

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 18, 2013  
PROJECT ANALYST: Bernetta Thorne-Williams  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: L-10177-13 / Bio-Medical Applications of North Carolina d/b/a FMC South Rocky Mount / Develop a new 12-station dialysis facility in Rocky Mount by relocating 12 existing dialysis stations from BMA Rocky Mount / Nash County

### 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 FMC South Rocky Mount, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to establish a new 12-station dialysis facility to provide in-center hemodialysis, home training for peritoneal dialysis and home hemo-dialysis, to be located at 1680 S. Wesleyan Boulevard in Rocky Mount, Nash County. The 12 station facility would consist of 10 dialysis stations on the treatment floor, one isolation station and one station dedicated to home hemo-dialysis training and support. The applicant proposes to relocate 12 existing dialysis stations from BMA Rocky Mount. BMA Rocky Mount is currently licensed for 42 certified dialysis stations with the proposed relocation of 12 stations to FMC South Rocky Mount; BMA Rocky Mount would have 30 certified dialysis stations upon project completion.

BMA will own the dialysis stations proposed in this application, and an unaffiliated property developer will purchase the land and develop the building. BMA will lease the building from the developer. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. The applicant states that the proposed in-county relocation of existing dialysis stations will enhance geographical accessibility of dialysis services in south Rocky Mount. This project is scheduled for completion on December 31,

2014. In this application, the applicant proposes to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2013 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because neither need methodology is applicable to the review. However, Policy ESRD-2 is applicable to this review. Policy ESRD-2 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 shall:*

- (A) 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*
- (B) 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.”*

In summary, the applicant proposes to relocate 12 certified dialysis stations within Nash County in order to develop a new 12-station dialysis facility. Consequently, there is no change in the ESRD inventory in Nash County, therefore the application is consistent with Policy ESRD-2 of the 2013 SMFP and 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, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Rocky Mount proposes to relocate 12 dialysis stations from BMA Rocky Mount to establish a new 12-station dialysis facility to provide in-center dialysis, home training for home hemo-dialysis and peritoneal dialysis in Nash County. The 12 station facility would consist of 10 dialysis stations on the treatment floor, one isolation station and one station dedicated to home hemo-dialysis training and support. In Section III.3(b), pages 46-47, the applicant states that FMC South Rocky Mount is projected to serve 41 patients at the end of the first year of operations. The proposed project is scheduled to be completed by December 31, 2014. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

### Population to be Served

In Section III.7, page 58, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

County	Operating Year 1			Operating Year 2			County Patients as a % of Total	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Nash	40.8	29.4	5.2	41.7	30.0	5.4	100.0%	100.0%
Total	41	29	5	42	30	5	100.0%	100.0%

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.3, page 46, the applicant states the proposed project is designed to make more effective use of existing certified dialysis stations in Rocky Mount and to ensure those patients residing in south Rocky Mount have access to ESRD services closer to their homes. The applicant further states on page 46 that the primary purpose for the proposed new facility is geographic accessibility and patient convenience. Further on page 46, the applicant states:

*“Geographic accessibility is not always a function of distance traveled or the amount of time a patient may spend commuting for dialysis treatment; it should also consider patient convenience. Relocation of these 12 stations to FMC South Rocky Mount would create a much more accessible facility for the patients of south Rocky Mount and Nash County ...”*

The applicant proposes to relocate 12 certified dialysis stations from an existing facility in Nash County to develop a new facility in the same county. The applicant projects the relocated stations will be utilized at 85.4% by the end of the first year of operation [41 patients / 12 stations = 3.41; 3.4 / 4 = .0854 or 85.4%].

In Section II, page 11 and Section III, page 55, the applicant states that BMA plans to transfer the entire home training program from its BMA Rocky Mount facility to the proposed new FMC South Rocky Mount facility. Thus, the applicant projects that all of the peritoneal dialysis patients and home hemo-dialysis patients currently utilizing BMA Rocky Mount will transfer to FMC South Rocky Mount.

In Section III.7, pages 54-58, the applicant provides its methodology and assumptions for projecting to serve 42 in-center patients by the end of the second year of operation. The applicant states:

“Assumptions

1. *The project is scheduled for completion December 31, 2014.  
Operating Year 1: January 1, 2015 through December 31, 2015.  
Operating Year 2: January 1, 2016 through December 31, 2016.*
2. *BMA is serving the overwhelming majority of Nash County dialysis patients at its facilities in Nash County. The July 2013 SDR, Table A identifies two dialysis facilities within Nash County. BMA operates both of these facilities.*
3. *BMA also operates the BMA East Rocky Mount dialysis facility, within Edgecombe County but within the city limits of Rocky Mount (Rocky Mount straddles the county line). The straight line distance between BMA Rocky Mount and BMA East Rocky Mount is less than five miles. The BMA East Rocky Mount facility is also serving a large number of Nash County dialysis patients.*
4. *BMA assumes that the patient population of FMC South Rocky Mount will be comprised of patients from Nash County. BMA will not deny access to patients from other counties, but for purposes of this application, BMA proposes to serve exclusively Nash County patients. ...*
5. *BMA does **not** assume that the patient population of Nash County will grow at the Nash County Five Year Average Annual Change Rate as published in the July 2013 SDR. Rather, BMA will use a much more conservative growth rate of 2.1%.*

*The growth rate as published within the SDR is suspect. The DHSR Medical Facilities Planning Section has developed this SDR using provider self reported information. This was the first time the SDR was prepared in such a manner. ... Unfortunately, the BMA Rocky Mount and BMA East Rocky Mount facilities erred in preparation of the self reported data. Rather than provide the county of residence for all patients, the facilities actually reported all patients as residing in the County of the dialysis facility. Consequently, while the information in Table A of the SDR is correct, the information in Table B contains errors.*

*BMA has brought the errors to the attention of the Division of Health Service Regulation and all other dialysis providers currently operating in North Carolina.  
...*

6. *...BMA will utilize a growth factor of 2.1% ... BMA has calculated a Five Year Average Annual Change Rate for Nash County using the more correct data from the BMA Rocky Mount and BMA East Rocky Mount facilities. ...*
7. *BMA is planning to transfer the home training program at BMA Rocky Mount to the new facility. Thus, BMA assumes that all of the peritoneal dialysis patients and home hemo-dialysis patients receiving their care through BMA Rocky Mount*

*will transfer to the new facility upon completion of the project. BMA will project growth of this patient population at the same rate as the in-center patient population ...”*

The applicant provides its three step methodology for in-center patient utilization in Section III.7, pages 55-57 and its five step methodology for its peritoneal and home hemo-dialysis, as summarized in the tables below:

**Methodology for In-Center Patients**

<i>BMA begins with the 40 Nash County in-center dialysis patients currently served and projected to transfer to the new facility upon certification of the project. This projection begins from the first day of Operating Year 1, January 1, 2015.</i>	<i>40 in-Center patients</i>
<i>BMA projects this patient population forward for 12 months to December 31, 2015 using a growth rate of 2.1% ... This is the end of Operating Year 1.</i>	$(40 \times .021) + 40 = 40.8$
<i>BMA projects this in-center patient population forward for 12 months to December 31, 2016. This is the end of Operating Year 2.</i>	$(40.8 \times .021) + 40.8 = 41.7$

*“BMA projects the home patient population in similar manner. However, inasmuch as BMA is proposing a total relocation of the home dialysis program ... BMA will demonstrate growth of the home patient population from September 1, 2013 (beginning of review period for this CON Application).”*

**Methodology for Peritoneal and Home Hemo-Dialysis Patients**

	<i>Peritoneal Dialysis</i>	<i>Home Hemo-Dialysis</i>
<i>Home patient population as of August 2013</i>	28	5
<i>BMA projects this population forward for 4 months (begins with September 2013) to December 31, 2013 using a growth rate of 2.1%.</i>	$[28 \times (.021 / 12 \times 4)] + 28 = 28.20$	$[5 \times (.021 / 12 \times 4)] + 5 = 5.04$
<i>BMA projects this population forward for 12 months to December 31, 2014. This is the projected certification date of this project.</i>	$(28.2 \times .021) + 28.2 = 28.79$	$(5.04 \times .021) + 5.04 = 5.14$
<i>BMA projects this population forward for 12 months to December 31, 2015. This is the end of Operating Year 1.</i>	$(28.79 \times .021) + 28.79 = 29.39$	$(5.14 \times 0.21) + 5.14 = 5.25$
<i>BMA projects this population forward for 12 months to December 31, 2016. This is the end of Operating Year 2.</i>	$(29.39 \times .021) + 29.39 = 30.01$	$(5.25 \times .021) + 5.25 = 5.36$

The applicant projects to serve 41 in-center patients or 3.4 patients per station by the end of Year 1 and 42 in-center patients or 3.5 patients per station by the end of Year 2 for the proposed 12-station facility. This exceeds the minimum 3.2 patients per station per week as of the end of the

first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

In Section II.7, page 18 and Section III.7, page 58, the applicant states that the entire home training program will be relocated from BMA Rocky Mount to FMC South Rocky Mount, as such, the applicant projects 28 patients currently receiving peritoneal dialysis services and the 5 home hemo-dialysis patients will transfer to the proposed facility upon project completion.

On page 47 the applicant states FMC South Rocky Mount provided 45 patient letters of support with three of those support letters coming from patients who utilize the home training component. Exhibit 22 contains patient letters of support expressing their willingness to consider transferring their care to the FMC South Rocky Mount facility. Each letter includes the patient name, the name of the dialysis facility in which the patient currently receives treatment, and the county and ZIP code of the patient residence, as illustrated in the following table:

<b><i>DIALYSIS FACILITY</i></b>	<b><i>27801</i></b>	<b><i>27803</i></b>	<b><i>27804</i></b>	<b><i>27878</i></b>	<b><i>27866</i></b>	<b><i>TOTALS</i></b>
<i>BMA Rocky Mount</i>	5	17	1	4	0	27
<i>BMA East Rocky Mount</i>	2	11	1	1	0	15
<i>Home Patients</i>	1	0	1	0	1	3
<i>Total</i>	8	28	3	5	1	45

Source: Page 47 of the Application and Exhibit 22

The applicant previously stated that the facility will begin with a census of 40 in-center patients. The table above is reflective of support letters found in Exhibit 22 and demonstrates that at least 40 patients have expressed interest in transferring their treatment to the new facility; therefore, a beginning census of 27 patients is reasonable and has been demonstrated.

Access to Services

In Section V, page 70, the applicant states that BMA currently operates 100 facilities in 42 North Carolina Counties, which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. On page 71, the applicant projects that 87.9% of FMC South Rocky Mount patients will have Medicare, Medicaid or VA as their payor source.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has to develop a new 12-station dialysis facility and the extent to which all residents of the area are likely to have access to the services proposed. 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

The applicant proposes to establish a new 12-station dialysis facility in Rocky Mount by relocating 12 existing dialysis stations from BMA Rocky Mount. In Section III.3, page 46, the applicant states:

*“This proposal is designed to make more effective use of existing certified dialysis stations and bring dialysis closer to the residence location of patients residing in south Rocky Mount.”*

*This application is based primarily upon geographic accessibility of services and patient convenience. ...”*

In Section III.3(c), pages 47–51, the applicant describes the impact of the relocation of stations from BMA Rocky Mount to the proposed FMC South Rocky Mount facility. The applicant provides a table on page 47 which identifies by zip code those patients that have expressed an interest in transferring to the proposed facility. The applicant further states on pages 47-48:

*“BMA has projected that 40 in-center patients would transfer their care to the new facility. BMA will assume that of the 42 in-center patients who have provided letters of support for this project, 26 patients from BMA Rocky Mount and 14 patients from BMA East Rocky Mount will transfer their care to the new facility.*

*BMA Rocky Mount is currently certified for 42 dialysis stations. According to the July 2013 SDR, the facility was operating at 91.07% utilization with 153 patients as of December 31, 2012.*

*Relocating 12 stations from BMA Rocky Mount to FMC South Rocky Mount will result in BMA Rocky Mount facility having 30 stations. ... The following table identifies the county of residence for the in-center patients at BMA Rocky Mount as of June 30, 2013:*

<b><i>BMA ROCKY MOUNT</i></b>	<b><i>JUNE 30, 2013 IN-CENTER</i></b>
<i>Nash</i>	95
<i>Edgecombe</i>	32
<i>Halifax</i>	25
<i>Wilson</i>	1
<i>Warren</i>	1
<i>Total</i>	154

*In addressing the needs of patients continuing to dialyze at BMA Rocky Mount subsequent to the relocation of 12 stations to FMC South Rocky Mount, BMA will project growth of the BMA Rocky Mount patient population to the projected date of project completion and certification of the new FMC South Rocky Mount facility: December 31, 2014. However, BMA will only project a change in the Nash County ESRD patient population of BMA Rocky Mount. The patients from Edgecombe, Halifax, Wilson and Warren Counties are assumed to be dialyzing at BMA Rocky Mount as a function of choice. The patients from other than Nash County are added back to the projected number of BMA Rocky Mount in-center dialysis patients as of December 31, 2014.*

*The ... table demonstrates the calculations necessary to project the in-center census of BMA Rocky Mount for December 31, 2014 .... BMA will use the same 2.1% growth rate as discussed in relation to projections of a future patient population at FMC South Rocky Mount.*

BMA begins with the in-center patient population residing in Nash County as of December 31, 2012.	95
BMA projects this patient population forward for one year to December 31, 2013.	$(95 \times .021) + 95 = 97.0$
BMA projects growth of this patient population for one year to December 31, 2014. This is the projected certification date of this project.	$(97.0 \times .021) + 97.0 = 99.0$
BMA subtracts the 26 Nash County patients projected to transfer to FMC South Rocky Mount.	$99 - 26 = 73$
BMA adds the patients from other counties.	$73 + 59 = 132$

As shown in the table above, the applicant projects to serve 132 dialysis patients on 30 dialysis stations for a utilization rate of 4.4 patients per station at the BMA Rocky Mount facility upon project completion of the FMC South Rocky Mount facility ( $132 / 30 = 4.4$ );  $132 / (4 \times 30) = 1.1$ , or 110%.

The applicant demonstrates that the remaining dialysis stations at the BMA Rocky Mount facility will continue to be adequately utilized following the proposed relocation.

The applicant proposes to develop a new 12-station dialysis facility in Rocky Mount in Nash County by relocating 12 existing stations from BMA Rocky Mount within the county. The

applicant adequately demonstrates that the BMA Rocky Mount facility from which dialysis stations would be transferred would be adequately utilized following the stations relocation. Therefore, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed dialysis station relocation, including services to the medically underserved. 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 III.9, page 59, the applicant describes the alternatives considered, which include:

- 1) Do nothing – BMA considered not applying to develop the facility. However, the applicant concluded that doing nothing would not be in the best interest of its patients, specifically the 45 patients that provided letters of support for the proposed project.
- 2) Selection of another location – BMA concluded the development of the project in south Rocky Mount would be the logical geographical choice based on where their current patients reside.
- 3) Relocation of more than 12 stations and the development of a larger facility – BMA concluded that the growth rate in Nash County of the ESRD population warranted only 12 relocated stations.
- 4) Development of a facility based on the Nash County Five Year Average Annual Change rate as reported in the July 2013 SDR – BMA stated its disagreement with the published July 2013 SDR, as misinformation was self-reported by BMA (see Exhibit 32 of the which further discusses the error in self-reporting by BMA).
- 5) The project as proposed – BMA states after considering those alternatives, it concluded the project as proposed is the best alternative.

The applicant adequately demonstrated that the proposed alternative is the most effective or least costly alternative.

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

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative. The applicant adequately demonstrated the need to develop a new 12-station dialysis facility by relocating 12 stations from BMA Rocky Mount based on the continued growth of the ESRD patient population of Nash County and the facility's projected

utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, 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 FMC South Rocky Mount shall materially comply with all representations made in the certificate of need application.**
  - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Rocky Mount shall develop and operate no more than 12 dialysis stations at FMC South Rocky Mount, which shall include any isolation and home hemo-dialysis training stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Rocky Mount shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations which shall include any isolation and home hemo-dialysis training stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 12 dialysis stations at BMA Rocky Mount for a total of no more than 30 dialysis stations at BMA Rocky Mount, upon completion of the relocation of those stations to the FMC South Rocky Mount facility.**
  - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Rocky Mount shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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 Section VIII.1, page 79, the applicant projects that the total capital cost will be \$1,679,564, including \$1,103,910 in construction costs, \$150,000 for water treatment equipment, \$205,976 for additional equipment, \$99,352 for architect and engineering fees, and \$120,326 allotted for contingency. In Section VIII.2, pages 80-81, the applicant states Fresenius Medical Care, Inc., parent company of BMA, will finance the project with accumulated reserves. In Section IX.3, page 86, the applicant states the proposed project will require \$101,535 in start-up expenses and \$2,177,850 in initial operating expenses for a total working capital of \$2,279,385. In Exhibit 24 the applicant provides an August 15, 2013 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

*“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc. BMA proposes to develop a new 12 station dialysis facility to serve the growing ESRD patient population of south Rocky Mount and Nash County.*

*This BMA proposal will be accomplished by relocation of 12 existing and certified dialysis stations from the BMA Rocky Mount dialysis facility. The project calls [for] the following capital expenditure on behalf of BMA:*

*Capital Expenditure* *\$1,679,564*

*As Vice President, I am authorized and do hereby authorize development of this 12 station dialysis facility, Fresenius Medical Care South Rocky Mount, for capital costs of \$1,679,564. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the capital expenditure, start up and working capital which may be needed for this project.”*

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2012 and 2011. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$341,071,000 with \$17,841,509,000 in total assets and \$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The Medicare/Medicaid rates in Section X.1, page 87 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services as shown in the following table:

Allowable Charges per Treatment

	In-Center	Home PD	Home Hemo
Commercial Insurance	\$1,375.00	\$1,375.00	\$1,375.00
Medicare	\$234.00	\$234.00	\$234.00
Medicaid	\$137.29	\$137.29	\$137.29
VA	\$146.79	\$147.85	\$147.85
Private Pay	\$1,375.00	\$1,375.00	\$1,375.00

Note – the applicant states that at the time the application was prepared, there was speculation that Medicare would cut dialysis reimbursement as much as 9%. Although the applicant continued to project Medicare reimbursement at the known rate of \$234, it also projected the Medicare reimbursement at the reduced rate of \$213 ( $234 \times 0.09 = 21$ ;  $234 - 21 = 213$ ) and the project would remain profitable.

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application on pages 88-93. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	<b>PY1</b>	<b>PY 2</b>
Net Revenue	\$4,124,008	\$4,189,017
Operating Expenses	\$3,266,776	\$3,343,479
Profit	\$857,232	\$845,538

Assumptions:

1. Average number of patients for the current year is increased by the county growth rate for the first two operating years as adjusted by the applicant due to a self reporting error, (see Exhibit 32 for additional information concerning the reporting error);
2. Average of 3 treatments per week per patient for 52 weeks reduced by a 6.5% allowance for missed treatment; and
3. Ancillary revenues and treatment numbers were derived from In-center treatments less Medicare treatments.
4. Average reimbursement per treatment is based upon the applicant's historical experience and expected future reimbursement.

Further on pages 89-90, the applicant discusses the projected revenue for its home hemo-dialysis services. The applicant states it projects that each home patient will perform 144 treatments annually and accounts for missed treatments. The applicant projects the beginning average of patients for Operating Year 1 and 2 to be 29 patients which was multiplied by 144 for a total of 4176 treatments ( $29 \times 144 = 4176$ ). The applicant projects the following revenue for its home hemo-dialysis services as summarized in the table below:

HOME PD	TREATMENTS	PT PAYMENT % BY REVENUE SOURCE	# OF TREATMENTS BY SOURCE	REIMBURSEMENT BY TREATMENT SOURCE	EXTENDED REVENUE BY SOURCE
<b>Revenue Source Year1</b>					
Commercial Insurance	4,176	29.05%	1,213	\$1,375.00	\$1,668,078
Medicare	4,176	65.34%	2,729	\$234.00	\$638,479
Medicaid	4,176	2.59%	108	\$137.29	\$14,847
VA	4,176	3.02%	126	\$147.85	\$18,654
<b>Total Year 1 Projected Revenue</b>					\$2,340,057
<b>Revenue Source Year2</b>					
Commercial Insurance	4,176	29.05%	1,213	\$1,375.00	\$1,668,078
Medicare	4,176	65.34%	2,729	\$234.00	\$638,479
Medicaid	4,176	2.59%	108	\$137.29	\$14,847
VA	4,176	3.02%	126	\$147.85	\$18,654
<b>Total Year 2 Projected Revenue</b>					\$2,340,057

Additionally, the applicant states on page 91, that FMC South Rocky Mount projects to serve 5 home hemo-dialysis patients in Operating Year 1 and 2 for a total of 720 treatments (5 X 144 = 720). The total revenue generated for each operating year for the home hemo-dialysis patients is projected to be \$403,458 per year.

In Section VIII.9, pages 82-83, the applicant states:

*“Machine Leases are executed as the machines are needed. FMC works with a capital leasing firm to ensure the best possible rates, which are competitive with regard to financial terms, at the time the lease is executed.”* Exhibit 26 contains a sample dialysis machine lease agreement.

In Section VII.1, page 75 and Section X, pages 92 and 94, the applicant provides projected staffing and salaries. On page 76, the applicant states that FMC South Rocky Mount will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 77. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital need of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to develop a new 12-station dialysis facility in Rocky Mount by relocating existing stations from BMA Rocky Mount to FMC South Rocky Mount in Nash County. The July 2013 SDR shows there is a deficit of 19 dialysis stations in Nash County; however, the applicant reports that information self reported by BMA concerning its utilization at its Rocky Mount facilities was in error. See Exhibit 32 for clarification of that error and the applicant's self reported corrected information. In this application, the applicant is not applying for additional stations due to a facility or county need methodology; but to relocate existing stations from an existing facility, BMA Rocky Mount to the proposed FMC South Rocky Mount facility in an effort to provide ESRD patients with services closer to home.

According to the July 2013 SDR, BMA Rocky Mount is one of two dialysis facilities currently in operation in Nash County (both of which are operated by Fresenius Medical Care Holding, Inc.), with utilization rates of 82.50% (FMC of Spring Hope) and 91.07%. (BMA Rocky Mount). The applicant adequately demonstrates the need to develop a new dialysis facility based on the number of in-center patients it proposes to serve. The applicant projects utilization rates for FMC South Rocky Mount as follows upon completion of operating years one and two:

End of operating year one: January 1, 2015 – December 31, 2015  
41 patients dialyzing on 12 stations = 3.4 patients per station  
 $41 / (4 \times 12) = .0854$  or 85%

End of operating year two: January 1, 2016 – December 31, 2016  
42 patients dialyzing on 12 stations = 3.5 patients per station  
 $42 / (4 \times 12) = .0875$  or 88%

Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

The applicant projects utilization rates for BMA Rocky Mount, as of January 1, 2015, the day after certification of the FMC South Rocky Mount facility, as stated below:

132 patients dialyzing on 30 stations = 4.4 patients per station  
 $132 / (4 \times 30) = 1.1$  or 110%

The applicant adequately demonstrates the need to relocate 12 dialysis stations to create FMC South Rocky Mount based on geographic accessibility and patient convenience. The total number of certified dialysis stations within Nash County will not change as a result of this project.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 75, the applicant provides the projected number of full-time equivalent (FTE) positions for the proposed new dialysis facility following completion of the project, as illustrated in the table below:

POSITION	PROJECTED # OF FTES
RN	2.50
Tech	4.00
Clinical Manager	1.00
Medical Director	Contract Position
Administration	0.10
Dietitian	0.67
Social Worker	0.67
Home Training Nurse	3.00
Chief Tech	0.20
Equipment Tech	0.45
In-Service	0.15
Clerical	1.00
<b>Total</b>	<b>13.74</b>

In Section VII.10, page 77, the applicant provides the direct care staff for each shift offered in the facility, as illustrated in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am - 12pm	3	3	3	3	3	3
Afternoon	12pm - 5pm	3	3	3	3	3	3
Evening	5pm - 10pm	2		2		2	

In Section V.4(c), page 66, the applicant states Dr. Michael Holland will serve as the Medical Director for FMC South Rocky Mount. In Exhibit 21, the applicant provides a July 30, 2013 letter from Dr. Holland agreeing to serve as Medical Director. In Section VII.4, page 76, the applicant states it anticipates no difficulty in hiring the necessary staff for the FMC South Rocky Mount dialysis facility, and describes the experience it has in recruiting and hiring staff necessary to operate dialysis facilities. The additional information provided in Sections V and VII is reasonable, credible and adequately supported. Therefore, this 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 V.1, page 63, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, beginning in Section II, page 29 of the application. Diagnostic and evaluation services, x-ray services, blood bank services, and acute dialysis in an acute care setting services will be provided by Nash Hospitals, Inc. Transplantation services will be provided by Duke University Medical Center. Exhibits 16-20 contain documentation on service agreements to include: Hospital Affiliation Agreement, Transplantation Agreement, Spectra Lab Agreement, and a Health Professional Educational Facility Agreement.

The information regarding coordination of services in Section V of the application and referenced exhibits is reasonable, credible, and adequately supported, thus the application is conforming 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

The applicant proposes construction of a 9,411 square foot dialysis facility. In Section VIII.1, page 79, the applicant provides a cost breakdown to include \$1,103,910 in construction cost, \$99,352 in architect and engineering fees and a \$120,326 for contingency costs. In Section XI.6(d), pages 99-102, the applicant discusses the methods by which BMA of North Carolina dialysis facilities utilize and maintain efficient energy operations and contain utility costs as stated below:

HVAC SYSTEM

1. If a new unit is required, its operating efficiency will equal current industry standards for high seasonal efficiency;
2. Systems are controlled via 7 day, 24 hour set back time clock; and
3. Systems are maintained and serviced quarterly along with air filter replacement.

ENERGY CONSERVATION MEASURES

1. Energy efficient exit signs;
2. Water flow restrictors at sink faucets;
3. Water conserving flush toilets;
4. Optical sensor water switches; and
5. External insulation wrap for hot water heaters

WATER TREATMENT EQUIPMENT

1. A percentage of the concentrate water is re-circulated into supply feed water, therefore, lowering the quantity of water discharged in the drain; and
2. Water treatment equipment electric motors are three phase, which run cooler and draw less amperage.

The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of cost and changes which is hereby incorporated by reference as if full set forth herein. 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 VI.1(a), page 70, the applicant discusses BMA's history of providing dialysis services to the underserved populations of North Carolina. 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 patient population of the FMC South Rocky Mount facility is expected to be similar to the BMA Rocky Mount facility and will likely be comprised of the following:*

<i>Facility</i>	<i>Medicaid/Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC South Rocky Mount</i>	<i>28.3%</i>	<i>46.2%</i>	<i>79.9%</i>	<i>48.9%</i>	<i>83.7%</i>

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 79.9% of the facility treatment reimbursement is from Medicare.*

*It is clear that FMC South Rocky Mount projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."*

The FMC South Rocky Mount facility is not an existing facility; therefore, there is no historical payor mix to report.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Nash County and statewide.

	<b>Total # of Medicaid Eligibles as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)</b>
Nash	20%	8.7%	19.7%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application at the same rate as the older segments of the population.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010: *"On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy."* Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

*"Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively."*

The report provides 2010 ESRD spending, by payor as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender as shown below:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicant demonstrated that medically underserved populations currently have adequate access to the services offered at Fresenius Medical Care owned and operated facilities, specifically, BMA Rocky Mount. 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 VI.1(f), page 72, 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 requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

This application is for a new facility. However, in Section VI.6(a), page 74, the applicant states, *“There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in 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 VI.1(c), page 71, the applicant states:

*“Projections of future in-center reimbursement is a function of historical performance of the BMA Rocky Mount facility.”*

Projected Payor Source

	In-Center	Home PD	Home Hemo
Commercial Insurance	12.2%	29.05%	29.05%
Medicare	81.4%	65.34%	65.34%
Medicaid	2.8%	2.59%	2.59%
VA	3.7%	3.02%	3.02%
<b>Total</b>	100.0%	100.0%	100.0%

As shown in the table above, the applicant projects that 84.2% of all in-center patients would continue to have some or all of their services paid for by Medicare or Medicaid with VA covering another 3.7%.

In Section VI.1(d), page 72, 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.”  
[Emphasis in original]

In Section VI.2, pages 72-73, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act (ADA) requirements.

The applicant demonstrates it will provide adequate access to the elderly and medically underserved populations. 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 VI.5(a), page 73, 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 South Rocky Mount 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.”*

The applicant adequately demonstrated that it will provide a range of means by which a person can access 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 V.3, page 65, the applicant states that 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. See Exhibit 19 for copies of letters sent to Wilson Community College, Nash Community College and Edgecombe Community College offering FMC South Rocky Mount as a clinical training site. The applicant adequately demonstrated that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is in conformity to this criterion.

- (15) Repealed effective July 1, 1987.
  - (16) Repealed effective July 1, 1987.
  - (17) Repealed effective July 1, 1987.
  - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

The applicant proposes to develop a new 12-station dialysis facility in Rocky Mount by relocating 12 existing dialysis stations from BMA Rocky Mount. According to the July 2013 SDR, BMA Rocky Mount is one of two dialysis facilities currently in operation in Nash County. The other facility is FMC of Spring Hope located in Spring Hope, in Nash County, which is also operated by Fresenius Medical Care. The July 2013 SDR reported the following utilization rates, as of December 31, 2012:

- FMC Spring Hope 82.50%
- BMA Rocky Mount 91.07%

In Section V.7, page 68, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states its proposal to develop a new dialysis facility by relocating existing dialysis stations within Nash County will not alter the competitive climate in Nash County, but rather, enhance patient access to care, thereby enhancing the quality of the ESRD patients' lives. The applicant further states on page 68:

*“...This facility will have added value stemming from the strength of our relationship with the nephrology physicians at Boice-Willis. ...*

*Thus, while approval of this application will allow introduction of a new dialysis facility into the county, the reality is that approval of this application will not alter the competitive climate of Nash County – no new dialysis stations are created as a result of approval of this application. ...*

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

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ...”*

See Sections II, III, V, VI and VII of the application for additional discussion by the applicant about the impact of relocating 12 existing ESRD stations on cost effectiveness, quality and access to end stage renal services in the service area.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates need based on geographic accessibility and patient convenience to relocate 12 dialysis stations from BMA Rocky Mount to develop a new 12-station dialysis facility in Rocky Mount. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional ESRD access to patients in Nash County;
- Projected utilization of ESRD services is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding historical and projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Pro Formas and Criterion (5) for discussion regarding financial feasibility which is incorporated hereby as if fully set forth herein. Therefore, the applicant adequately demonstrated the cost effectiveness of its proposal.
- The applicant has and will continue to provide adequate access to medically underserved groups, including commercial insurance patients, VA patients, Medicare beneficiaries and Medicaid recipients. See Section VI of the application and Criterion (13c) for discussion regarding projected access by these groups which is incorporated hereby as if fully set forth herein.
- ◆ The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

Additionally, in Section II, page 33, the applicant states, “*BMA is a high quality health care provider.*”

In Section VI.1, page 70, the applicant states:

*“It is clear that FMC South Rocky Mount projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

The applicant provides the following table to demonstrate that the medically underserved population will have access to its services, as illustrated in the table below:

<i>Facility</i>	<i>Medicaid/Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC South Rocky Mount</i>	<i>28.3%</i>	<i>46.2%</i>	<i>79.9%</i>	<i>48.9%</i>	<i>83.7%</i>

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 79.9% of the facility treatment reimbursement is from Medicare.*

The applicant further states on page 70 that BMA of North Carolina has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, and physical or mental conditions. 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

The applicant currently provides dialysis services at other dialysis facilities in Nash County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Rocky Mount and FMC Spring Hope operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

The 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.

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

**.2202 INFORMATION REQUIRED OF APPLICANT**

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

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant provides the utilization rate, as reported in the July 2013 SDR, as 91.07% with 153 patients dialyzing on 42 dialysis stations at BMA Rocky Mount.

(2) *Mortality rates;*

-C- In Section II.1, page 11, the applicant provides the mortality rates as 18.7%, 19.4% and 23.0% for 2010, 2011 and 2012, respectively for BMA Rocky Mount.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section II.1, page 11, the applicant states, “BMA Rocky Mount has 30 home trained patients. The new FMC South Rocky Mount dialysis facility will have a home training program.” In Section III.7, page 55, the applicant states that the existing home training services currently offered at BMA Rocky Mount will be relocated to the proposed FMC South Rocky Mount facility.

(4) *The number of transplants performed or referred;*

-C- In Section II.1, page 11, the applicant states, BMA Rocky Mount referred 17 transplant patients in 2011 and 18 in 2012. Six transplants were performed in 2011 and seven were performed in 2012.

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section II.1, page 12, the applicant states that BMA Rocky Mount currently has 22 patients on the transplant waiting list.

- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section II.1, page 12, the applicant states that there were 289 hospital admissions in 2012 for BMA Rocky Mount, 88 of which were dialysis related and 201 were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section II.1, page 12, the applicant states there were no patients at BMA Rocky Mount in 2011 or 2012 with an infectious disease. However, there is currently one patient with an infectious disease (Hepatitis B) dialyzing at BMA Rocky Mount.
- (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:*
- (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.*
- C- See Exhibit 16. for a copy of the hospital service agreement between BMA North Carolina, Inc. and Nash Hospital, Inc. which describes the services that the hospital will provide to patients of the dialysis facility.
- (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- See Exhibit 17 for a copy of the transplantation agreement between Duke University Medical Center and FMC South Rocky Mount.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- The applicant states that documentation of power and water availability is included within site specific exhibits (Primary Site, Exhibit 30; Secondary Site, Exhibit 31). The applicant state in Section I.7, page 2 and Section XI.2, page 96, the identified primary and secondary sites are both located on the same 10 acre parcel of land which the owner is willing to subdivide.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 12 for copies of written policies and procedures for back up electrical service in the event of a power outage.
- (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 II.1, page 13 and in Exhibits 30 and 31 the applicant provides information regarding the site on which the dialysis services are to be offered, as required by this rule.
- (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- In Section II.1, page 13, the applicant states, “*All services approved by the Certificate of Need will be provided in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC South Rocky Mount.*”
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section II.1, pages 14-18, as well as pages 20-29, and Section III.7, pages 54-58 for the methodology and assumptions the applicant uses to project patient origin, as illustrated in the table below:

County	Operating Year 1			Operating Year 2			County Patients as a % of Total	
	In-Center	PD	HH	In-Center	PD	HH	Year 1	Year 2
Nash	40.8	29.4	5.2	41.7	30.0	5.4	100.0%	100.0%
Total	41	29	5	42	30	5	100%	100%

(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 II.1, page 18, the applicant states that BMA expects that all patients to be served by the new FMC South Rocky Mount facility will reside within 30 miles of the facility. The applicant further states that thirty miles from the primary and secondary sites of the proposed facility covers the entirety of Nash County. See Exhibit 27, map 3 for a visual map of the 30 mile radius of the site as it compares to the proposed service area.

(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 rate for such services.*

-C- In Section II.1, page 19, 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.”

**.2203 PERFORMANCE STANDARDS**

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-C- The applicant provides the assumptions and methodology with which it projects the need for the new 12-station dialysis facility in Nash County. BMA has demonstrated within 10A NCAC 14C .2202(b)(7) that the new facility is projected to serve 41 in-center patients on 12 dialysis stations at the end of Operating Year 1. Furthermore, the applicant adequately demonstrates that those patients who signed letters indicating they would consider transferring their care would be better served by the proposed FMC South Rocky Mount facility due to its proximity to the patient’s residence. The applicant provides evidence of 45 patients (three of which are receiving home hemo-dialysis services) who would consider transferring their care to the proposed facility. When the Five Year adjusted AACR for Nash County is applied to that, the projected utilization for the first year of operation is 3.4 patients per station per week, based on 41 patients

dialyzing on 12 stations (41 / 12 =3.41). Therefore, the application is conforming to this rule.

(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- BMA proposes to relocate 12 stations from BMA Rocky Mount to establish a new facility, FMC South Rocky Mount.

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- In Section II.1, page 29, the applicant states, “*Patients will be referred to Boice-Willis Clinic, or Nash General Hospital (patient choice).*”

(2) *maintenance dialysis;*

-C- In Section II.1, page 29, the applicant states, “*The facility will provide in-center dialysis.*”

(3) *accessible self-care training;*

-C- In Section II.1, page 30, the applicant states, “*Patients desiring self care training will be referred to the facility home training department for on site training and follow-up care.*” The applicant further states that home training service are currently provided at BMA Rocky Mount and that once the proposed project is completed, all home training services will be relocated to the proposed facility.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- In Section II.1, page 30, the applicant states, “*Patients desiring to dialyze at home will be referred to the facility home training department.*”

(5) *x-ray services;*

-C- In Section II.1, page 30, the applicant states, “*Patients will be referred to Boice-Willis Clinic, or Nash General Hospital (patient choice).*” See Exhibit 16 for a copy of the hospital affiliation agreement with Nash Hospital, Inc.

(6) *laboratory services;*

-C- In Section II.1, page 30, the applicant states, “*BMA provides on site laboratory services through [sic] contract with Spectra Labs. Documentation of the agreement is included in Exhibit 18.*”

(7) *blood bank services;*

-C- In Section II.1, page 30, the applicant states, “*Patients in need of blood transfusion will be referred to Nash General Hospital.*” See Exhibit 16 for a copy of the hospital affiliation agreement with Nash Hospital, Inc.

(8) *emergency care;*

-C- In Section II.1, page 30, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to Nash General Hospital, emergency services are summoned via phone call to 911.*”

(9) *acute dialysis in an acute care setting;*

-C- In Section II.1, page 30, the applicant states, “*Patients in need of hospital admission will be referred to Nash General Hospital.*” See Exhibit 16 for a copy of the hospital affiliation agreement with Nash Hospital, Inc.

(10) *vascular surgery for dialysis treatment patients;*

-C- In Section II.1, page 30, the applicant states, “*Patients will be referred to Raleigh Access Center, Hardee’s Heart Center, or Triangle Interventional Center.*” See Exhibit 16 for a copy of the hospital affiliation agreement with Nash Hospital, Inc.

(11) *transplantation services;*

-C- In Section II.1, page 30, the applicant states, “*A copy of an executed transplant agreement is included in Exhibit 17.*” See Exhibit 17 for a copy of a transplant agreement with Duke University Medical Center

(12) *vocational rehabilitation counseling and services; and*

-C- In Section II.1, page 30, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Nash County Vocational Rehabilitation Office.*”

(13) *transportation.*

-C- In Section II.1, page 31, the applicant states, “*Transportation services will be provided by Tar River Transit.*”

**.2205 STAFFING AND STAFF TRAINING**

(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.*

-C- In Section VII.2, page 76, the applicant states that FMC South Rocky will provide sufficient staffing on each dialysis shift as required in 42 C.F.R., Section 405.2100. Table VII.1 identifies all staff for the facility. FMC South Rocky Mount plans to operate two patient shifts, six days a week, and a third shift three days a week.

(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 II.1, page 31 the applicant states that FMC South Rocky Mount will provide ongoing training for nurses and technicians in dialysis techniques, including training in facility and corporate policies and procedures; safety precautions, regulations, CPR, and in-service training on changes/developments in procedures, product line, equipment, Center for Disease Control and Prevention guidelines and OSHA compliance. See Section VII.5, pages 76-77 of the application for information concerning the training and continuing education programs currently in place at FMC operated facilities. Exhibit 14 contains copies of FMC’s Dialysis Services Training Manual which outlines its training program and Exhibit 15 contains examples of information presented as part of staff’s mandatory in-service and continuing education training.