GASTONIA	In-Center Patients
BMA begins with the Gaston County ESRD patient population of FMC Gastonia as of June 30, 2016.	136
BMA projects this population forward 6 months to December 31, 2016, applying the Gaston County Five Year AACR of 6.9%.	$[136 \times (0.69/12 \times 6)] + 136 = 140.7$
BMA projects this population forward 12 months to December 31, 2017.	$(140.7 \times .069) + 140.7 = 150.4$
BMA projects this population forward 12 months to December 31, 2018.	$(150.4 \times .069) + 150.4 = 160.8$
BMA subtracts 24 Gaston County patients projected to transfer to FKC North Gaston.	$160.8 - 24 = 136.8$
BMA adds the 6 patients from counties outside Gaston County for the ending census for December 31, 2018, the date FKC North Gaston is projected to be certified.	$136.8 + 6 = 142.8$

The applicant states that as of December 31, 2018, FMC Gastonia is projected to have 142.8 IC patients rounded up to 143 IC dialysis patients dialyzing on 27 stations for a utilization rate of 5.3 patients per station per week, or 132.% ($143/27 = 5.3$; $5.3/4 = 1.32$ or 132.%).

The applicant states that FMC Gastonia has historically operated a third shift and there are 23 patients dialyzing on the third shift. Therefore, the utilization rate is reduced to 111% ($143 - 23 = 120$; $120 \text{ patients} / 27 \text{ stations} = 4.44 \text{ patients per station per week}$; $4.44/4 = 1.11\%$). The applicant states that patients will continue to dialyze on a third shift through the certification of FKC North Gaston. In addition, the applicant states that FMC Gastonia qualifies for an additional six stations. The applicant uses the Facility Need Methodology to demonstrate the need for six additional stations in Section D-1, page 32. The applicant filed a certificate of need (CON) application on March 17, 2017 to add six dialysis stations to FMC Gastonia for a total of 33 stations upon completion of this project and Project ID# F-11309-17.

On pages 32-33, the applicant states,

*“Approval of this application will not adversely affect any patients. No patients will be denied treatment ...
The relocation of stations from FMC Gastonia will not alter or affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care.”*

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Gastonia will continue to be adequately met following the proposed relocation of 12 dialysis stations from FMC Gastonia to FKC North Gaston 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.

CA

In Section E-1, page 34, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo – the applicant states that there is a “*significant*” number of dialysis patient who live in or near Dallas and northern Gaston County. The proposed facility would shorten their travel time for their dialysis treatments. Therefore, this is not an effective alternative.
- Develop a facility in another area of Gaston County - the applicant states that it evaluated existing and projected populations served by BMA and that the population in northeast Gaston County 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 North Gaston 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(b). 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 and the limitations in the capacity of the physical plants 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 North Gaston 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 North Gaston shall relocate no more than 12 dialysis stations from FMC Gastonia.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care North Gaston 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 12 dialysis stations at FMC Gastonia for a total of no more than 27 dialysis stations at FMC Gastonia upon completion of this project.**
 5. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care North Gaston 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 Gaston County, FK North Gaston, by relocating 12 stations from FMC Gastonia. In addition, the applicant proposes to offer home training and support services for HH and PD patients at the proposed facility.

Capital and Working Capital Costs

In Section F-1, page 36, the applicant projects \$1,837,078 in capital costs to develop the proposed project, summarized as follows:

FKC NORTH GASTON Capital Costs	
Category	Cost
Construction	\$1,253,623
Miscellaneous Project Costs	
(RO) Water Equipment	\$220,000
Other Equipment and Furniture	\$182,307
Architect/Engineering Fees	\$112,826
Contingency	\$68,322
Subtotal Miscellaneous	\$583,455
Total Project Capital Costs	\$1,837,078

In Section F-10, page 39, the applicant states that it will have \$159,996 in start-up expenses and in Section F-11, page 40, it states it will have eight months of initial operating expenses of \$2,067,938. The total estimated working capital for the project will be \$2,227,934.

Availability of Funds

In Section F-2, page 37, and Section F-13, page 41, the applicant states it will finance the capital costs and working capital costs with owner's equity/accumulated reserves of Fresenius Medical Care Holdings, Inc. (FMC). Exhibit F-1 contains a letter dated October 15, 2016, from the Senior Vice President and Treasurer of FMC, authorizing and committing \$1,837,078 in capital costs for the project. In addition, the letter from the Senior Vice President and Treasurer of FMC 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, \$19.3 billion in total assets and \$10.1 billion 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

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

FKC NORTH GASTON		
Projected Revenues and Operating Expenses		
	OY1 CY2019	OY2 CY2020
Total Treatments*	5,928	6,076
Total Gross Revenues (Charges)	\$26,001,760	\$27,772,432
Total Net Revenue	\$4,619,600	\$4,925,153
Total Operating Expenses (Costs)	\$3,101,907	\$3,279,862
Net Income	\$1,517,693	\$1,645,291

*Adjusted for missed treatments

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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.

C

The applicant, BMA, proposes to develop a new 12-station dialysis facility in Gaston County, FKC North Gaston, by relocating 12 stations from FMC Gastonia. In addition, the applicant proposes to offer home training and support services for HH and PD patients at the proposed facility.

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

According to the July 2016 SDR, there are four dialysis facilities in Gaston County. All of the four facilities are operational, with one having been approved to relocate to another site. The applicant or its parent company owns and operates all of the four dialysis facilities in Gaston County as shown below in the table.

GASTON 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 Gastonia	BMA	Gastonia	39	89.74%
FMC South Gaston	BMA	Gastonia	20	96.25%
FMC Belmont	BMA	Belmont	18	93.06%
BMA Kings Mountain	BMA	Kings Mountain	16	82.81%
BMA Kings Mountain*	BMA	Kings Mountain	**16	0.00%

*Proposed new site consisting of existing stations. **CON issued, not certified.

As shown in the table above, all four of BMA’s operational dialysis facilities are operating above 80% utilization (3.2 patients per station). BMA Kings Mountain is being relocated to a new site in Gaston County. The applicant provides 52 letters in Exhibit C-1 from in-center and home trained dialysis patients at BMA facilities in Gaston County, indicating that the proposed facility, in the northern portion of Gaston County, would be closer to their homes, and therefore, more convenient.

The applicant is not increasing the number of dialysis stations in Gaston 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 Gaston 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 Gastonia 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. Therefore, 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 48, the applicant provides the proposed staffing for the new facility, which includes 12.85 full-time equivalent (FTE) employee positions, summarized as follows:

FKC NORTH GASTON	
Position	Projected # of FTE Positions
Medical Director*	0.00
RN	2.00
Patient Care Technician	6.00
Clinical Manager	1.00
Administrator	0.15
Dietician	0.50
Social Worker	0.50
Home Training RN	1.00
Chief Technician	0.15
Equipment Technician	0.60
In-Service	0.15
Clerical	0.80
Total FTE Positions	12.85

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

In Section H-3, page 49, the applicant describes its experience and process for recruiting and retaining staff.

In Section H-7, page 51, the applicant provides the projected direct care staff hours for OY2. The number of proposed staff positions and the direct care staff hours are the same in Section H-1, page 48 and Section H-7, page 51. The applicant's projected direct care staff hours are illustrated as follows:

FKC NORTH GASTON					
Projected Direct Care Staff Hours – OY2					
Direct Care Positions	# FTEs	Hours / Year / FTE**	Total Annual FTE Hours	Total Annual Hours of Operation	FTE Hours / Hours of Operation
	[a]	[b]	[c] = [a] x [b]	[d]	[e] = [c] ÷ [d]
RN*	2.00	2,080	4,160	3,120	1.33
Patient Care Technician	6.00	2,080	12,480	3,120	4.00
Home Training RN	1.00	2,080	2,080	3,120	0.67
Total	9.00	2,080	18,720	3,120	6.00

*The applicant states, in Section H.7, page 51, that the Nurse position does not include the nurse Clinical Manager.

Exhibit I-5 contains a copy of a letter signed by Gene Radford, MD, dated October 12, 2016, stating that he will serve as the Medical Director for the facility.

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 52, 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 North Gaston. Exhibits I-2, 3 and 4 contain documentation regarding the availability of laboratory, hospital, and kidney transplant services, respectively. Exhibit I-5 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system in Section I-2, 3 and 4, pages 53-55. 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

In Section K-2, page 59, the applicant proposes to construct a 3,573 square foot building to house the proposed services which will be located in Dallas in northern Gaston County. In Section F-1, page 36, the applicant lists the project costs, including \$1,253,623 for construction, \$583,455 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,837,078. In Section K-1 and 2, pages 57-59, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R – Pro formas. 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 are 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 64, 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.

FKC North Gaston would be a new facility, thus, it has no historical payor mix. In Section L-7, page 68, the applicant provides the payor mix for FMC Gastonia for CY2015. FMC Gastonia will be contributing stations to develop the proposed facility and from which at least some patients will transfer (See Exhibit C-1 for letters of support from patients). The historical payor mix for FMC Gastonia illustrated as follows:

FMC GASTONIA Historical Payor Mix CY2015	
Payor Type	Percent of In-Center Patients
Medicare	66.82%
Medicaid	3.57%
Commercial Insurance	13.26%
Medicare Commercial	10.17%
Medicare/ Medicaid	0.00%
VA	2.09%
Other: Self/Indigent/Charity	4.08%
Total	100.00%

*Totals may not foot due to rounding.

As illustrated in the table above, 80.56% of FMC Gastonia’s patients were Medicare or Medicaid recipients.

In addition, the applicant describes its admission and financial policies in Section L-3, pages 66-67, 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 Gaston County, 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
Gaston	15%	52%	25%	17%	13%	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."

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ 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%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

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 66, 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 67, the applicant states there have been no civil rights access 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 65, the applicant provides the projected payor mix for FKC North Gaston for the second operating year, (CY2020). The applicant states that the projected payor mix for the proposed facility is based on the historical payor mix for FMC Gastonia. The projected payor mixes for IC, HH and PD patients are illustrated in the following table:

FKC NORTH GASTON PY2 – CY2020				
Payor Source	Percent of In-Center Patients	Percent of HH Patients	Percent of PD Patients	Percent of Total Patients
Medicare	68.82%	69.51%	69.51%	68.80%
Medicaid	3.57%	2.00%	2.00%	2.10%
Commercial Insurance	13.26%	21.82%	21.82%	14.60%
Medicare Commercial	10.17%	6.67%	6.67%	8.30%
Medicare/ Medicaid	0.00%	0.00%	0.00%	0.00%
VA	2.09%	0.00%	0.00%	2.10%
Other: Self/Indigent/Charity	4.08%	0.00%	0.00%	4.20%
Total	100.00%	100.00%	100.00%	100.00%

As illustrated in the table above, the applicant projects that 79.2% of all of the patients receiving dialysis services through FKC North Gaston 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 North Gaston. 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 67, the applicant states that patients will have access to the facility for dialysis services upon referral from nephrologists with admitting privileges at the facility. The applicant states, “*Transient patients are accepted “upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”*”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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 69, the applicant states that FKC North Gaston will be available to all health education-related education and training programs to receive instruction and to observe operations. Exhibit M-1 contains a copy of correspondence to the dean of nursing at Carolinas College of Health Services inviting the school to do clinical rotations for student nurses 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, BMA, proposes to develop a new 12-station dialysis facility in Gaston County, FKC North Gaston, by relocating 12 stations from FMC Gastonia. In addition, the applicant proposes to offer home training and support services for HH and PD patients at the proposed facility.

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

According to the July 2016 SDR, there are four dialysis facilities in Gaston County. All of the four facilities are operational, with one having been approved to relocate to another site. The applicant or its parent company owns and operates all of the four dialysis facilities in Gaston County as shown below in the table.

GASTON 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 Gastonia	BMA	Gastonia	39	89.74%
FMC South Gaston	BMA	Gastonia	20	96.25%
FMC Belmont	BMA	Belmont	18	93.06%
BMA Kings Mountain	BMA	Kings Mountain	16	82.81%
BMA Kings Mountain*	BMA	Kings Mountain	**16	0.00%

*Proposed new site consisting of existing stations. **CON issued, not certified.

As shown in the table above, all four of BMA’s operational dialysis facilities are operating above 80% utilization (3.2 patients per station). BMA Kings Mountain will relocate to a new site in Gaston County. The applicant provides 52 letters in Exhibit C-1 from in-center and home trained dialysis patients at BMA facilities Gaston County, indicating that the proposed facility, in the northern portion of Gaston County, would be closer to their homes, and therefore, more convenient.

In Section N-1, pages 70-71, 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 80% 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, D, E, G, I, K, L, N, 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 B, pages 12-13, the applicant discusses the methods it uses to insure and maintain quality. In Section O-3, pages 75-76 and in Exhibit O-3, the applicant provides a listing of and discusses three BMA dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. However, each facility is back in compliance as of the date of this decision.

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has 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 17, the applicant adequately demonstrates that FKC North Gaston will serve at least 40 in-center patients on 12 dialysis stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 83.3% ($40/12 = 3.3$; $3.3/4 = 0.833$). 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 17-19, 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.