

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 17, 2014

PROJECT ANALYST: Tanya S. Rupp
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: N-10194-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pembroke / Add six stations to existing facility for a facility total of 19 in-center dialysis stations / Robeson 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.

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Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pembroke is currently certified for 13 in-center dialysis stations and provides in-center hemo-dialysis and home hemo-dialysis and peritoneal dialysis training and support services. In this application, the applicant proposes to add six (6) in-center dialysis stations to the existing facility for a facility total of 19 in-center dialysis stations upon completion of this project.

The July 2013 SDR reports that as of December 31, 2012 there were 13 dialysis stations at the FMC Pembroke facility, dialyzing 48 in-center patients. The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Robeson 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 Pembroke is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.69 patients per station, or 92.3%. This utilization rate was calculated based

on 48 in-center dialysis patients and 13 certified dialysis stations as of December 31, 2012 (48 patients / 13 stations = 3.69 patients per station). See the following table, from Section III.1, page 35 of the application:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		92.3%
Certified Stations		13
Pending Stations		
Total Existing and Pending Stations		13
In-Center Patients as of 12/31/12 (SDR2)		48
In-Center Patients as of 6/30/12 (SDR1)		40
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.4000
(ii)	Divide the result of Step (i) by 12	0.0333
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.4000
(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	67.2000
(v)	Divide the result of Step (iv) by 3.2 patients per station	21.0000
	and subtract the number of certified and pending stations as recorded in SDR2 [13] to determine the number of stations needed	8

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, and based on the number of certified dialysis stations in Robeson County, the FMC Pembroke facility has a need for eight additional stations. The applicant proposes to add six new stations and, therefore, the application is consistent with the facility need determination for dialysis stations. Thus, at the completion of this project, FMC Pembroke will be certified for 19 in-center dialysis stations.

Policy GEN-3 in the 2013 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 II.1, page 23, the applicant states:

“BMA is a high quality health care provider. BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare® certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”

On page 24, the applicant provides more detailed information about UltraCare. The applicant states,

“All of the nearly 40,000 FMCNA employees share the company’s UltraCare commitment of delivering excellent care to patients through innovative programs, the latest technology, continuous quality improvement and a focus on superior customer service. UltraCare is delivered by highly trained staff and demonstrated through dedication, leadership and compassion, by every team member, every day.

There are six underlying elements of UltraCare:

Clinical Leadership. Continuous Quality Improvement. Superior Customer Service Team Approach to Care. Innovative Technology. Patient-Centered Care

Every year since its launch in 2004, FMCNA staff participates in various supplementary training courses designed to incorporate these underlying elements into their work lives. In addition to professional certifications and regular training in their respective responsibilities, all employees engaged in patient care must achieve annual re-certification related to their UltraCare training. New employees participate in specialized Destination UltraCare training to ensure the mission is pervasive throughout our corporate culture.”

In addition, in Exhibit 13, the applicant provides a copy of Fresenius Medical Care’s Quality Assessment and Performance Improvement policies and procedures. Exhibit 11 contains a copy of BMA’s policy with regard to water quality in its facilities. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Robeson County.

Promote Equitable Access

In Section II.1, pages 24 - 25, 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 90.4% of the In-center dialysis treatments will be covered by Medicare or Medicaid; an additional 4.6% are expected to be covered by VA. Thus, 95.0% of the In-center revenue is derived from government payors. These projections reflect the current payor mix at FMC Pembroke dialysis facility.

...

BMA is also keenly sensitive to the second element of “equitable access” - time and distance barriers. At this time, Robeson County has six operational dialysis facilities. As the dialysis patient population of Robeson County continues to increase, the need for dialysis stations will continue to increase. ... BMA is planning to add three additional stations to meet a growing need in Robeson County and the BMA Lumberton facility.”

In addition, in Section VI.1, page 49 the applicant states that in FY 2012, 84.8% of BMA North Carolina dialysis patients had some or all of their treatments paid for by Medicare. The applicant states,

“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 adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

In Section II.1, page 25, the applicant states:

“BMA is projecting a capital expenditure of \$273,630 for this project. ... BMA is not seeking State or Federal monies to accomplish this transfer of stations; BMA is not seeking charitable contributions to accomplish this addition of stations. Rather, BMA, through its parent company, FMC is taking on the financial burden to complete this addition of stations in an effort to bring dialysis treatment closer 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 90.4% of the treatments are covered by Medicare and Medicaid, and an additional 4.6% 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.”

In Section XI.6(d), page 73, the applicant states:

“Methods, [sic] which BMA of North Carolina dialysis facilities utilize to maintain efficient energy operations and, therefore, contain utility costs, are as follows:

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,*
- 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*
- 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, [sic] lowering the quantity of water discharged in the drain,*
- 2. Water treatment equipment electric motors are three phase, which run cooler and draw less amperage.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

SMFP Policy GEN-4, regarding Energy Efficiency and Sustainability for Health Service Facilities is not applicable in this review because there is the projected capital cost for the project is less than \$2 Million.

In summary, the application is consistent with the facility need determination and Policy GEN-3. 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.

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pembroke proposes to add six in-center dialysis stations to the existing facility, pursuant to the facility need determination, for a facility total of 19 stations upon completion of this project. The July 2013 SDR reports that as of December 31, 2012 there were 48 Robeson County patients dialyzing on 13 in-center dialysis stations at the FMC Pembroke facility. This calculates to a 92% utilization rate [48 / 13 = 3.69; 3.69 / 4 = 0.923].

Population to be Served

In Section III.7, page 39 of the application, the applicant projects the following patient origin:

COUNTY	OPERATING YEAR 1	OPERATING YEAR 2	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	IN-CENTER	YEAR 1	YEAR 2
Robeson	61.8	65.8	100.0%	100.0%
Total	61.8	65.8	100.0%	100.0%

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section II.7, pages 17 - 19, Section III.7, pages 36 - 39, the applicant provides the assumptions and methodology it used to project its need for six additional dialysis stations at the FMC Pembroke facility, based on the facility need methodology. The applicant states,

1. *“This project is scheduled for completion December 31, 2015.
 Operating Year 1: January 1, 2016 through December 31, 2016.
 Operating Year 2: January 1, 2017 through December 31, 2017.*
2. *The July 2013 SDR reports that FMC Pembroke was operating at 92.31% utilization with a census of 48 patients dialyzing on 13 certified dialysis stations as of December 31, 2012.*
3. *BMA does not assume that the patient population of Robeson County will grow at the Robeson County Five Year Average Annual Change Rate as published in the July 2013 SDR (10.9%). Rather, BMA will use a growth rate of 6.5%.*

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.

BMA, like all other providers in North Carolina has participated in the Self Reporting process. Unfortunately, the FMC Pembroke facility erred in preparation of the self reported data. Rather than provide the county of residence for all patients, the facility 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. A copy of the information provided to DHSR is included in Exhibit 32 of this application.

- 4. BMA notes that 100% of the patient population of FMC Pembroke resides within Robeson County. BMA does not project FMC Pembroke to serve patients of other counties. This is not to say that FMC Pembroke will restrict admissions, but rather that BMA is simply not projecting ESRD patients residing in other counties will seek care and treatment at the facility. BMA will admit any patient with appropriate referral from a nephrology physician with admitting privileges at the facility.*
- 5. As noted above, BMA will utilize a growth factor of 6.5%. This growth rate is higher than the County Five Year Average Change Rate, but less than the facility annual growth rate as calculated by the Facility Need Methodology. The methodology indicates that the annual growth rate was 40% for the period ended December 31, 2012. BMA is certainly cognizant of the significant growth of the facility but does not believe this rate can be sustained for several years. The 6.5% growth rate used by BMA is significantly less than the growth rate of the facility and is very conservative considering the performance of the facility. Further, the 6.5% rate will assure a sufficient number of dialysis stations for the ESRD patient population of the area.*
- 6. BMA notes for the Project Analyst that growth rates utilized by providers are not limited to the growth rate as published in the SDR. In CON Project ID # J-10038 - 12, the Total Renal Care (DaVita) application to add five dialysis stations to its Wake Forest Dialysis facility (Wake County, NC), the applicant utilized a growth rate of 20%, a five-fold increase over the published growth rate. The applicant suggested that it was reasonable to employ a rate of 20%. This was a rate of approximately one half the growth rate demonstrated by the Facility Need Methodology. That application was approved on February 14, 2013. The Required State Agency Findings for the project indicated that the Applicant had successfully identified the population to be served and the need for the stations.”*

In Step 3, the applicant refers to a Five Year Average Annual Change Rate for Robeson County of 10.9%, which the applicant states is taken from the July 2013 SDR. However, the July, 2013 SDR, in *Table B: ESRD Dialysis Station Need Determination by Planning Area*, shows a Five Year AACR in Robeson County of 1.3%. In the applicant's own exhibits, in Exhibit 30, Appendix E, the applicant provides a copy of Table B from the July 2013 SDR, which confirms an AACR of 1.3% [0.013] in Robeson County.

The project analyst evaluated the last four SDRs to determine utilization history at the FMC Pembroke facility. The results are illustrated in the table below:

**FMC Pembroke Historical Utilization
 January 2012 SDR – July 2013 SDR**

SDR	# PATIENTS	% GROWTH	% OVERALL GROWTH
January 2012	33	--	
July 2012	39	18%	
January 2013	40	3%	
July 2013	48	20%	45%

FMC Pembroke experienced a 45% increase in utilization from January 2012 – July 2013, as reported in the SDR for those reporting periods. Calculation of the Compound Annual Growth Rate (CAGR) yields a 20.6% growth during that same time. The applicant projects utilization at FMC Pembroke will increase 6.5% per year, which it states is reasonable, given the historical utilization at this facility. Therefore, the applicant projects to serve the following number of dialysis patients on 19 in-center dialysis stations:

Begin with 48 Robeson County in-center dialysis patients as of 12/31/12.	48
Project forward 12 months to 12/31/13 using a 6.5% growth rate.	$48 \times 1.065 = 51.1$
Project forward 12 months to 12/31/14, using 6.5% growth rate.	$51 \times 1.065 = 54.4$
Project forward 12 months to 12/31/15, using a 6.5% growth rate.	$54 \times 1.065 = 57.9$
Project forward 12 months to 12/31/16, using a 6.5% growth rate.	$58 \times 1.065 = 61.7$
Project forward 12 months to 12/31/17, using a 6.5% growth rate.	$62 \times 1.065 = 65.8$

In Section III.8, page 37, the applicant states Operating Year One is Calendar Year 2016 and Operating Year Two is Calendar Year 2017.

There are currently six dialysis facilities in Robeson County, five of which are operated by the applicant. The following table shows utilization at the BMA facilities in Robeson County as reported in the July 2013 SDR:

FACILITY	NUMBER OF STATIONS	NUMBER OF PATIENTS	PATIENTS PER STATION	UTILIZATION
BMA of Red Springs*	14	39	2.78	69.6%
FMC Dialysis Services of Robeson	23	65	2.82	70.6%
FMC Pembroke	13	48	3.69	92.3%
BMA Lumberton	30	97	3.23	80.8%
FMC of St. Pauls*	13	42	3.23	80.8%
Total	93	291	3.13	78.2%

*Pursuant to Project ID#N-10067-12, FMC of St. Pauls was approved to relocate two of its existing in-center stations to the BMA of Red Springs facility. That project is under development.

As reported in the July 2013 SDR, both the BMA Lumberton and FMC Pembroke facilities are utilized at 80% or above. Currently, two stations are being relocated from BMA of Red Springs to FMC of St. Pauls, reflecting the higher utilization at the St. Pauls facility. The analyst reviewed the aggregate utilization of all dialysis stations operated by BMA in Robeson County. There are a total of 291 in-center stations and 93 patients, which is a current utilization rate of just under 80% [$291 \text{ patients} / 93 \text{ stations} = 3.13$; $3.13 / 4 = 0.782$]. Once the station relocation between BMA of Red Springs and FMC of St. Pauls is complete, another option would be to transfer stations out of FMC Dialysis Services of Robeson County in Fairmont, since its utilization was reported at 65 patients and 23 stations, or 2.83 patients per station and 70.7% of capacity [$65 / 23 = 2.83$; $2.83 / 4 = 0.707$]. However, only three stations would be transferrable before the utilization rate in that facility would be 3.2 or 80%. See the following table:

CURRENT UTILIZATION WITH 23 STATIONS AND 65 PATIENTS	UTILIZATION WITH 22 STATIONS	UTILIZATION WITH 21 STATIONS	UTILIZATION WITH 20 STATIONS
65 / 23 = 2.83 (70.6%)	2.95 (73.8%)	3.09 (77.3%)	3.25 (81.3%)

Based on the utilization at the FMC Pembroke facility, combined with the county-wide utilization by BMA and the pending station transfers, the proposal by the applicant to add six in-center dialysis stations to the FMC Pembroke facility, for a facility total of 19 in-center stations is reasonable. Furthermore, the methodology used by the applicant to project utilization is based on credible and supported assumptions.

BMA filed another application for an increase in dialysis stations in Robeson County simultaneously with this application (BMA Lumberton, Project ID# N-10195-13). Each application was submitted pursuant to the facility need methodology, which is specific to that particular facility. Thus, any difference in growth rates used by the applicant between the two applications is due to the fact that the growth rate for each facility is based on the history of the particular facility for which an application was filed.

Projected utilization at the end of Operating Year One equals 3.2 in-center patients per station per week which is equal to the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b) and the number of in-center patients projected to be served is based on reasonable, credible and supported assumptions regarding future growth in the FMC Pembroke facility. Between June 30, 2012 and December 31, 2012, the number of in-center patients increased from 40 to 48, which is an increase of 8 patients, or 20.0% over a six-month period. The annual rate of change (compound annual growth rate) equals 20.6%. The applicant assumes a rate of growth that is less than half the actual growth rate the facility experienced during 2012.

Access to Services

In Section VI, pages 49 - 53, 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. The applicant projects that 95% of its patients will be covered by Medicare, Medicaid and VA. The applicant adequately demonstrates the need that this population has for the dialysis services 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.

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In Section III.9, page 40, 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 increasing demand for dialysis services at FMC Pembroke. The applicant has projected utilization in excess of 80% in the first operating year at this facility.
- 2) Maintain the status quo: The applicant states that this alternative is neither cost-effective nor consistent with the demonstrated need for additional dialysis stations at FMC Pembroke.
- 3) Add three stations: BMA chose this alternative as most effective and least costly to meet the growing demand for services at FMC Pembroke.

The applicant adequately demonstrates the need for three additional stations based on the continued growth of the ESRD patient population in Robeson 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 Pembroke 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 Pembroke shall develop and operate no more than three additional stations for a total of no more than 19 certified in-center dialysis stations, which shall include any isolation or home hemodialysis stations following completion of this project.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pembroke shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 19 dialysis stations which shall include any isolation or home hemodialysis stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pembroke shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pembroke 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(b), page 58, the applicant projects the capital cost of the project will be \$273,600, including \$180,000 in construction costs, \$78,714 in miscellaneous consultant fees, and \$14,916 in contingency fees. In Section IX, page 58, the applicant states there will be no start-up or initial operating costs associated with this project, since the facility is currently operational.

In Section VIII.2, on page 59, the applicant states the capital cost will be funded with the accumulated reserves of Fresenius Medical Care Holdings, Inc., the ultimate parent company of FMC Pembroke.

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. for the fiscal year ended December 31, 2011 and 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 64, the applicant provides the allowable charges per treatment for each payment source for BMA Lumberton as follows:

PAYOR	IN-CENTER
Commercial Insurance	\$1,375.00
Medicare	\$ 234.00
Medicaid	\$ 137.29
VA	\$ 146.79
Private Pay	\$1,375.00

On page 64, the applicant states that the commercial charges listed do not reflect actual reimbursement rates. 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 (\$234). This fee 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 Section X.2 - X.4, pages 65 - 69, the applicant projects revenues and expenses for FMC Pembroke as follows:

FMC PEMBROKE		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$2,431,889	\$2,601,441
Total Operating Costs	\$2,158,203	\$2,284,488
Net Profit	\$ 273,686	\$ 316,953

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, pages 60 - 71, for the applicant’s assumptions.

In summary, the applicant states that there are no capital and working capital costs for this project. In addition, the applicant adequately demonstrates 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 Pembroke proposes to add six in-center dialysis stations to its existing facility for a total of 19 in-center dialysis stations upon project completion. Currently there are two dialysis providers in Robeson County, BMA and DaVita. In addition, there are six dialysis facilities, five of which are operated by BMA. In Section V.7, on page 47, the applicant states:

“This proposal will not have any effect on competition within Robeson County. The patients to be served by this facility are existing dialysis patients, and future patients residing in western Robeson County.

The DaVita St. Pauls facility is approximately 20 road miles from the FMC Pembroke facility. In addition, there is another BMA facility closer to the DaVita facility. Consequently, this facility is not likely to be serving patients who might otherwise choose to receive dialysis treatment at the DaVita location.”

In addition, the July 2013 SDR shows there is a surplus of four dialysis stations in Robeson County; however, in this application, the applicant is applying for six additional stations based on the facility need methodology that is specific to this facility. The applicant adequately demonstrates the need for six additional stations at FMC Pembroke based on the number of in-center patients it proposes to serve. The July 2013 SDR reports that as of December 31, 2012, the FMC Pembroke facility was operating at 92.3% capacity, with 48 patients dialyzing on 13 stations [$48 / 13 = 3.69$; $3.69 / 4 = 0.9231$]. 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 19 in-center dialysis stations serving up to 61 dialysis patients at the end of Operating Year 1 (Calendar Year 2016), which is a utilization rate of 80% [$61 / 19 = 3.23$; $3.23 / 4 = 0.8026$]. Therefore, the application is conforming to the performance standard promulgated in 10A NCAC 14C .2203.

In addition, the aggregate utilization of BMA’s facilities in Robeson County is just under 80% [$291 \text{ patients} / 93 \text{ stations} = 3.13$; $3.13 / 4 = 0.782$]. See the following table:

FACILITY	NUMBER OF STATIONS	NUMBER OF PATIENTS	PATIENTS PER STATION	UTILIZATION
BMA of Red Springs*	14	39	2.78	69.6%
FMC Dialysis Services of Robeson	23	65	2.82	70.6%
FMC Pembroke	13	48	3.69	92.3%
BMA Lumberton	30	97	3.23	80.8%

FMC of St. Pauls*	13	42	3.23	80.8%
Total	93	291	3.13	78.2%

*Pursuant to Project ID#N-10067-12, FMC of St. Pauls was approved to relocate two of its existing in-center stations to the BMA of Red Springs facility. That project is under development.

Based on the utilization at the FMC Pembroke facility, combined with the county-wide utilization by BMA and the pending station transfers, the proposal by the applicant to add six in-center dialysis stations to the FMC Pembroke facility, for a facility total of 19 in-center stations is reasonable. Furthermore, the methodology used by the applicant to project utilization is based on credible and supported assumptions.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Robeson 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 54, the applicant provides projected staffing for FMC Pembroke upon project completion, which shows the addition of one FTE RN position to the current staff. See the following table:

FMC PEMBROKE FULL-TIME EQUIVALENT (FTE) POSITIONS	
RN	3.00
Tech	6.00
Clinical Mgr.	1.00
Area Mgr.	0.20
Dietician	0.30
Social Worker	0.30
Chief Tech	0.10
Equip Tech	0.25
In-Service	0.20
Clerical	0.75
Total FTEs	12.1

The applicant projects a total of 12.1 FTE positions upon project completion. In Section V.4(c), page 46, the applicant identifies the current Medical Director for FMC Pembroke as Dr. William Buchanan. In Exhibit 21 the applicant provides a letter from Dr. Buchanan indicating his 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, page 43, the applicant lists the providers of the necessary ancillary and support services that will provide service to FMC Pembroke. Exhibit 16 contains a copy of a hospital affiliation agreement with Scotland Memorial Hospital. Exhibit 17 contains documentation of an agreement with a transplantation center. In Section V.4(b), on page 46, the applicant provides a list of area physicians who support the proposed project. See also BMA's response to 10A NCAC 14C .2204, Section II, pages 20 - 21. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will continue to 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 49 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 Pembroke facility is comprised of the following:”

FACILITY	MEDICAID /LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Pembroke	24.4%	62.2%	62.2%	51.1%	91.1%

This Medicare percentage represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 62.2% of the facility treatment reimbursement is from Medicare.

In Section, VI.1(a) and VI.1(b), on pages 49 - 50, the applicant provides the current and projected payor mix for FMC Pembroke. The applicant expects no change in the current payor mix once this project is complete. See the following table:

SOURCE OF PAYMENT	% PAYMENT
Commercial Insurance	5.0%
Medicare	87.9%
Medicaid	2.5%
VA	4.6%
Total	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 Robeson County and statewide.

	CY 2010 Total # of Medicaid Eligibles as % of Total Population *	CY 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Robeson County	31%	13.2%	23.9%
Statewide	17%	6.6%	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 BMA Lumberton. In fact, only 5.8% of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina’s Network 6 were under the age of 35.

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 and 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states,

“Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”

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:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
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:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
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%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

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

The applicant demonstrates that medically underserved populations have adequate access to the dialysis services provided at BMA Lumberton. 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 53, the applicant states there have been no civil rights access complaints filed against FMC Pembroke or any BMA North Carolina 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 50, the applicant provides the projected payor mix for the proposed services at FMC Pembroke, as shown in the table below. The applicant projects no change from the current payor mix.

SOURCE OF PAYMENT	% PAYMENT
Commercial Insurance	5.0%
Medicare	87.9%
Medicaid	2.5%
VA	4.6%
Total	100.0%

The applicant adequately 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, page 52, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Fresenius Medical Care Pembroke 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 hospitals.”

The applicant adequately demonstrates that FMC Pembroke will 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, page 45, the applicant refers to Exhibit 19, which includes a letter to Robeson Technical Community College, inviting the Director of Nursing Education Services to include FMC Pembroke 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 Pembroke proposes to add six dialysis stations to its existing facility for a total of 19 in-center dialysis stations upon project completion.

The July 2013 SDR shows there is a surplus of four dialysis stations in Robeson County; however, in this application, the applicant is applying for six additional stations based on the facility need methodology. The applicant adequately demonstrates the need for six additional stations at FMC Pembroke based on the number of in-center patients it proposes to serve. The July 2013 SDR reports that as of December 31, 2012, the FMC Pembroke facility was operating at 92.3% capacity, with 48 patients dialyzing on 13 stations [$48 / 13 = 3.69$; $3.69 / 4 = 0.923$]. 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).

In Section V.7, pages 47 - 48, 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 that the DaVita dialysis facility (Saint Pauls) is approximately 20 road miles from FMC Pembroke. The applicant states its proposal to add six dialysis stations to its own facility will not adversely affect those patients who choose to dialyze at the DaVita or one of the other BMA facilities. In addition, the applicant states the two dialysis providers do not share nephrologists in Robeson County.

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 Pembroke will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need, based on the facility need methodology, to add six dialysis stations for a total of 19 certified in-center dialysis stations upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to FMC Pembroke dialysis patients;
- The applicant adequately demonstrates it 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 45 - 46), and VII (pages 54 - 57), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 49, the applicant states:

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

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Pembroke	24.4%	62.2%	62.2%	51.1%	91.1%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 62.2% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI.1(a), page 49, that BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations.

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 Pembroke. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Pembroke 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 11, the applicant states the utilization rate was 92.3% or 3.69 patients per station ($48 / 13 = 3.69$).
- (2) *Mortality rates;*
 - C- In Section II.1, page 11, the applicant states the mortality rates were 0.0%, 19.5% and 15.7% in 2010, 2011 and 2012, respectively.

- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-NA- In Section II.3, page 11, the applicant states FMC Pembroke does not offer home training; those patients who are candidates for home training are referred to BMA Lumberton.
- (4) *The number of transplants performed or referred;*
-C- In Section II.1, page 11, the applicant states FMC Pembroke referred one transplant in 2011 and two in 2012. Two transplants were actually performed in 2012 (no transplants were performed in 2011).
- (5) *The number of patients currently on the transplant waiting list;*
-C- In Section II.1, page 11, the applicant states FMC Pembroke has three patients currently 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 95 hospital admissions in 2012, 26 of which were dialysis related and 69 that 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 that there were no patients at the facility in 2011 or 2012 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 Pembroke is an existing facility. The applicant, however, provides a copy of the hospital affiliation agreement it currently has with Southeastern Regional Medical Center in Exhibit 16.
- (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 Pembroke is an existing facility.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- FMC Pembroke 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- See Exhibit 12 for a copy of the Emergency/Disaster Manual (which has policies and procedures for back-up electrical service in the event of a power outage) for FMC Pembroke.

- (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 Pembroke 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 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 Pembroke.”*

- (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 13 - 16, and Section III.7, pages 36 - 39, 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 PERCENT OF TOTAL	
	IN-CTR.	IN-CTR.	YEAR 1	YEAR 2
Robeson	61.8	65.8	100.0%	100.0%
Total	61.8	65.8	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 Pembroke 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, page 16, 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 Pembroke does not propose to establish a new End Stage Renal Disease 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 Pembroke projects utilization of 80.3%, with 3.21 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 17 - 19, and Section III.7, pages 36 - 39. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

(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 - 19, and Section III.7, pages 36 - 39. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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 20, the applicant states, *“Patients will be referred to Southeastern Regional Medical Center.”*

(2) *maintenance dialysis;*

-C- In Section II.1, page 20, the applicant states, *“The facility will provide in-center dialysis.”*

(3) *accessible self-care training;*

C- In Section II.1, page 20, the applicant states, *“Patients desiring self care training will be referred to the BMA Lumberton home training department for training and follow-up care.”*

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

C- In Section II.1, page 24, the applicant states, *“Patients desiring to dialyze at home will be referred to the BMA Lumberton [sic] home training department.”*

(5) *x-ray services;*

C- In Section II.1, page 20, the applicant states, *“Patients will be referred to Southeastern Regional Medical Center.”*

(6) *laboratory services;*

-C- In Section II.1, page 20, the applicant states, *“BMA provides on site laboratory services through contract with Spectra Labs.”* See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.

(7) *blood bank services;*

-C- In Section II.1, page 20, the applicant states, *“Patients in need of blood transfusion will be referred to Southeastern Regional Medical Center.”*

(8) *emergency care;*

-C- In Section II.1, page 20, 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 Scotland General Hospital [sic], emergency services are summoned via phone call to 911.”*

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

-C- In Section II.1, page 24, the applicant states, *“Patients in need of hospital admission will be referred to Southeastern Regional Medical Center or Scotland Memorial Hospital in Laurinburg. The facility has agreements with both hospitals.”*

- (10) *vascular surgery for dialysis treatment patients;*
-C- In Section II.1, page 21, the applicant provides a list of vascular surgeons in the area to whom the patient would be referred. The applicant states it would be the patient's choice.
- (11) *transplantation services;*
-C- In Section II.1, page 21, the applicant refers to Exhibit 17, in which it provides a copy of an existing transplantation agreement.
- (12) *vocational rehabilitation counseling and services; and*
-C- In Section II.1, page 21, the applicant states, "*Patients in need of vocational rehabilitation services will be referred to the Robeson County Department of Social Services for referral to Vocational Rehabilitation.*"
- (13) *transportation.*
-C- In Section II.1, page 25, the applicant states, "*Transportation services will be provided by Southeastern Area Transportation Services, SEATS.*"

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 21, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 55, 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, pages 21 - 22, and Section VII.5, page 55, 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, 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 14 contains an outline of the training program and Exhibit 15 contains the outline of the continuing education information.