

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 1, 2014

PROJECT ANALYST: Tanya S. Rupp

TEAM LEADER: Lisa J. Pittman

PROJECT I.D. NUMBER: M-10253-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Roseboro / Add 3 dialysis stations to existing facility for a facility total of 13 stations upon project completion / Sampson 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. d/b/a FMC Roseboro is currently certified for 10 in-center dialysis stations and provides in-center hemo-dialysis and home hemo-dialysis. In this application, the applicant proposes to add three (3) in-center dialysis stations to the existing facility for a facility total of 13 in-center dialysis stations upon completion of this project.

The January 2014 SDR reports that as of June 30, 2013 there were 10 certified dialysis stations at FMC Roseboro and 34 in-center patients, which is an 85% utilization rate [34 patients / 10 certified stations = 3.40; 3.40 / 4 = 0.8500].

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for any additional dialysis stations in Sampson County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, FMC Roseboro is eligible to apply for

additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.4 patients per station, or 85%, as calculated above. See the following table, which illustrates the facility need methodology:

APRIL 1 REVIEW-JANUARY SDR

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		85.0%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 6/30/13 (SDR2)		34
In-Center Patients as of 12/31/12 (SDR1)		28
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.4286
(ii)	Divide the result of step (i) by 12	0.0357
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.2143
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	41.2857
(v)	Divide the result of step (iv) by 3.2 patients per station	12.9018
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	3

Step (C) of the facility need methodology states, "The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations." As shown in the table above, based on the facility need methodology for dialysis stations, the FMC Roseboro facility has a need for three additional stations. The applicant proposes to add three new stations and, therefore, the application is consistent with the facility need methodology for dialysis stations. Thus, at the completion of this project, FMC Roseboro will be certified for 13 in-center dialysis stations.

Policy GEN-3 in the 2014 SMFP is also applicable to this review. Policy GEN-3 states:

"A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant

shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section I.13, pages 4 - 8, the applicant describes its corporate structure and how that structure contributes to the provision of quality dialysis services, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments as discussed below:

- Clinical Services Department
 - Serves as a clinical resource for the entire FMC network
 - Provides facilities with the best procedures and equipment available
 - Assists facility managers and medical personnel with questions and concerns on clinical operations
 - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program
- Technical Services Department
 - Oversees the technical and mechanical aspects of dialysis
 - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
- Regulatory Affairs and Law Departments
 - Deals with legal and regulatory issues
 - Provides interpretation of legislation and government policy to ensure compliance
- Other Management Resources, including but not limited to:
 - Health, Safety and Risk Management - provides safety and risk management services to each facility
 - Research – The Renal Research Institute involves dialysis facilities with strong ties to academic research institutions to ensure that all BMA dialysis facilities utilize the latest technology to deliver quality dialysis services to its patients.
 - Regional Vice Presidents – provide operational direction and monitoring of daily operations

In addition, in Section II.1, on pages 32 - 33, the applicant describes the programs currently in place for staff training and orientation, such as a 10-week training program for each new employee, followed by continuous updates. The applicant states staff members are trained in all clinical aspects of their jobs, in facility and corporate policies and procedures, in safety precautions, regulations, and CPR. The applicant further states that training is part of a well-defined *Quality Improvement Program*, and is continually updated by the In-Service Instructor and Director of Nursing.

Additionally, in Exhibit 8, the applicant provides a copy of Fresenius Medical Care’s (FMC) corporate *Quality Assessment and Performance Improvement for FMS Inpatient Services Programs*, which details FMC’s procedures regarding safety and quality in its dialysis facilities. In Section II.1, on page 26, the applicant describes the *UltraCare*® certification which all BMA facilities strive for. In Section II.3, on pages 28 - 34, the applicant describes additional corporately mandated measures for all BMA facilities to ensure the provision of quality services in its dialysis facilities.

In Section V.7, page 51, the applicant states that all BMA facilities continue to find ways to contain operating costs while providing quality care to its patients. The applicant further states that the proposed project will not adversely affect quality, but will enhance the quality of life for ESRD patients in Sampson County.

The applicant adequately demonstrates that the proposal will promote quality and safety.

Promote Equitable Access

In Section II.1, page 26, the applicant states:

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 85.2% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. An additional 2.7% of the treatments will be reimbursed by VA. Thus, 87.9% of the In-Center revenue is derived from government payors.

...

BMA is also keenly sensitive to the second element of ‘equitable access’ – time and distance barriers. At this time, Sampson County has one operational dialysis facility. As the dialysis patient population of Sampson County continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. In this case, BMA is applying for two [sic] additional stations to meet a growing need in Sampson County.”

In addition, in Section VI.1, on page 52, the applicant states that BMA has a long history of providing dialysis services to the underserved populations in North Carolina. The applicant states that in North Carolina BMA facilities in FY 2013, Medicare represented 83.97% of dialysis treatments, and Medicaid represented an additional 4.82% of treatments.

The applicant provides a table on page 52 to illustrate the payor mix of BMA Lumberton, as shown below:

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
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FMC Roseboro	5.3%	44.7%	78.9%	36.8%	65.8%
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The applicant adequately demonstrates that the proposal will promote equitable access to dialysis services in Sampson County.

Maximize Healthcare Value

In Section II.1, on page 27, the applicant states:

“BMA is projecting a capital expenditure of \$8,250 for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis stations at the facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 85.2% of the treatments are covered by Medicare and Medicaid, and an additional 2.73% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates that the proposal will maximize healthcare value.

Consequently, the applicant demonstrates that the proposed services incorporate *Policy GEN-3: Basic Principles* in meeting the needs of the patients to be served. The application is also consistent with the facility need determination in the 2014 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Roseboro proposes to add three in-center dialysis stations to the existing facility, pursuant to the facility need determination, for a facility total of 13 stations upon completion of this project. The January 2014 SDR reports that as of June 30, 2013 there were 10 certified dialysis stations at FMC Roseboro, and 34 in-center patients, which is 3.4 patients per station, or 85% utilization [34 patients / 10 certified stations = 3.4; 3.4 / 4 + 0.850]. BMA is the only provider of dialysis services in

Sampson County. The other BMA facility, BMA Clinton, is located approximately 14 miles east of Roseboro, and has been certified since 1992. The January 2014 SDR reports that as of June 30, 2013, there were 36 certified dialysis stations at BMA Clinton, and 97 in-center patients, which is 2.7 patients per station, or 67% utilization [97 patients / 36 stations = 2.69; 2.69 / 4 = 0.674].

Population to be Served

In Section III.7, page 40 of the application, the applicant projects the following population for FMC Roseboro, which is based on the current patient population:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Sampson	40.4	3.3	42.5	4.6	91.6%	92.2%
Cumberland	4.0	0	4.0	0	8.4%	7.8%
Total	44.4	3.3	46.5	4.6	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.1, on page 35, the applicant states the application is filed pursuant to the Facility Need Methodology in the 2014 SMFP. In Section II.1, on pages 12 – 16, and Section III.7, on pages 36 - 41, the applicant provides the following assumptions and methodology it used to project the need for three additional stations at FMC Roseboro:

1. *“The January 2014 SDR reports that FMC Roseboro was operating at 85.0% utilization with a census of 34 in-center patients dialyzing on 10 certified dialysis stations as of June 30, 2013.*

2. *This project is scheduled to be completed December 31, 2015.*

*Operating Year 1 is the period from January 1, 2015 [sic] - December 31, 2016.
 Operating Year 2 is the period from January 1, 2016 [sic]- December 31, 2017.*

3. *BMA does **not** assume that the patient population of FMC Roseboro will increase at a rate commensurate with the Sampson County Five Year Average Annual Change Rate as published in the January 2014 SDR. [emphasis in original] The Sampson County growth rate is 3.6%.*

4. *The Facility Need Methodology calculations indicate that the facility is increasing at a rate of 42.9% (see III.2, Facility Need Methodology). This rate of growth is obviously far exceeds [sic] the Sampson County average. Despite this demonstrated growth rate, BMA does not project the facility to continue such growth and will necessarily utilize a modest 7.69% growth factor.*

5. *BMA assumes the facility census will increase at a rate of 7.29%. [sic] This rate is based upon a average [sic] of the FMC Roseboro facility census, since it has opened. The facility was certified in March 2012. The first reported census in an SDR was for June 30, 2012 and was 26 patients. Since opening the growth of the facility has been consistent....*

BMA has calculated a growth rate for the facility in the following manner:

Step 1: Determine the difference between the census on December 31, 2013 and June 30, 2012.

$$38 - 26 = 12$$

Step 2: Determine the percentage of change for the above by dividing the difference by the beginning census.

$$12 / 26 = .4615385 \text{ or, } 46.15\%$$

Step 3: Determine a monthly rate of change by dividing the result of Step 2 by 18 (the number of months).

$$.4615385 / 18 = .025641 \text{ or, } 2.56\%$$

Step 4: Multiply the result of Step 3 by 12 to determine an annual growth rate.

$$.025641 \times 12 = .3076923 \text{ or, } 30.77\%$$

Step 5: BMA prefers to use conservative growth rates and has elected to use 25% of the calculated annual growth of the facility.

$$.3076923 \times .025 = .0769231 \text{ or, } 7.69\%$$

BMA suggests that growth of the facility in the short period of time since opening is typical for new facilities. BMA suggests that the growth rate of the FMC Roseboro facility will eventually become commensurate with the Sampson County Five Year Average Annual Change Rate as may be published within the SDR. However, at this point, based upon the rapid growth of the facility and BMA expectations that the while growth is going to slow, a rate of 7.69% is appropriate through the end of 2018.

Clearly, the Facility Need Methodology and the average of the facility growth since opening are far greater than 3.6%. The growth rate of 7.69% used by BMA is more appropriate.

6. *FMC Roseboro was serving 34 Sampson County residents, and four patients from Cumberland County. as of December 31, 2013. BMA will project the four patients from Cumberland County to continue dialysis at FMC Roseboro as a function of patient choice. All other future patients are projected to be residents of Sampson County.*
7. *BMA is also projecting to serve home training patients at the facility. BMA will*

project a modest change in the patient population of the facility and projects one patient in 2015, 2016, and 2017 will change to home dialysis.

Within the most recent years, the growth of the home patient population has increased at a rate greater than the ESRD patient population as a whole. For example, based upon SEKC zip code reports for the periods indicated below, BMA has calculated changes within the ESRD patient population.”

In addition, the applicant projects to serve patients who are able to dialyze at home. On page 38, the applicant provides a table, reproduced below, to illustrate the change in home dialysis patient population in North Carolina from 2007 to 2012, based on data reported in the Southeastern Kidney Council Network 6 ZIP Code Reports:

	IN-CTR.	HOME HD	HOME PD	IN-CTR. PD	OTHER	TOTAL
3/31/12	12836	277	1420	2	0	14535
12/31/09	12128	123	1186	1	6	13444
12/31/07	11704	59	1115	0	6	12884
Raw change 2007 - 2012	1132	218	305	2	-6	1651
% of change 2007 – 2012	9.67%	369.49%	27.35%	NA	NA	12.81%
Annualized Change	2.28%	86.94%	6.44%	NA	NA	3.02%

On page 39, the applicant states:

- *“The overall growth of the ESRD patient population from December 31, 2007 through March 31, 2012 averaged slightly over 3% annual growth. This figure is calculated by dividing the percentage of change for the period (51 months) by 51 and then multiplying by 12 to annualize.*
- *During this time, the in-center hemodialysis patient population increased by an average of 2.28% annually. This figure is calculated in the same manner as the annualized change discussed in a) above.*
- *During the same period of time, the PD patient population grew at a rate of 6.44% annual. This figure is calculated in the same manner as the annualized change discussed in a) above.*
- *However, the home hemodialysis patient population increased at significantly higher rate of 86.94%. This figure is calculated in the same manner as the annualized change discussed in a) above.*
- *BMA assumes the growth in the home hemodialysis patient population during this time is largely attributable to changes in technology (i.e. NxStg home hemodialysis), increased nephrology physician support, and a more educated dialysis patient and family.”*

On page 39, the applicant provides a table, reproduced below, to illustrate the projected in-center patient population of FMC Roseboro:

Project one year (12/31/14) using BMA calculated change rate	$34 \times 1.0769 = 36.6$
Project one year (12/31/15) using BMA calculated change rate	$36.6 \times 1.0769 = 39.4$
Subtract one patient to transfer to home dialysis	$39.4 - 1 = 38.4$
Add four Cumberland County patients. Beginning census	$38.4 + 4 = 42.4$
Project one year (12/31/16) using BMA calculated change rate	$38.4 \times 1.0769 = 41.4$
Subtract one patient to transfer to home dialysis	$41.1 - 1 = 40.4$
Add four Cumberland County patients. Ending census for Operating Year 1	$40.4 + 4 = 44.4$
Project one year (12/31/17) using BMA calculated change rate	$40.4 \times 1.0769 = 43.5$
Subtract one patient to transfer to home dialysis	$43.5 - 1 = 42.5$
Add four Cumberland County patients. Ending census for Operating Year 2	$42.5 + 4 = 46.5$

The applicant projects the following mix of in-center and home dialysis patients for FMC Roseboro following the addition of three stations:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Sampson	40.4	3.3	42.5	4.6	91.6%	92.2%
Cumberland	4.0	0	4.0	0	8.4%	7.8%
Total	44.4	3.3	46.5	4.6	100.0%	100.0%

Therefore, in Operating Year One, the applicant projects to serve 44 in-center patients on 13 dialysis stations, which is 3.38 patients per station, or 85% of capacity [$44 / 13 = 3.38$; $3.38 / 4 = 0.846$]. Likewise, in Operating Year Two, the applicant projects to serve 46 in-center patients on 13 stations, which is 3.5 patients per station, or 88% of capacity [$46 / 13 = 3.54$; $3.54 / 4 = 0.885$]. Thus, in the first operating year, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b).

Furthermore, the assumptions are based on projected growth of only Sampson County patients, to which the applicant then added the remaining patients who currently receive dialysis services at FMC Roseboro, but who reside in a county other than Sampson. Projected utilization is based on reasonable and supported assumptions regarding historical dialysis patient population increases, and continued growth of dialysis patients at FMC Roseboro.

Access to Services

In Section VI.1, pages 52 - 55, the applicant states that BMA currently operates 100 facilities in 42 North Carolina counties, all of which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 87.93% of its patients will be covered by Medicare and Medicaid. The applicant adequately demonstrates the need that this population has for the three additional dialysis stations as proposed. Furthermore, the applicant adequately demonstrates the extent to which all residents of the area; 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 dialysis services proposed.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional in-center dialysis stations 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.

NA

- (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, pages 42 - 44, the applicant describes the alternatives it considered prior to the submission of this application, which include:

- 1) Apply for fewer than three stations: The applicant states that this alternative is not consistent with the growing patient censuses at FMC Roseboro. The applicant states the facility census is growing at 42.94% annually, which is more than the Sampson County Five Year AACR.
- 2) Maintain the status quo: The applicant states that this alternative is not an option because failure to apply for these stations eventually removes choice from patients seeking dialysis treatment in Sampson County. The applicant projects the facility will exceed 80% utilization, and to maintain the status quo would potentially deny existing and future patients a choice of dialysis services at FMC Roseboro.

In addition, the applicant states:

“... BMA ... notes that two of the stations at BMA Clinton are planned to be utilized as dedicated home hemodialysis training and support stations. CON Project ID # M-10115-13 approved the addition of home dialysis services at BMA Clinton. That application proposed to dedicate two of the existing and certified dialysis stations to home dialysis. Thus, those two stations will not be available for In-Center dialysis. Consequently, for planning purposes, there are only 44 dialysis stations available for In-Center dialysis.”

BMA calculates overall utilization for the dialysis stations in Sampson County as 130 patients dialyzing on 44 stations. This equates to a utilization rate of 2.95 patients per station, or 73.9%. This is as of March 31, 2014.

<i>BMA begins with the total In-Center census for BMA Clinton and FMC Roseboro as of March 1, 2014.</i>	<i>130 patients</i>
<i>BMA increases this population forward to December 31, 2014 using 10/12 of the Sampson County Change Rate of 3.6%.</i>	<i>$[130 \times (0.36 / 12 \times 10)] + 130 = 133.9$</i>
<i>BMA increases this population forward to December 31, 2015 using Sampson County Change Rate of 3.6%. This is the projected certification date for this project.</i>	<i>$(133.9 \times .036) + 133.9 = 138.7$</i>
<i>BMA increases this population forward to December 31, 2014 using Sampson County Change Rate of 3.6%. This is the end of Operating Year 1 for this project.</i>	<i>$(138.7 \times 0.36) + 138.7 = 143.7$ Rounded down to 143 patients</i>

Based upon the above calculations, there will be 143 In-Center dialysis patients dialyzing at both Fresenius facilities as of December 31, 2016. At that time ... there will be 47 In-Center dialysis stations This equates to 3.04 patients per station, or a utilization rate of 76.1% for the overall In-Center population of the county.

... BMA is proposing that FMC Roseboro would have 44.4 In-Center dialysis patients as of December 31, 2016. Subtracting those projected Roseboro patients from the projected In-Center population of Sampson County leaves 99 dialysis patients projected to dialyze at BMA Clinton, on 34 In-Center stations. The resultant utilization would be 72.8%. While this is not at the 80% threshold, BMA suggests this is strong support for not requesting to relocation additional stations from BMA Clinton to FMC Roseboro.”

The applicant adequately demonstrates the need for three additional dialysis stations based on the continued growth of the ESRD patient population in Sampson County and the facility’s projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

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 Roseboro 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 Roseboro shall develop and operate no more than three additional stations for a total of no more**

than 13 certified in-center dialysis stations, which shall include any home hemodialysis training and isolation stations, following completion of this project.

- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Roseboro shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 13 dialysis stations which shall include any home hemodialysis training and isolation stations**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Roseboro 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, pages 61 - 62, the applicant projects the capital cost for FMC Roseboro will be \$8,250, which includes \$1,500 for RO water treatment equipment and \$6,750 for other equipment and furniture. In Section IX, page 65, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project, since FMC Roseboro is currently operational.

In Section VIII.2, on page 62, the applicant states the entire capital cost of the project will be funded with the accumulated reserves of FMC Holdings, Inc. Exhibit 24 includes a March 17, 2014 letter from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA is submitting a Certificate of Need Application to add three dialysis stations to its FMC Roseboro facility in Sampson County. The project calls for the following capital expenditure:

<i>Capital Expense</i>	<i>\$8,250</i>
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As Vice President, I am authorized and hereby do authorize the addition of three dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$8,250 as may be needed for this project.”

In Exhibit 4, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. for the fiscal year ended December 31, 2012. As of December 31, 2012, FMC had \$341,071,000 in cash and cash equivalents, \$17,841,509,000 in total assets and

\$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

In Section X.1, page 66, the applicant provides the allowable charges per treatment for each payment source for FMC Roseboro as follows:

FMC ROSEBORO	
PAYOR	ALLOWABLE CHARGE PER IN-CENTER TREATMENT
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$137.29
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
VA	\$146.79
Other: Self/Indigent	\$1,425.00

The applicant states that the commercial charge listed does not reflect the actual reimbursement. In addition, the applicant states that BMA has “*opted in*” completely to Medicare’s “*bundling*” reimbursement program, which provides one basic fee per dialysis treatment, which the applicant states on page 66 is “*approximately \$240 per treatment.*” This fee “*bundles,*” or includes all ancillary services which were previously billed separately.

The applicant projects revenues in Section X.2 and operating expenses in Section X.4 of the application. In Sections X.2 - X.4, pages 68 - 75, the applicant projects revenues and expenses for FMC Roseboro as follows:

FMC ROSEBORO		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$1,955,041	\$2,053,100
Total Operating Costs	\$1,784,128	\$1,869,234
Net Profit	\$ 170,913	\$ 183,866

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X.2, page 69, for the applicant’s assumptions regarding in-center revenue, and Section X.2, page 71, for the applicant’s assumptions with regard to home revenue.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the project, and that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Roseboro proposes to add three stations to the existing facility for a total of 13 stations upon completion of the proposed project. The January 2014 SDR reports that FMC Roseboro was dialyzing 34 patients on ten stations as of June 30, 2013, which is a utilization rate of 85% [$34 / 10 = 3.4$; $3.4 / 4 = 0.850$]. Therefore, according to the facility need methodology in the 2014 SMFP, FMC Roseboro is eligible to apply for three additional stations.

According to the January 2014 SDR, there are two dialysis facilities in Sampson County, both of which are operated by BMA: BMA Clinton and FMC Roseboro. BMA Clinton is currently certified for 36 in-center stations and was dialyzing 97 in-center patients as reported in the January 2014 SDR. The following table illustrates the two facilities' utilization rates as reported in the July 2013 SDR and the January 2014 SDR, as well as data reported by the applicant on page 42 of the application:

Sampson County ESRD Utilization Data as Reported in the July 2013 SDR for 12/31/12

FACILITY	# CERTIFIED STATIONS	# IN-CTR. PATIENTS	% UTILIZATION
BMA Clinton	33	97	73.48%
FMC Roseboro	10	28	70.00%
Total	43	125	72.67%

Sampson County ESRD Utilization Data as Reported in the January 2014 SDR as of 6/30/13

FACILITY	# CERTIFIED STATIONS	# IN-CTR. PATIENTS	% UTILIZATION
BMA Clinton	36	97	67.36%
FMC Roseboro	10	34	85.00%
Total	46	131	71.20%

Sampson County ESRD Utilization Data as Reported in Application page 42 for 2/28/14

FACILITY	# CERTIFIED STATIONS	# IN-CTR. PATIENTS	% UTILIZATION
BMA Clinton	36	92	63.89%
FMC Roseboro	10	38	95.00%
Total	46	130	70.65%

In this application, the applicant is applying for three additional stations at FMC Roseboro, based on the facility need methodology that is specific to this facility. The applicant adequately demonstrates the need for three additional stations at FMC Roseboro based on the number of in-center patients it proposes to serve. The January 2014 SDR reports that as of June 30, 2013, the FMC Roseboro facility was operating at 85.0% capacity, with 34 patients dialyzing on 10 certified stations [$34 / 10 = 3.4$; $3.4 / 4 = 0.8500$]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the

facility, pursuant to 10A NCAC 14C .2203(b). Based on the calculations above, the applicant is eligible to expand its facility based on the facility need methodology and may apply for additional stations. Upon completion of the proposed project, the facility will have 13 in-center dialysis stations serving up to 44 dialysis patients at the end of Operating Year 1, which is a utilization rate of 85% [44 / 13 = 3.38; 3.38 / 4 = 0.846]. Therefore, the application is conforming to the performance standard promulgated in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Sampson 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

In Section VII.1, page 57, the applicant provides projected staffing for FMC Roseboro upon project completion, as illustrated in the following table:

FMC ROSEBORO			
FULL-TIME EQUIVALENT (FTE) POSITIONS			
	CURRENT	ADD	TOTAL
RN	1.50	0.50	2.00
Tech	3.00	1.00	4.00
Clinical Manager (DON)	1.00	-	1.00
FMC Director of Operations	0.20	-	0.20
Dietician	0.50	-	0.50
Social Worker	0.50	-	0.50
Home Training Nurse	0.50	-	0.50
Chief Tech	0.10	-	0.10
Equip Tech	0.50	-	0.50
In-Service	0.20	-	0.20
Clerical	0.80	-	0.80
Total FTEs	8.80	1.50	10.30

The applicant projects a total of 10.30 FTE positions upon project completion. In Section VII.4, on page 58, the applicant states it anticipates no difficulty recruiting additional staff for the facility. In Section V.4(c), on page 50, the applicant states the current Medical Director for FMC Roseboro is Emily Sun, MD. In Exhibit 21 the applicant provides a February 19, 2014 letter of support from Dr. Sun which also indicates her willingness to continue to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 V.1, on page 47, the applicant identifies the providers of the necessary ancillary and support services for FMC Roseboro. The applicant provides further detail of the ancillary and support services in Section V, on pages 48 - 51. In Exhibits 20, 21, 25, and 26 the applicant provides documentation to support the statements regarding the provision of necessary ancillary and support services. The applicant adequately demonstrates that necessary ancillary and support services are available and will continue to be available, and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

- (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, page 52 the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... The patient population of the FMC Roseboro facility is comprised of the following:”

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Roseboro	5.3%	44.7%	78.9%	36.8%	65.8%

The applicant states:

“The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.9% of the facility treatment reimbursement is from Medicare.”

In Section, VI.1(b) and VI.1(c), pages 52 and 53 respectively, the applicant provides the current and projected payor mix for FMC Roseboro. The applicant expects no change in the current payor mix once the three stations are added. The payor mix is illustrated in the following table.

FMC ROSEBORO CURRENT PAYOR MIX		
PAYOR SOURCE	IN-CENTER	HOME
Commercial Insurance	5.78%	32.1%
Medicare	78.07%	67.1%
Medicaid	7.13%	0.7%
Medicare / Medicaid	2.73%	0.0%
State Kidney Program	6.29%	0.0%
Total	100.00%	100.0%

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 Mecklenburg County and statewide.

	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) *
Sampson County	25.4%	10.1%	24.0%
Statewide	16.5%	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 does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by FMC Roseboro. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina’s Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

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 *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*¹ (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

¹ www.usrds.org/adr.aspx

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$45.5 billion, including Medicare Part D (p. 118).

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

*Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.²

The 2012 United States Renal Data System (USRDS) Annual Data Report Provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 327.

² www.esrdnetwork6.org/publications/reports.html

The applicant demonstrates that medically underserved populations have adequate access to the dialysis services provided at FMC Roseboro. 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.6(a), page 56, the applicant states there have been no civil rights access complaints filed against any North Carolina BMA facilities in the last 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 53, the applicant provides the projected payor mix for the proposed services at FMC Roseboro, as shown in the table below. The applicant projects no change in the current payor mix for both in-center patients and home dialysis patients at FMC Roseboro.

FMC ROSEBORO PROPOSED PAYOR MIX		
PAYOR SOURCE	IN-CENTER	HOME
Commercial Insurance	5.78%	32.10%
Medicare	78.07%	67.10%
Medicaid	7.13%	0.70%
Medicare/Medicaid	2.73%	0.00%
State Kidney Program	6.29%	0.00%
Total	100.00%	100.00%

The applicant demonstrates that medically underserved populations would 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 VI.5, on pages 55 -56, 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 Roseboro 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 demonstrates that FMC Roseboro will continue to offer a range of means by which a person can access its 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, on page 49, the applicant states:

“All health related education and training programs are welcomed [sic] to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment.”

In Exhibit 19, the applicant provides a January 20, 2014 letter from FMC to the Director of the nursing program at Fayetteville Technical Community College, requesting to include FMC Roseboro in its clinical rotation schedule for student nurses.

The application is conforming to this criterion.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Roseboro proposes to add three new dialysis stations to its existing facility for a total of 13 stations upon project completion.

The applicant is applying for additional stations based on the facility need methodology.

According to the January 2014 SDR, there are two dialysis facilities in Sampson County, both of which are operated by BMA, parent company to FMC Roseboro. BMA Clinton is located in Clinton, and FMC Roseboro is located in Roseboro, approximately 14 miles distant. The January 2014 SDR, Table A reports that, as of June 30, 2013, the 10 station FMC Roseboro facility was operating at 85.0% capacity, with 34 patients on 10 stations ($34 / 10 = 3.4$; $3.4 / 4 = 0.850$, or 85.0%). The target utilization, pursuant to 10A NCAC 14C §2203(b) is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. The other dialysis facility, BMA Clinton, was operating at 67.36% capacity, with 97 patients on 36 stations ($97 / 36 = 2.69$. $2.69 / 4 = 0.673$).

In Section V.7, page 51, 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 to dialysis services. The applicant states its proposal to add three dialysis stations will not adversely affect quality, but rather, enhance the quality of life for the ESRD patients. The applicant further states:

“... 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. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding three dialysis stations to the existing FMC Roseboro dialysis facility will have a positive impact on quality and access to the proposed dialysis service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need, based on the facility need methodology, to add three dialysis stations for a total of 13 certified dialysis stations to FMC Roseboro upon completion of the proposed project.
- 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 (pages 47 - 48 and 49 - 51), and VII.2 (page 58), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 52, the applicant states:

“It is clear that FMC Roseboro provides 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 medically underserved populations will continue to have adequate access to dialysis services provided by FMC Roseboro, as illustrated below.

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Anson County	5.3%	44.7%	78.9%	36.8%	65.8%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.9% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI.1(a), page 52, that BMA will continue to provide dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations.

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 FMC Roseboro. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Roseboro has 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.

10A NCAC 14C .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 10, the applicant provides the utilization rate of 85.0% with 3.4 patients per station ($34 / 10 = 3.4$) as reported in the January 2014 SDR.

(2) Mortality rates;

-C- In Section II.1, page 10, the applicant provides the mortality rates as 20.7% and 12.1% for 2012 and 2013, respectively. The facility was certified in 2012 and thus that was the first year for reporting purposes.

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

-C- In Section II.3, page 10, the applicant states, “*FMC Roseboro currently has one patient dialyzing at home. The facility providing [sic] dialysis training to four patients in 2013.*”

(4) The number of transplants performed or referred;

-C- In Section II.1, page 10, the applicant states FMC Roseboro referred 3 transplants in 2012 and 4 in 2013. One transplant was performed in 2012 and none in 2013.

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

-C- In Section II.1, page 10, the applicant states, “*FMC Roseboro has three 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 11, the applicant states that there were 55 hospital admissions in 2013, 3 of which were dialysis related and 52 of which 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 11, the applicant states that there were no patients at the facility in 2012 or 2013 or at the time of the application with an infectious disease.

(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.

-NA- FMC Roseboro is an existing facility. However, the applicant provides a copy of the hospital affiliation agreement with Cape Fear Valley Health System in Exhibit 25.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with 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.*

-NA- FMC Roseboro is an existing facility. However, the applicant provides a copy of a transplant agreement with Duke University Medical Center in Exhibit 26.

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

-NA- FMC Roseboro is an existing facility.

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

-C- In Exhibit 12 the applicant provides a copy of the *Emergency Management and Disaster Planning* policy, which provides procedures for back-up electrical service in the event of a power outage for FMC Roseboro.

(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.*

-NA- FMC Roseboro is an existing facility.

(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 12, the applicant states, “*BMA will provide all services approved by the Certificate of Need 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 Roseboro.*”

(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 II.1, pages 12 - 16, and Section III.7, pages 38 - 41, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A % OF TOTAL	
	In-Ctr.	Home	In-Ctr.	Home	Year 1	Year 2
Sampson	40.4	3.3	42.5	4.6	91.6%	92.2%
Cumberland	4.0	0.0	4.0	0.0	8.4%	7.8%
Total	44.4	3.3	46.5	4.6	100.0%	100.0%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

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

-NA- FMC Roseboro is an existing facility.

(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, pages 17, 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.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC Roseboro is an existing facility.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- FMC Roseboro projects utilization of 3.38 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 13 – 16 and 18 – 22; and Section III.7, pages 36 - 41.

(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 17 - 21, and Section III.7, pages 36 – 41.

10A NCAC 14C .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 23, the applicant states, "Patients will be referred to Sampson Regional Medical Center."

(2) maintenance dialysis;

-C- In Section II.1, page 23, the applicant states, "The facility will provide in-center dialysis."

(3) accessible self-care training;

C- In Section II.1, page 23, the applicant states, "Patients who are candidates for self-care will be referred to the facility home training department."

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

C- In Section II.1, page 23, the applicant states, "Patients who are candidates for home dialysis will be referred to the facility home training department."

(5) x-ray services;

C- In Section II.1, page 23, the applicant states, "Patients will be referred to Sampson Regional Medical Center."

(6) laboratory services;

-C- In Section II.1, page 23, the applicant states, "BMA provides on site laboratory services through contract with Spectra Labs." See Exhibit 15 for the laboratory services agreement with Spectra Laboratories.

(7) blood bank services;

-C- In Section II.1, page 23, the applicant states, "Patients in need of blood transfusion will be referred to Cape Fear Valley Medical Center (Fayetteville) or Wayne Memorial Hospital (Goldsboro)."

(8) emergency care;

-C- In Section II.1, page 23, 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 a hospital, emergency services are summoned via phone call to 911.”

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

-C- In Section II.1, page 23, the applicant states, *“Patients admitted to hospital [sic] will be referred to Cape Fear Valley Medical Center (Fayetteville) or Wayne Memorial Hospital (Goldsboro).”*

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

-C- In Section II.1, page 24, the applicant states, *“Patients will be referred to Carolina Kidney Care Access Center, Triangle Vascular Associates, or Dr. Tommy Chang. The surgeons of these locations will coordinate with the patient and schedule vascular surgery.”*

(11) *transplantation services;*

-C- In Section II.1, page 24, the applicant states, *“FMC Roseboro has a transplant agreement with Duke UMC.”* See Exhibit 26 for a copy of the transplant agreement with Duke University Medical Center.

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

-C- In Section II.1, page 24, the applicant states, *“Patients in need of vocational rehabilitation services will be referred to the Sampson County Division of Vocational Rehabilitation.”*

(13) *transportation.*

-C- In Section II.1, page 24, the applicant states, *“Transportation services are provided by Sampson County Department of Social Services or VanGo Transportation.”*

10A NCAC 14C .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 II., page 24, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 58, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

(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 24, and Section VII.5, page 58, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten-week training program, and that staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 9 contains an outline of the training program and Exhibit 10 contains the outline of the continuing education information.