

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 4, 2015

Findings Date: September 4, 2015

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11055-15

Facility: Fresenius Medical Care High Point

FID #: 150332

County: Guilford

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

Project: Develop a new 10-station dialysis facility by relocating 10 dialysis stations from BMA South Greensboro

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a Fresenius Medical Care (FMC) High Point (“the applicant”) proposes to develop a new 10-station dialysis facility in High Point by relocating 10 dialysis stations from BMA South Greensboro. Both facilities are located in Guilford County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant is proposing to relocate dialysis stations within Guilford County; therefore, there are no need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 38 of the 2015 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 2015 SMFP is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 32 of the 2015 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 currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. Demonstrate that the proposal shall not result in a 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*
- 2. Demonstrate that the proposal shall not result in a 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 10-station dialysis facility, FMC High Point, in Guilford County, by relocating existing Guilford County dialysis stations from BMA South Greensboro. Because both facilities are located in Guilford County, there is no change in dialysis station inventory in Guilford County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policy in the 2015 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 proposes to establish a new 10-station dialysis facility in High Point, Guilford County, by relocating 10 existing dialysis stations from BMA South Greensboro. BMA South Greensboro has been certified for 59 dialysis stations since September 28, 2004. At completion of this project, FMC High Point will be certified for 10 dialysis stations and BMA South Greensboro will be certified for 49 total dialysis stations.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

FMC High Point will be a new facility in Guilford County and therefore has no existing patient origin. Though the applicant proposes to relocate stations from BMA South Greensboro; on page 19, the applicant states that it assumes the dialysis patients who transfer to the new FMC High Point facility are a part of the Guilford County BMA ESRD patient population as a whole, as opposed to being specific patients who transfer from BMA South Greensboro.

In Section C.1, page 18, the applicant provides a table showing the projected patient origin of the patients to be served at FMC High Point for Operating Years (OY) 1 and 2 following completion of the project, as shown below. The following table includes in-center dialysis (IC) patients, home hemodialysis (HH) patients and home peritoneal dialysis (PD) patients.

Projected FMC High Point Patient Origin

County	Operating Year 1			Operating Year 2			County Patients as % of Total	
	IC	HH	PD	IC	HH	PD	OY 1	OY2
Guilford	29.9	0.0	1.0	29.8	1.0	1.0	88.5%	88.8%
Randolph	3.0	0.0	0.0	3.0	0.0	0.0	8.6%	8.4%
Davidson	1.0	0.0	0.0	1.0	0.0	0.0	2.9%	2.8%
Total	33.9	0.0	1.0	33.8	1.0	1.0	100.0%	100.0%

BMA South Greensboro is located in south-central Guilford County. High Point is located in the southwestern corner of Guilford County. Guilford County is contiguous to Davidson and Randolph counties. On page 19, the applicant states that it has letters from 46 patients residing in Guilford, Randolph and Davidson counties who express support for the project and who could be better served by dialyzing at the proposed facility. The applicant provides a table identifying the patient residence zip code and current dialysis facility of the 46 patients providing the support letters and expressing a willingness to transfer their care.

Exhibit C-1 includes letters of support from the 46 dialysis patients, stating they support the proposed project and that they live closer to the proposed FMC High Point facility. The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 22, the applicant discusses the need that the population to be served has for the proposed project, stating that an ESRD patient’s need for frequent and regular treatments necessitates that a patient is able to dialyze conveniently and in close proximity to their home. The applicant further states that the new facility in High Point will be closer and more convenient for a number of ESRD patients currently dialyzing at a BMA facility.

In Section C.5, pages 24-25, the applicant discusses the necessity to relocate stations to a new facility, stating:

“BMA is providing dialysis treatment for a large number of patients residing in southwest Guilford County, in close proximity to High Point. BMA is also providing care to several patients from Randolph and Davidson Counties who reside in close proximity to High Point.

BMA has contacted the patients who are dialyzing with BMA at one of its facilities and has asked the patients if they would consider transferring their care to the new facility. Of the patients residing in the area, 39 have signed letters of support saying they would consider transferring their care to the new facility in High Point.

As BMA considered the patient population it serves, the southwest corner of Guilford County is the only area of the county in which BMA does not have a dialysis facility, but does have patients dialyzing with BMA. Consequently, BMA has chosen to relocate stations to High Point.

The applicant provides a map on page 24 of the application which depicts the seven existing dialysis facilities in Guilford County; the BMA facility in Randolph County; and the residence location of dialysis patients currently served by BMA facilities in Guilford, Davidson and Randolph counties. The map also shows the primary and secondary sites for the proposed facility. The applicant states that the map demonstrates a significant number of patients dialyzing at existing BMA facilities, but residing closer to the proposed facility.

In Section C.1, pages 19-22, the applicant provides the assumptions and methodology it uses to determine the need for an additional dialysis facility in Guilford County and to project FMC High Point’s patient utilization. The assumptions and methodology are summarized below:

- The applicant polled its BMA Guilford County patients and determined that a significant number of BMA dialysis patients residing in southwestern Guilford County and Davidson and Randolph counties could be better served by a BMA dialysis center located in High Point. Exhibit C-1 contains support letters from 46 of these patients, expressing a willingness to transfer to the proposed facility to reduce travel time and thereby enhance quality of life. On page 19, the applicant identifies these patients, where they currently dialyze and the zip code of their residence, as follows:

BMA Patients Willing To Transfer by Zip

Current Dialysis Facility	27260	27262	27263	27265	27282	27350	27360	27370	27317	27407	Total
BMA Greensboro		1				1				4	6
BMA Northwest Greensboro				2	1					3	6
BMA South Greensboro	1										1
BMA Southwest Greensboro	9	2	1	6	5		2	1			26
BMA Asheboro									7		7
Total	10	3	1	8	6	1	2	1	7	7	46

- Based upon the 46 support letters from current BMA dialysis patients, the applicant projects 30 Guilford County dialysis patients will transfer their care to the new facility in High Point. In Section D.1, page 35, the applicant states that two patients will transfer from BMA South Greensboro.
- The project is scheduled for completion on December 31, 2016. Operating Year 1 is January 1 – December 31, 2017. Operating Year 2 is January 1 – December 31, 2018. (On page 19, the applicant erroneously listed the same dates for both operating years; however, other verbiage and the pro forma financial statements presented in Section R, demonstrate that the correct operating years are listed above.)
- The applicant assumes that the patients residing within Guilford County and transferring to the new FMC High Point facility are a part of the Guilford County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Guilford County Five Year Average Annual Change Rate of 3.0%, as published in the July 2015 Semiannual Dialysis Report (SDR).
- The applicant assumes those patients from Davidson and Randolph counties who signed letters of support for the new facility will choose to dialyze at the new FMC High Point facility. However, BMA states that it does not project any growth of this segment of the patient population.
- The applicant assumes that in each of the first two years, one in-center patient from the new FMC High Point facility will choose to dialyze at home. The assumption is that the patient will choose home hemodialysis the first year and peritoneal dialysis in the second year. The applicant states this is conservative because more than one patient may choose home dialysis each year and existing home patients could choose to transfer their care.
- The applicant assumes the initial patient population at FMC High Point will be comprised of 30 Guilford County residents, one Davidson County resident and three Randolph County residents.

Projected Utilization

In Section C.1, page 21, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Year 1, ending December 31, 2017 and Operating Year 2, ending December 31, 2018, as shown below.

FMC High Point	In-Center Dialysis
<i>BMA begins with 30 Guilford County in-center dialysis patients projected to transfer their care to the new facility upon certification of the project. This is December 31, 2016.</i>	30
<i>BMA projects growth of the census by the Guilford County Five Year Average Annual Change Rate for one year to December 31, 2017.</i>	$(30 \times .030) + 30 = 30.9$
<i>BMA subtracts one patient projected to change to home dialysis.</i>	$30.9 - 1 = 29.9$
<i>BMA adds the 4 patients from Randolph and Davidson Counties. This is the project census for the end of Operating Year 1</i>	$29.9 + 4 = 33.9$
<i>BMA again projects growth of the patients by the Guilford County Five Year Average Annual Change Rate for one year.</i>	$(29.9 \times .030) + 29.9 = 30.8$
<i>BMA subtracts one patient projected to change to home peritoneal dialysis.</i>	$30.8 - 1 = 29.8$
<i>BMA adds the 4 patients from Randolph and Davidson Counties. This is the project census for the end of Operating Year 2.</i>	$29.8 + 4 = 33.8$

As shown in the previous table, at the end of Operating Year 1, the applicant is projecting an in-center patient census at FMC High Point of 33.9 patients, which the applicant rounds down to 33, for a utilization rate of 82.5% or 3.3 patients per station (33 patients / 10 stations = 3.3 / 4 = .825). At the end of Operating Year 2, the applicant is projecting an in-center patient census of 33.8, rounded to 33, for a utilization rate of 82.5%. The projected utilization of 3.3 patients per station per week for Operating Year 1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The following table illustrates home dialysis projections of one patient at the end of Operating Year 1 and two patients at the end of Operating Year 2, based on the applicant's assumptions.

FMC High Point	Home Dialysis
BMA begins with the zero home dialysis patients projected to transfer their care to the new facility upon certification of the project. This is June 30, 2016.	0
BMA adds one patient projected to change to home hemo dialysis. This is the projected ending census for Operating Year 1, December 31, 2017.	$0 + 1 = 1$
BMA projects growth of patients by the Guilford County Five Year Average Annual Change Rate for one year.	$(1 \times .030) + 1 = 1.03$
BMA adds one patient projected to change to peritoneal dialysis. This is the projected ending census for Operating Year 2, December 31, 2018.	$1.03 + 1 = 2.03$

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, pages 22-23, the applicant states:

Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

The applicant states that the patient population of the proposed facility is expected to be comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC High Point	19%	33%	60%	50%	60%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 60% of the facility treatment reimbursement is from Medicare.

The applicant states that the above projections are based on census facts for Guilford, Randolph and Davidson counties; additional factors related to the facilities where the patients are currently dialyzing; and BMA experience in Randolph and Guilford counties.

The applicant further states that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of dialysis treatments in BMA facilities in fiscal year 2014. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by BMA and that the facility will conform with all codes and standards for handicapped access.

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

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, 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 relocate ten existing certified dialysis stations from its BMA South Greensboro facility in Guilford County to develop a new, 10-station dialysis facility, FMC High Point, also in Guilford County. In Section C.13, pages 31-32, the applicant states that BMA South Greensboro has operated below 80% utilization for the most recent five year period. The July 2015 SDR shows BMA South Greensboro with 59 stations and a utilization rate of 77.12% as of December 31, 2014.

In Section D, pages 35-36, the applicant discusses how the needs of dialysis patients at BMA South Greensboro will continue to be met after the relocation of stations to the proposed FMC High Point dialysis facility. The applicant states that the development of the proposed facility results in the following changes to the BMA South Greensboro.

	Current Stations	Stations to be Relocated	Stations Remaining	Transferring Patients
BMA South Greensboro	59	10	49	2

The applicant states the relocation of stations and transfer of patients is projected to occur on December 31, 2016.

On page 35 of the application, the applicant provides the assumptions used to project BMA South Greensboro's utilization on December 31, 2016. The assumptions are summarized below:

- BMA will project the patient population of BMA South Greensboro forward for 18 months from June 30, 2015.
- BMA South Greensboro's census was 178 patients on June 30, 2015 and was comprised of 171 Guilford County patients and 7 patients from outside Guilford County.
- The applicant projects growth of the Guilford County patient population using the 3% Guilford County Five Year Average Annual Change Rate as published in the July 2015 SDR.
- The applicant assumes the 7 patients from outside Guilford County are dialyzing at BMA South Greensboro as a function of patient choice and does not project an increase in the patient population.
- The applicant states that it expects two patients to transfer from BMA South Greensboro to FMC High Point.

Based on the above assumptions, the projected utilization at BMA South Greensboro is as follows:

(a.)	BMA begins with the 171 Guilford County dialysis patients at BMA South Greensboro as of June 30, 2015. (59 stations)	171
(b.)	BMA projects this population forward for 6 months to December 31, 2015, using one half the Guilford County five Year Average Annual Change Rate. (3%)	$[171 \times (.5 \times 0.030)] + 171 = 173.6$
(c.)	BMA projects this population forward for 12 months to December 31, 2016, the projected date of certification of this project.	$(173.6 \times .030) + 173.6 = 178.8$
(d.)	BMA subtracts 2 patients expected to transfer their care to the new FMC High Point facility upon certification.	$178.8 - 2 = 176.8$
(e.)	BMA adds the 7 patients residing outside of Guilford County. This is the projected patient census for December 31, 2016, the date this project is planned for certification (49 stations)	$176.8 + 7 = 183.8$

Note: the applicant's projection as presented on page 36 is incorrectly calculated beginning in row (c.) where the applicant's calculation results in 176.2 patients, instead of 178.8 and is carried through row (e.) with a total of 181.2 patients, instead of 183.8, resulting in a more conservative projection by the applicant.

Thus, as of December 31, 2016, following the relocation of stations and transfer of patients, BMA of South Greensboro is projected to have 183.8 patients, rounded down to 183, and 49 stations, which is a utilization rate of 93.3% ($183 \text{ patients} / 49 \text{ stations} = 3.73 / 4 = 0.933$).

On page 36, the applicant states:

“Using the calculations from the above discussions, BMA notes that BMA South Greensboro is projected to be at or above 80% utilization on December 31, 2016. Thus, the facility would qualify for application of the Facility Need Expansion methodology in the July 2016 SDR; applications arising from that SDR will be due on September 15, 2017.”

The applicant demonstrates that the needs of the population presently served at BMA South Greensboro will continue to be adequately met following the proposed relocation of ten dialysis stations from BMA South Greensboro to FMC High Point 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, pages 37-38, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo - the applicant states that this option ignores the patient population dialyzing with BMA and residing in or near High Point.
- 2) Development of the new facility in another area of Guilford County - BMA states that it evaluated its existing patient populations and projections of future patient populations and determined the BMA patient population in the High Point area could be better served by a new facility in that area.
- 3) The development of a larger facility with more in-center dialysis stations - BMA determined the proposed facility size is optimal for the need demonstrated for its patients in and near High Point at this time.
- 4) Relocation of stations into existing BMA facilities in Guilford County -the applicant states that an application of this nature ignores the patients dialyzing with BMA but residing in or near High Point.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served at the High Point facility, and the physical plant capacity issues, BMA believes developing the new FMC High Point facility, is the most effective alternative.

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 this 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 Medical Care High Point 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 Medical Care High Point shall relocate no more than 10 dialysis stations from BMA South Greensboro.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care High Point shall install plumbing and electrical wiring through the walls for no more than 10 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 10 dialysis stations at BMA South Greensboro for a total of no more than 49 dialysis stations at BMA South Greensboro upon project completion.**
5. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care High Point 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

In the table in Section F.1, page 40, the applicant shows the capital cost of the project as summarized in the following table:

Project Capital Costs

Construction Contract	\$ 797,355
Water Treatment Equipment	\$ 203,873
Equipment/Furniture	\$ 212,548
Architect & Engineering Fees	\$ 71,762
Other: Contingency	\$ 60,838
Total Capital Cost	\$ 1,346,376

Totals may not sum due to rounding.

In Section F.10, pages 43-45, the applicant discusses FMC High Point's working capital needs. The applicant states that start-up expenses are estimated at \$160,988, comprised of four weeks of clinical supplies at \$7,337 and salaries of \$153,650. The applicant further states:

“Clinical supply amount is derived by dividing the annual clinical supply cost (Form A, Medical Supplies) by 13, resulting in an estimate of four weeks supply.”

A table detailing the projected staffing start-up expenses appears on page 44. Because the applicant expects clinical staff to transfer from existing BMA facilities, staff training should be minimal; however, to be conservative, BMA projects startup expenses as if the direct patient care positions are new positions. Other staff salaries anticipated, i.e., the social worker, dietitian, and technical staff, will be shared FTEs with other BMA facilities in the area. The clerical position is expected to be a new hire, but will require only a two-week training period. The applicant also allows an additional expense for PRN staff during the transition.

In Section F.10, pages 43-44, the applicant estimates the initial operating period at eight months and initial operating expenses at \$1,995,283 for a total working capital need of \$2,156,271, when added to the total start up expense of \$160,988 as listed on page 43.

In Section F.5, page 41, the applicant states, “*BMA is utilizing accumulated reserves to finance this project.*” The applicant further states:

“Please refer to Exhibit F-1 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc. This letter will verify the availability of the FMC funds necessary for the project.”

Exhibit 24 contains a July 15, 2015 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states,

“BMA is submitting a Certificate of Need Application to develop a new 10 station dialysis facility, Fresenius Medical Care High Point, and relocation of dialysis stations from BMA South Greensboro within Guilford County. The project calls for the following capital expenditure:

Capital Expenditure \$ 1,346,376

As Vice President, I am authorized and do hereby authorize the development of this new Fresenius Medical Care High Point, and relocation of dialysis stations from BMA South Greensboro for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$1,346,376 as may be needed for this project. I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location.”

In F.8, page 43, the applicant states:

“This application will not interfere with the financing of any other projects currently filed, or being filed by BMA. The amount shown in the financial statements is more than adequate to finance all CON projects proposed, and under development.”

In Section F.7, page 42, the applicant refers to Exhibit F-2 for a copy of the most recent audited FMC Holdings, Inc, financial statements (years ended December 31, 2014 and 2013). As of December 31, 2014, Fresenius Medical Care Holdings, Inc. and Subsidiaries had \$195,280,000 in cash and cash equivalents with \$18,507,042,000 in total assets and \$8,428,400,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section R, Form C, pages 98-101, the applicant provides its total charge per treatment (before deductions or contractual adjustments) for each payment source.

The applicant provides the following assumptions for patient treatments:

- Treatments = Patients (rounded down) x 3 treatments per week x 52 weeks
- Missed Treatments for In-center patients = 5%
- A single patient converts to home hemodialysis in the first year of the project
- A single patient converts to home peritoneal dialysis in the second year of the project

Calculations performed on Form B as presented in Section R, page 97, show the following contractual adjustment percentages:

	Operating Yr 1	Operating Yr 2
Medicare	94.01%	94.01%
Medicaid	96.48%	96.48%
Commercial Insurance	64.27%	64.27%

Furthermore, Form B projects charity care and bad debt in the first two years of operation as follows:

	Operating Yr 1	Operating Yr 2
Charity Care as a % of Net Income	6.69%	6.77%
Bad Debt as a % of Net Income	12.76%	13.77%

The applicant projects revenues in Section R, Form B, page 97, and operating expenses in Section R, Form A, page 94, as summarized in the table below:

FMC High Point	Operating Year 1 1/1/17-12/31/17	Operating Year 2 1/1/18-12/31/18
Total Net Revenue	\$ 5,621,133	\$ 5,617,123
Total Operating Expenses	\$ 3,072,400	\$ 3,100,299
Net Profit	\$ 2,548,733	\$ 2,516,824

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. A careful analysis of Forms B and C shows that the applicant erroneously included the OY1 home-hemodialysis Medicare revenue twice, which overstates the OY1 gross patient revenue by \$295,112. This amounts to a 1.49% overstatement of total gross patient revenue in OY1 and has no effect on OY2; therefore it is insignificant and of no consequence. The applicant's projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

In Section H.1, pages 56-57, the applicant provides projected staffing and salaries. Form A in Section R, page 94, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs. 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

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to develop a new 10-station dialysis facility, FMC High Point, in Guilford County, by relocating ten existing dialysis stations from BMA South Greensboro, also located in Guilford County. The July 2015 SDR indicates there are seven dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	74.11%	2.96
BMA of South Greensboro (BMA)	59	77.12%	3.08
BMA of Southwest Greensboro (BMA)	31	81.45%	3.26
FMC of East Greensboro (BMA)	35	75.00%	3.00
High Point Kidney Center (WFUHS)*	42	84.52%	3.38
Northwest Greensboro Kidney Center (BMA)**	25	87.00%	3.48
Triad Dialysis Center (WFUHS)	22	79.55%	3.18

Source: July 2015 SDR, Table A.

*Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Point Kidney Center upon project completion.

**Approved to add eight stations for a total of 33 stations upon completion of Project ID #G-10338-14; Stations were certified as of June 29, 2015.

As illustrated above, the applicant operates five of the seven dialysis facilities in Guilford County. Wake Forest University Health Sciences operates the other two Guilford County dialysis facilities. All of the Guilford County dialysis facilities are reasonably well-utilized, operating at or above 74% utilization or approximately three patients per station. The applicant provides a map in Section G.2, page 53, which it states illustrates that the existing Guilford County facilities are widely dispersed across the county. The applicant states that the map on page 54 depicts the residence location of the patients dialyzing with BMA at its facilities within Guilford County, not the patients served by High Point Kidney Center or Triad Dialysis Center. The applicant further states:

“Development of any new dialysis facility in Guilford County will necessarily be within a few miles, or closer, to another dialysis facility. However, based upon patient-physician relationships and nephrology physician admitting privileges, development of the FMC High Point facility will not impact the High Point Kidney Center or the Triad Dialysis Center.

...

One could question the ability of the patients to transfer to the existing provider in High Point. BMA notes that the nephrology physicians of Carolina Kidney Associates do not have admitting privileges at the existing dialysis facility in High Point. Without admitting privileges, they can not refer patients to that facility.

...

Those patients dialyzing with BMA, residing in, or near to High Point, and being followed by the nephrology physicians of Carolina Kidney Associates, need a dialysis facility in High Point.”

BMA is not adding dialysis stations in Guilford County, rather it is relocating stations from an existing Guilford County facility, BMA South Greensboro. In Exhibit C-1, the applicant provides letters from 46 dialysis patients currently receiving care at BMA dialysis facilities who have indicated that the proposed FMC High Point facility would be more convenient for them and closer to their residence.

In Section C.1, page 18, the applicant demonstrates that FMC High Point will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5% ($33/10 = 3.3$; $3.3/4 = 0.825$) The applicant states that the projected utilization rates are based entirely on patients currently served at BMA dialysis facilities who have expressed their willingness to consider transferring to the proposed FMC High Point facility because it will be more convenient for them.

The applicant adequately demonstrates the need to relocate BMA stations to develop a new dialysis facility in Guilford County based on the number of and geographical location of the BMA in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Guilford County. 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

The following table illustrates the projected staffing for FMC High Point, as provided by the applicant in Section H.1, page 56. The table provided by the applicant erroneously shows the total FTE positions as 1.50. The correct total is 10.11 FTE positions.

Position	Projected # of FTEs
Medical Director*	
RN	1.50
Technician	4.50
Clinical Manager	1.00
Administration – FMC Director of Operations	0.15
Dietitian	0.33
Social Worker	0.33
Home Training Nurse	0.50
Chief Technician	0.15
Equipment Technician	0.50
In-Service	0.15
Clerical	1.00
Total	10.11

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

The following table shows the applicant’s projected number of direct care staff FTEs at FMC High Point for Operating Year 2, per page 59.

Projected Direct Care Staff Hours – Operating Year 2

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]
RN	1.5	2,080	3,120	3,120	1.0
Patient Care Tech	4.5	2,080	9,360	3,120	3.0
Total	6.0	2,080	12,480	3,120	4.0

* FTEs should match the direct care Total FTE Positions [a+c] listed in the Facility Staffing table in Section H, Question 1.

** Total annual hours of operation from the Proposed Hours of Operation table in Section H, Question 6.

In Section H.1, page 57, the applicant states that the Medical Director for FMC High Point will not an employee of the facility. In Section I.3, page 61, the applicant states that Dr. Michael Mattingly is the proposed Medical Director for the facility. In Exhibit I-6, the applicant provides a letter dated July 13, 2015, signed by Dr. Mattingly of Carolina Kidney Associates, P.A. confirming his commitment to serve as Medical Director. Exhibit I-7 contains Dr. Mattingly’s curriculum vitae. In Section H.3, page 57, the applicant states, “*BMA anticipates no difficulties in filling staff positions.*” In Section I.3, page 62, the applicant lists nine nephrologists who will provide medical coverage at the proposed facility.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of 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, pages 60-63, the applicant discusses the providers of the necessary ancillary and support services to be provided for the proposed facility and provides a list of service providers on page 60. The applicant discusses coordination with the existing health care system on pages 61-62. Exhibits I-3, I-4 and I-5 contain documents from Spectra Labs, Cone Health and Duke Medicine, respectively, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and the Exhibits mentioned above is reasonable and supports a finding of conformity with 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 67, the applicant states there is 3,204 square feet of treatment area, which includes home training and isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts a 7,728 square foot facility, with eight main floor dialysis stations, an isolation dialysis station, and a home hemodialysis station, for a total of 10 stations. In Section F.1, page 40, the applicant lists its project costs, including \$797,355 for construction, \$549,021 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,346,376. In Section K.1, pages 65-66, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.
- HVAC system operating efficiency "will equal current industry standards for high seasonal efficiency." In addition, the system will be controlled via 7 day/24 hour set back time clock.
- Energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches and external insulation wrap for hot water heaters will be used for energy and water conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 40-51, and in Section R proforma financial statements. 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, pages 72-73, the applicant states that Fresenius Medical Care Holdings, Inc., parent company to BMA, currently operates 100¹ dialysis facilities in 42 North Carolina counties (including affiliations with Renal Research Institute facilities). The applicant further states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

The applicant states that BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. The applicant further states in Section C.3, page 23, that Medicare and Medicaid represented 82.54% and 4.63%, respectively, of North Carolina dialysis treatments in BMA facilities in FY 2014.

In Section L.7, page 76, the applicant reports that as of December 31, 2014, 90.4% of the patients who were receiving treatments at BMA South Greensboro had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment source for BMA of South Greensboro.

¹Section C.3, page 22, states that BMA currently operates 102 dialysis facilities in North Carolina counties.

HISTORICAL PAYOR MIX

SOURCE OF PAYMENT	BMA South Greensboro
Private Pay	0.4%
Commercial Insurance	5.5%
Medicare	88.7%
Medicaid	1.7%
VA	3.7%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Guilford, Randolph, and Davidson counties and statewide.

County	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Guilford	15.3%	5.9%	19.5%
Randolph	18.6%	7.2%	19.5%
Davidson	17.2%	6.9%	18.4%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).²

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.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: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.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 applicants;

C

In Section L.3(e) page 74, the applicant states,

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

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 75, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.”*

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 C.3, page 23, the applicant states that the patient population of the FMC High Point facility is expected to be comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
FMC High Point	19%	33%	60%	50%	60%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say that 60% of the facility treatment reimbursement is from Medicare.

In Section L.3(c), page 74, the applicant states,

“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

On page 73, the applicant reports that it expects over 87.95% of the in-center patients who receive treatments at FMC High Point to have all or part of their services paid for by Medicare or Medicaid, as indicated below.

**FMC High Point
Projected Payor Mix Project Year 2**

Payor Source	In-Center	Home PD	Home-hemo
Private Pay	1.36%	0.00%	0.00%
Commercial Insurance	7.50%	0.00%	0.00%
Medicare	84.10%	100.00%	100.00%
Medicaid	3.85%	0.00%	0.00%
VA	3.18%	0.00%	0.00%
TOTAL	100.00%	100.00%	100.00%

Totals may not sum due to rounding.

On page 73, the applicant states:

“BMA has assumed that the payor mix for the FMC High Point facility will essentially mirror the average payor mix at BMA facilities in Guilford County. BMA is serving 640 of the 886 Guilford County ESRD residents at its facilities in the county. All of the patients projected to transfer to this facility are currently dialyzing with BMA at one of the BMA facilities in either Guilford or Randolph Counties. Based upon service to such a large segment of the Guilford County ESRD patient population BMA believes that it is reasonable to expect the future payor mix at FMC High Point to resemble the average of BMA facilities in Guilford County.”

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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 75, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC High Point will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.

Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility.

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, page 77, the applicant states:

"All health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. This experience enhances the clinical experience of the students enrolled in these programs enabling them to learn about the disease, prognosis and treatment for the patient with end stage renal disease.

...

Exhibit M-1 contains a letter to the Dean of UNC Greensboro Nursing School encouraging the school to include the FMC High Point facility in their clinical rotations for nursing students."

Exhibit M-1 contains a copy of a letter from Fresenius Medical Care to the Dean of University of North Carolina at Greensboro inviting the college to include FMC High Point in the clinical rotation for its nursing students. The information provided in Section M is reasonable and supports a finding of conformity with 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

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to develop a new 10-station dialysis facility, FMC High Point, in Guilford County, by relocating ten existing dialysis stations from BMA South Greensboro, also located in Guilford County. The July 2015 SDR indicates there are seven dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/14	Percent Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	74.11%	2.96
BMA of South Greensboro (BMA)	59	77.12%	3.08
BMA of Southwest Greensboro (BMA)	31	81.45%	3.26
FMC of East Greensboro (BMA)	35	75.00%	3.00
High Point Kidney Center (WFUHS)*	42	84.52%	3.38
Northwest Greensboro Kidney Center (BMA)**	25	87.00%	3.48
Triad Dialysis Center (WFUHS)	22	79.55%	3.18

Source: July 2015 SDR, Table A.

*Approved to relocate 10 stations to North Randolph Dialysis Center in Randolph County in Project ID #G-10262-14, leaving a total of 32 stations at High Pint Kidney Center upon project completion.

**Approved to add eight stations for a total of 33 stations upon completion of Project ID #G-10338-14; Stations were certified as of June 29, 2015.

As illustrated above, the applicant operates five of the seven dialysis facilities in Guilford County. Wake Forest University Health Sciences operates the other two Guilford County dialysis facilities. All of the Guilford County dialysis facilities are reasonably well-utilized, operating at or above 74% utilization or approximately three patients per station.

In Section N.1, pages 78-79, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA does not expect this proposal to have effect on the competitive climate in Guilford County. BMA does not project to serve dialysis patients currently being served by another provider.

...

BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who are already choosing dialysis at a BMA facility.

...

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 91% of the In-center patients will be relying upon government payors (Medicare / Medicaid / VA). The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. 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 C, F, G, H, L and P 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 BMA will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates BMA will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (6) 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 Section O, pages 80-84, the applicant discusses the methods it uses to insure and maintain quality. In Section C.3, page 84, the applicant states:

“BMA has incurred one Immediate Jeopardy citation within the recent 18 month period.”

The applicant further states:

“A Plan of Correction was provided to the Surveyor, and the Immediate Jeopardy [sic] was removed before implementation by CMS. The facility is back in full compliance.”

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company.

Based on a review of this 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 application is conforming or conditionally conforming to all applicable criteria, as discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) *An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

.2202(a)(1) Utilization rates;

- C- In Section P, page 86, and Exhibit G-1 (copy of the July 2015 SDR, Tables A and B), the applicant provides the utilization rates for BMA South Greensboro. The December 31, 2014 utilization is 77.12% with 182 patients dialyzing on 59 stations.

.2202(a)(2) Mortality rates;

- C- In Section P, page 86, the applicant states, “*The CMS Compare web site reports that the South Greensboro mortality rates are, “As Expected.” See Exhibit P-1.*”

.2202(a)(3) The number of patients that are home-trained and the number of patients on home dialysis;

- C- In Section P, page 86, the applicant states that BMA South Greensboro is not certified to provide home dialysis services.

.2202(a)(4) The number of transplants performed or referred;

- C- In Section P, page 86, the applicant reports that BMA South Greensboro referred 44 patients for transplant evaluation in 2014.

.2202(a)(5) The number of patients currently on the transplant waiting list;

- C- In Section P, page 86, the applicant states that BMA South Greensboro has 15 patients on the transplant waiting list.

.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

- C- In Section P, page 87, the applicant reports a total of 259 hospital admissions in 2014 for BMA South Greensboro; none were dialysis related.

.2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

- C- In Section P, page 87, the applicant reports that BMA South Greensboro does not have any patients with infectious disease, e.g. hepatitis and there were no conversions to infectious status during the last calendar year.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in*

an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).

- C- Exhibit I-4 contains a copy of a letter, dated July 14, 2015, and signed by the Director of Nursing and Patient Services at Cone Health, which states the hospital's intention to enter into an agreement with FMC High Point to provide a range of services to patients receiving dialysis care at the facility. A listing of services to be provided by Cone Health is included in the letter.

.2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- C- The applicant states that a signed written agreement with a transplantation center is included at Exhibit I-5. Exhibit I-5 contains an agreement from Duke Transplant Center to provide transplantation services to the proposed facility.

.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

- C- Exhibits K-5 and K-6 contain documentation of power and water at the primary and secondary sites in.

.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

- C- Exhibit K-3 contains written policies and procedures for back up electrical service in the event of a power outage.

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-C- In Section K.4(c), page 68, the applicant states that its primary site is located at 1628 S. Main Street, High Point. Exhibit K-5 also identifies the primary site address as 1628 S. Main Street. It appears that Section A.8(b), page 4, erroneously identifies the the primary site address as 1328 S. Main Street. The applicant states that BMA will work with the developer and diligently pursue the primary site subsequent to CON approval. In Section K.6, page 70, the applicant states that the secondary site is located at 213 N. Lindsay Street in High Point. Exhibits K-5 and K-6 contain information on the availability of each site, respectively.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- The applicant states, in Section P, page 88, that BMA of North Carolina “provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements.” See also Section B.4 and B.5, pages 11-17; Section C.3, page 23; Section H.2, page 57; Section K.1 (6), page 67; and Exhibits K-2 and K-3.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section C.1, page 18, the applicant provides projected patient origin by county for FMC High Point, based on the patients that are expected to transfer from the existing BMA Guilford County facilities. The applicant’s assumptions and methodology for its projections are provided on pages 19-22 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section C.4, page 23, the applicant states, “BMA reasonably expects that most patients of the facility will travel less than 10 miles, and all patients will travel less than 30 miles.” In addition, the applicant provides a map on page 24, which shows Guilford County; the proposed FMC High Point facility and a 30-mile radius; other Guilford County dialysis facilities; and the residence locations of BMA dialysis patients, including those patients who signed support letters indicating their

willingness to transfer to the proposed facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section P, page 89, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

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 P, page 89, the applicant states:

“BMA has documented its projection of 32 patients to transfer their care to the new facility after certification of the stations. Thus, BMA begins the project with 3.2 patients per stations [sic] per week at the beginning of the first operating year of the facility. Following opening, BMA does not anticipate that the patient census will decline, ...”

In Section C.1, pages 18-22, the applicant documents the need for the project and demonstrates that it will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5%. 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 not 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. The applicant is seeking to develop a new 10-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 18-22, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) Diagnostic and evaluation services;

- C- In Section P, page 89, and Section I.1, page 60, the applicant states that diagnostic and evaluation services will be referred to Cone Health. Exhibit I-4 contains a letter from the Director of Nursing and Patient Services at Cone Health documenting their intention to provide the above services to the proposed facility.

.2204(2) Maintenance dialysis;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states BMA will provide in-center dialysis maintenance at the proposed facility.

.2204(3) Accessible self-care training;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states candidates for self-care are referred to the facility home training department. In Section P, the applicant further states, “*Upon completion of the training, the patient will perform self-care dialysis at the facility.*”

.2204(4) Accessible follow-up program for support of patients dialyzing at home;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states the proposed facility will provide follow-up services to its patients upon certification of the program.

.2204(5) X-ray services;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states that x-ray services will be referred to Cone Health. Exhibit I-4 contains a letter from the Director of Nursing and Patient Services at Cone Health documenting their intention to provide the above services to the proposed facility.

.2204(6) Laboratory services;

- C- Laboratory services will be provided on-site by the applicant through a contract with

Spectra Labs, as stated by the applicant in Section P, page 90, and Section I.1, page 60. Exhibit I-3 contains a letter from the Vice President at Spectra Laboratories and an agreement documenting their intention to provide the above services to the proposed facility.

.2204(7) Blood bank services;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states that blood bank services will be referred to Cone Health. Exhibit I-4 contains a letter from the Director of Nursing and Patient Services at Cone Health documenting their intention to provide the above services to the proposed facility.

.2204(8) Emergency care;

- C- The applicant states, in Section P, page 90, and Section I.1, page 60, that facility staff will provide emergency care on site until emergency responders arrive and that a fully stocked 'crash cart' will be available for use at the proposed facility. Patients in need of emergency care at a hospital are transported via emergency services. Exhibit I-4 contains a letter from the Director of Nursing and Patient Services at Cone Health documenting their intention to provide emergency room care to patients of the proposed facility.

.2204(9) Acute dialysis in an acute care setting;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states that acute dialysis services will be referred to Cone Health. Exhibit I-4 contains a letter from the Director of Nursing and Patient Services at Cone Health documenting their intention to provide the above services to the proposed facility.

.2204(10) Vascular surgery for dialysis treatment patients;

- C- In Section P, page 90, and Section I.1, page 60, the applicant states that vascular surgery patients will be referred to Vascular Vein Specialists of Greensboro.

.2204(11) Transplantation services;

- C- In Section P, page 91, and Section I.1, page 60, the applicant states that transplantation services will be referred to Duke University Medical Center. Exhibit I-5 contains a letter from Duke Medicine's Director of Quality, Compliance and Finance and an agreement, documenting their intention to provide transplantation services to the proposed facility.

.2204(12) Vocational rehabilitation counseling and services; and

- C- Vocational rehabilitation counseling and services will be provided by the North

Carolina Division of Vocational Rehabilitation Services at the Greensboro Vocational Rehabilitation Office, as stated by the applicant in Section P, page 91, and Section I.1, page 60.

.2204(13) Transportation

- C- In Section P, page 91, and Section I.1, page 60, the applicant states that transportation services will be provided by Specialized Community Area Transit or Piedmont Authority Regional Transportation.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).

- C- In Section H.1, page 56, the applicant provides a proposed staffing chart. In Section H.2, page 57, the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

- C- In Section P, page 91, the applicant discusses the required training for staff and states that training at BMA facilities is continually updated by the In-Service Instructor and Director of Nursing. In Section H.4, page 57, the applicant further discusses its ongoing training program. Exhibit H-1 contains the FMC Training Program Outline and Exhibit H-2 contains an outline of FMC's continuing education programs, annual training requirements and a training module content summary.