

## 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-10195-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit (BMA Lumberton) / Add 3 in-center dialysis stations to existing facility for a facility total of 33 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.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit (BMA Lumberton) is currently certified for 30 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 three (3) in-center dialysis stations to the existing facility for a facility total of 33 in-center dialysis stations upon completion of this project.

The July 2013 SDR reports that as of December 31, 2012 there were 29 dialysis stations at the BMA Lumberton facility; however, the facility data that was reported by the applicant to the North Carolina State Medical Facilities Planning Section was inaccurate. In Exhibit 1, the applicant provides correspondence dated June 28, 2011 from the North Carolina Acute and Home Care Licensure and Certification Section that confirms that the BMA Lumberton facility is certified for and currently operates 30 in-center dialysis stations.

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, BMA Lumberton is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.32 patients per station, or 80%. This utilization rate was calculated based on 97 in-center dialysis patients and 30 certified dialysis stations as of December 31, 2012 (97 patients / 30 stations = 3.32 patients per station).

**OCTOBER 1 REVIEW-JULY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		80.8%
Certified Stations		30
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>30</b>
In-Center Patients as of 12/31/12 (SDR2)		97
In-Center Patients as of 6/30/12 (SDR1)		86
Step	Description	
(i)	Difference (SDR2 - SDR1)	11
	Multiply the difference by 2 for the projected net in-center change	22
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.2558
(ii)	Divide the result of Step (i) by 12	0.0213
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.2558
(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	121.8140
(v)	Divide the result of Step (iv) by 3.2 patients per station	38.0669
	and subtract the number of certified and pending stations as recorded in SDR2 [30] 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 BMA Lumberton facility has a need for eight additional stations. The applicant proposes to add three new stations and, therefore, the application is consistent with the facility need determination for dialysis stations. [If the analyst were to use 29 in-center patients to calculate the utilization for purposes of the Facility Need Methodology, the applicant would be eligible to apply for 9 stations rather than 8]. Thus, at the completion of this project, BMA Lumberton will be certified for 33 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 27, 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 28, 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 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 28 - 29, 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 91.0% of the in-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 1.9% are expected to be covered by VA. Thus, 92.9% of the In-Center revenue is derived from government payors. These projections reflect the current payor mix at BMA Lumberton 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 57 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 VIII.1(c), the applicant states it will not incur any capital or operating costs with this project, since it leases dialysis machines and this proposal is to add three stations to an existing facility.

In addition, in Section XI6(d), page 81, 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 no projected capital cost for the project.

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.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit (BMA Lumberton) proposes to add three in-center dialysis stations to the existing facility, pursuant

to the facility need determination, for a facility total of 33 stations upon completion of this project. The July 2013 SDR reports that as of December 31, 2012 there were 29 dialysis stations at the BMA Lumberton facility; however, in Exhibit 1, the applicant provides correspondence dated June 28, 2011 from the Acute and Home Care Licensure and Certification Section, DHSR, which confirms that the BMA Lumberton facility has 30 in-center dialysis stations. The applicant states inaccurate data regarding facility census was inadvertently reported to the State Medical Facilities Planning Branch. In this application, the applicant projects facility utilization based upon both 29 in-center dialysis stations and 30 in-center dialysis stations. Since the information from the Acute and Home Care Licensure and Certification Section, DHSR, confirms 30 in-center dialysis stations, the analyst reviewed the application based upon a facility total of 30 in-center dialysis stations at BMA Lumberton.

Population to be Served

In Section III.7, page 46 of the application, the applicant projects the following payor mix:

COUNTY	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR.	PD	HOME	IN-CTR.	PD	HOME	YEAR 1	YEAR 2
Robeson	107.4	12.6	3.156	110.2	13.0	3.24	94.6%	94.8%
Bladen	6	0	0	6	0	0	4.6%	4.5%
Columbus	1	0	0	1	0	0	0.8%	0.7%
Total	114.4	12.6	3.2	117.2	13.0	3.2	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section II.7, pages 13 - 18, Section III pages 39 - 46, the applicant provides the assumptions and methodology it used to project its need for three additional dialysis stations at the BMA Lumberton facility, based on the facility need methodology. The applicant projects utilization based on 29 in-center dialysis stations and 30 in-center dialysis stations at the facility. The analyst reviewed the application based on 30 in-center dialysis stations at BMA Lumberton, as discussed above. On pages 39 - 40, the applicant states,

*“Based upon the Certification Letter contained within Exhibit 1 of this application, BMA believes the number of stations at BMA Lumberton is actually 30 stations rather than the 29 indicated within Table A of the SDR.*

*The information regarding the number of dialysis stations is incorrect. The facility was certified for 30 dialysis stations effective May 9, 2011. BMA is unsure as to the source of the error as reported within the current SDR. Regardless, the facility utilization on December 30, 2012 exceeded the 80% threshold to qualify for this Facility Need Expansion.*

*Based upon 97 dialysis patients dialyzing on 30 dialysis stations at December 31, 2012, the correct utilization was:*

*97 patients dialyzing on 30 stations = 3.23 patients per station  
 $97 / (4 \times 30) = .808$ , or 80.8%*

*Despite the error, the facility remains eligible to apply for additional stations using the Facility Need Methodology. Facility Need Calculations using the SDR number of 29 stations would allow BMA to apply for up to nine additional stations. Calculations using the true number of 30 dialysis stations allow BMA to apply for up to eight additional stations. This is an application for only three additional stations.”*

On pages 43 – 46, the applicant provides the following assumptions:

- 1. This project is scheduled for completion June 30, 2014. Operating Year 1: July 1, 2014 through June 30, 2015. Operating Year 2: July 1, 2015 through June 30, 2016*
- 2. The July 2013 SDR reports the utilization rate for BMA Lumberton as 83.62% with 97 patients dialyzing on 29 dialysis stations, or 3.3448 patients per station.*

*The information regarding the number of dialysis stations is incorrect. The facility was certified for 30 dialysis stations effective May 9, 2011. BMA is unsure as to the source of the error as reported within the current SDR. Regardless, the facility utilization on December 30, 2012 exceeded the 80% threshold to qualify for this Facility Need Expansion.*

*Based upon 97 dialysis patients dialyzing on 30 dialysis stations at December 31, 2012, the correct utilization was:*

*97 patients dialyzing on 30 stations = 3.23 patients per station  
 $97 / (4 \times 30) = .808$ , or 80.8%*

- 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%). [emphasis in original] Rather, BMA will use a growth rate of 2.6%.*

*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 BMA Laurinburg 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. *As of June 30, 2013 BMA Lumberton was serving seven in-center patients from Bladen and Columbus Counties. BMA will not project growth for this segment of the facility census. Both Bladen and Columbus Counties have dialysis facilities. BMA assumes that these patient [sic] dialyze with BMA Lumberton as a function of patient choice. In projections of future patient populations to be served at BMA Lumberton, BMA will simply add these patients to the facility census at appropriate points in time.*
5. *As of June 30, 2013 BMA Lumberton was serving one home dialysis patient from Bladen County. BMA will not project growth for this segment of the facility census. As noted Bladen County has a dialysis facility. Futhermore, [sic] BMA has filed a CON application seeking approval to develop a free standing home Peritoneal Dialysis facility in Elizabethtown, Bladen County (CON Project ID # N-10153-13). In that application, BMA assumed that home patients of Bladen County would transfer their care to the new facility. Thus, in order to remain consistent with past projections, BMA must continue that assumption. Therefore, BMA will not project to serve home patients from Bladen County in this application.*

*This should not be construed to suggest that BMA will restrict admissions to the facility. BMA will accept any patient with appropriate referral from a physician with admitting privileges at the facility.*

*The point of this assumption is to remain consistent with past representations by BMA and to not overstate projections of patients to be served and resultant projections of revenues and expenses.*

*CON Project ID # M-10153-13 was projected to be certified as of June 30, 2014. Thus, BMA will continue representations of the Bladen County home patient in the current year projections but will not reflect that patient in Operating Years 1 and 2 projections.*

6. *BMA notes that the census has increased from 97 on December 31, 2012 to 109 in-center patients as of June 30, 2013. The following table identifies the June 30, 2013 census by county of residence and dialysis modality.”*

COUNTY	JUNE 30, 2014*		
	IN-CENTER	PD	HOME HEMO
Robeson	102	12	3
Bladen	6	1	0
Columbus	1	0	0



Total	109	13	3
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\*In the table on page 44 of the application, the date given is June 30, 2013; however, based on the applicant's assumptions, the analyst concludes that it is a typographical error and the correct date is June 30, 2014.

Project ID #N-10153-13, to which the applicant refers, was conditionally approved by the CON Section and a certificate of need was issued with an effective date of December 6, 2013.

BMA filed another application for an increase in dialysis stations in Robeson County simultaneously with this application (FMC Pembroke, Project ID# N-10194-13). 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.

The following table illustrates projected growth in the in-center patient population at FMC Lumberton, as calculated by the applicant on page 45 of the application:

Begin with 102 Robeson County in-center dialysis patients as of June 30, 2013.	102
Project forward 12 months to June 30, 2014 using a 2.6% growth rate.	$102 \times 1.026 = 104.7$
Add 7 patients from Bladen and Columbus Counties. This is the beginning census projected for the facility.	$104.7 + 7 = 111.7$
Project the Robeson County in-center patient population forward 12 months to June 30, 2015, using 2.6% growth rate.	$104.7 \times 1.026 = 107.4$
Add 7 patients from Bladen and Columbus Counties. This is the end of Operating Year 1.	$107.4 + 7 = 114.4$
Project the Robeson County in-center patient population forward 12 months to June 30, 2016, using a 2.6% growth rate.	$107.4 \times 1.026 = 110.2$
Add 7 patients from Bladen and Columbus Counties. This is the end of Operating Year 2.	$110.2 + 7 = 117.2$

In its assumptions, the applicant states it projects utilization using a growth rate of 2.6%. The calculations in the table above are a result of using a 2.6% growth rate. In the table within the application, however, the applicant shows a multiplier of 2.3%, not 2.6% as it states. The analyst concludes this is a typographical error, since all the calculations are in fact made using 2.6%, as shown in the table above.

With regard to home hemodialysis services and PD training and support, the applicant provides the following assumptions in Section III, on pages 45 – 46. The applicant states:

*“BMA projects future home patient population in similar manner. The notable difference is that BMA does not project to serve home patients from other counties at BMA Lumberton. Again, this is not an indication that BMA will deny treatment and*

*care to patients residing in other counties, but simply a statement that BMA is not expecting, and therefore not projecting, to serve home patients residing in counties other than Robeson.”*

The applicant’s projections for the number of home hemo-dialysis patients are provided in the following table:

Begin with 3* Robeson County home hemo-dialysis patients served as of June 30, 2013	3
Project that population forward to June 30, 2014 using a growth rate of 2.6**%	$3 \times 1.026 = 3.08$
Project that population forward to June 30, 2015 using a growth rate of 2.6%	$3.08 \times 1.026 = 3.15$
Project that population forward to June 30, 2016 using a growth rate of 2.6%	$3.15 \times 1.026 = 3.24$

\*The applicant states “12” patients in this section of the table in the application; however, the analyst concludes it is a typographical error.

\*\*As noted in Criterion (3) and elsewhere in these findings, the applicant states it uses a 2.3% growth rate in these tables; however, in the assumptions provided in Sections II and III, and the actual calculations, the applicant uses a growth rate of 2.6%

The applicant’s projections for the number of home PD patients are provided in the following table:

Begin with 12 Robeson County home PD patients served as of June 30, 2013	12*
Project that population forward to June 30, 2014 using a growth rate of 2.6**%	$12 \times 1.026 = 12.3$
Project that population forward to June 30, 2015 using a growth rate of 2.6%	$12.3 \times 1.026 = 12.63$
Project that population forward to June 30, 2016 using a growth rate of 2.6%	$12.63 \times 1.026 = 13.0$

\*In the table in the application on page 45, the applicant states 102 in this part of the table. The analyst concludes this is a typographical error.

\*\*As noted in Criterion (3) and elsewhere in these findings, the applicant states it uses a 2.3% growth rate in these tables; however, in the assumptions provided in Sections II and III, and the actual calculations, the applicant uses a growth rate of 2.6%

The applicant projects the following mix of in-center, home hemo-dialysis and home PD patients for BMA Lumberton following the addition of three stations:

COUNTY	OPERATING YEAR 1			OPERATING YEAR 2			COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CTR	PD	HOME HEMO	IN-CTR	PD	HOME HEMO	YEAR 1	YEAR 2
Robeson	107.4	12.6	3.156	110.2	13.0	3.24	94.6%	94.8%
Bladen	6	0	0	6	0	0	4.6%	4.5%
Columbus	1	0	0	1	0	0	0.8%	0.7%

Total	114.4	12.6	3.156	117.2	13.0	3.24	100.0%	100.0%
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In Operating Year One, the applicant projects to serve 114 in-center patients on 33 stations, which is 3.4 patients per station, or 86% of capacity [114 / 33 = 3.45; 3.45 / 4 = 0.863]. Likewise, in Operating Year Two, the applicant projects to serve 117 in-center patients on 33 stations, which is 3.5 patients per station, or 88% of capacity [117 / 33 = 3.54; 3.54 / 4 = 0.886]. 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). The applicant bases its assumptions on historical utilization at BMA Lumberton, and a growth rate of 2.6%. 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 Exhibit 30, Appendix E, the applicant provides a copy of Table B from the July 2013 SDR, which confirms an AACR of 1.3% in Robeson County. In that same Exhibit, Appendix F, the applicant provides “*Revised Table B Calculations for Affected Counties: Edgecombe, Nash, Scotland, Halifax, Wilson, Warren, Robeson, Richmond (Prepared by BMA).*” The calculations provided in that table are based upon the information regarding the data reporting errors and the corrections that the applicant submitted to the Medical Facilities Planning Branch. In that table, the applicant proposes that the corrected Five Year AACR for Robeson County, based on corrected patient data reported by BMA is 2.6%, as shown in the applicant’s calculations in its need methodology and assumptions.

Furthermore, the assumptions are based on projected growth of only Robeson County patients, to which the applicant then added the remaining patients who currently receive dialysis services at BMA Lumberton, but who reside in a county other than Robeson. It is possible that additional patients from those other counties (Bladen and Cumberland) could also choose to dialyze at BMA Lumberton, and thus the patient census from outside Robeson County could also grow. However, since the applicant’s growth projections include only Robeson County residents, the numbers are reasonable. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

**Access to Services**

In Section VI, pages 57 - 61, 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 92% 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.

CA

In Section III.9, pages 47 - 48, 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 in Robeson County; in particular, at BMA Lumberton. 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 BMA Lumberton. In the application, the applicant refers to utilization rates at the FMC Pembroke facility. The analyst concludes this is a typographical error and the applicant was in fact referring to the BMA Lumberton facility.
- 3) Add three stations: BMA chose this alternative as most effective and least costly to meet the growing demand for services at BMA Lumberton.

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 Lumberton Dialysis Unit (BMA Lumberton) shall materially comply with all representations made in the certificate of need application.**
  - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit (BMA Lumberton) shall develop and operate no more than three additional stations for a total of nor more than 33 certified in-center dialysis stations, which shall include any isolation stations, following completion of this project.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit (BMA Lumberton) shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 33 dialysis stations which shall include any isolation stations**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit (BMA Lumberton) 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, pages 65 - 66, the applicant states that BMA will not incur a capital cost to develop this project. In Section IX.3, page 69, the applicant likewise projects no working capital (start-up and initial operating expenses) associated with the proposed project.

Exhibit 24 includes a September 16, 2013 letter from the Vice President of Fresenius Medical Care North America, which states in part:

*“BMA proposes to add three dialysis stations to its BMA Laurinburg [sic] facility for a facility total of 33 dialysis stations upon completion of this project[.] The project does not require any capital costs on behalf of BMA.”*

In the letter, the applicant refers to the BMA Laurinburg facility; however, the analyst concludes this is a typographical error and the reference was intended to be to the BMA Lumberton facility. The Agency is aware that BMA typically prepares many applications simultaneously and it is reasonable that an occasional typographical error caused by the inadvertent transfer of words from one application to another would occur, notwithstanding editing by the applicant.

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).

In Section X.1, page 70, the applicant provides the allowable charges per treatment for each payment source for BMA Lumberton as follows:

<b>BMA LUMBERTON ALLOWABLE CHARGES PER TREATMENT</b>			
<b>PAYOR</b>	<b>IN-CENTER</b>	<b>HOME PD</b>	<b>HOME HEMO</b>
Commercial Insurance	\$1,375.00	\$1,375.00	\$1,375.00
Medicare	\$ 234.00	\$ 234.00	\$ 234.00
Medicaid	\$ 137.29	\$ 137.29	\$ 137.29
VA	\$ 146.79	\$ 146.85	\$ 146.85
Private Pay	\$1,375.00	\$1,375.00	\$1,375.00

On page 70, 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 71 - 79, the applicant projects revenues and expenses for BMA Lumberton as follows:

<b>BMA LUMBERTON</b>		
	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$4,773,099	\$4,925,365
Total Operating Costs	\$4,334,589	\$4,453,972
<b>Net Profit</b>	<b>\$ 438,510</b>	<b>\$ 471,393</b>

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 70 - 79, 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 BMA Lumberton proposes to add

three in-center dialysis stations to its existing facility for a total of 33 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 55, the applicant states:

*“The DaVita St. Pauls facility is approximately 12 road miles from the BMA Lumberton 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 three additional stations based on the facility need methodology that is specific to this facility. The applicant adequately demonstrates the need for three additional stations at BMA Lumberton based on the number of in-center patients it proposes to serve. The July 2013 SDR reports that as of December 31, 2012, the BMA Lumberton facility was operating at 83.6% capacity, with 97 patients dialyzing on 29 stations [ $97 / 29 = 3.34$ ;  $3.34 / 4 = 0.8362$ ]. In Sections II and III of the application, and in Exhibit 30, the applicant provides information to illustrate that the data reported in the July 2013 SDR was in error, and that the BMA Lumberton facility in fact currently operates 30 in-center dialysis stations. Therefore, the utilization of the BMA Lumberton facility as of December 31, 2012, the last reporting period for the July 2013 SDR, is actually 80.8%, with 97 in-center patients dialyzing on 30 in-center stations [ $97 / 30 = 3.23$ ;  $3.23 / 4 = 0.808$ ]. 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 33 in-center dialysis stations serving up to 114 dialysis patients at the end of Operating Year 1 (7/1/2014 - 6/30/2015), which is a utilization rate of 86% [ $114 / 33 = 3.45$ ;  $3.45 / 4 = 0.863$ ]. 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 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 62, the applicant provides projected staffing for BMA Lumberton upon project completion, which is the same as the current staffing at the facility. See the following table:

<b>BMA LUMBERTON</b>
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<b>FULL-TIME EQUIVALENT (FTE) POSITIONS</b>	
RN	5.00
Tech	10.00
Clinical Mgr.	1.00
Area Mgr.	0.20
Home Training Nurse	1.50
Dietician	0.75
Social Worker	0.75
Chief Tech	0.33
Equip Tech	1.00
In-Service	0.25
Clerical	1.00
<b>Total FTEs</b>	<b>21.78</b>

The applicant projects a total of 21.78 FTE positions upon project completion. In Section V.4(c), page 54, the applicant identifies the current Medical Director for BMA Lumberton as Dr. Kenneth Melton. In Exhibit 21 the applicant provides a letter from Dr. Melton 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 51, the applicant lists the providers of the necessary ancillary and support services that will provide service to BMA Lumberton. Exhibit 16 contains a copy of a hospital affiliation agreement with Southeastern Regional Medical Center. Exhibit 17 contains documentation of an agreement with a transplantation center. In Exhibit 21 the applicant provides referral letters from area physicians offering their support for the proposed project. See also BMA's response to 10A NCAC 14C .2204, Section II, pages 24 - 25. 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 57 the applicant states:

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

FACILITY	MEDICAID /LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Lumberton	13.6%	28.8%	67.2%	57.6%	68.0%

This Medicare percentage represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 67.2% of the facility treatment reimbursement is from Medicare.

In Section, VI.1(a) and VI.1(b), on page 58, the applicant provides the current and projected payor mix for BMA Lumberton. The applicant expects no change in the current payor mix once this project is implemented. See the following table:

SOURCE OF PAYMENT	IN-CENTER	HOME
Commercial Insurance	7.1%	32.1%
Medicare	81.9%	67.9%
Medicaid	9.1%	0.0%
VA	1.9%	0.0%
Total	100.0%	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 is 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:

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

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

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

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%

55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

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 61, the applicant states there have been no civil rights access complaints filed against BMA Lumberton 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 58, the applicant provides the projected payor mix for the proposed services at BMA Lumberton, as shown in the table below. The applicant projects no change from the current payor mix.

SOURCE OF PAYMENT	IN-CENTER	HOME
Commercial Insurance	7.1%	32.1%
Medicare	81.9%	67.9%
Medicaid	9.1%	0.0%
VA	1.9%	0.0%
Total	100.0%	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 60, the applicant states,

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Lumberton 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 BMA Lumberton 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 53, the applicant refers to Exhibit 19 which includes a letter to Robeson Technical Community College inviting the Director of Nursing Education Services to include BMA Lumberton 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 BMA Lumberton proposes to add three dialysis stations to its existing facility for a total of 33 in-center dialysis stations upon project completion.

The July 2013 SDR shows there is a surplus of four dialysis stations in Lumberton County; however, in this application, the applicant is applying for three additional stations based on the facility need methodology. The applicant adequately demonstrates the need for three additional stations at BMA Lumberton based on the number of in-center patients it proposes to serve. The July 2013 SDR reports that as of December 31, 2012, the BMA Lumberton facility was operating at 83.6% capacity, with 97 patients dialyzing on 29 stations [ $97 / 29 = 3.34$ ;  $3.34 / 4 = 0.8362$ ]. In Sections II and III of the application, and in Exhibit 30, the applicant provides information to illustrate that the data reported in the July 2013 SDR was in error, and that the BMA Lumberton facility in fact currently operates 30 in-center dialysis stations. Therefore, the utilization of the BMA Lumberton facility as of December 31, 2012, the last reporting period for the July 2013 SDR, is actually 80.8%, with 97 in-center patients dialyzing on 30 in-center stations [ $97 / 30 = 3.23$ ;  $3.23 / 4 = 0.808$ ]. 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 55 - 56, 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 12 road miles from BMA Lumberton. The applicant states its proposal to add three 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 BMA Lumberton 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 three dialysis stations for a total of 33 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 BMA Lumberton 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 51 - 55), and VII

(pages 62 - 64), 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 45, the applicant states:

*“It is clear that BMA Lumberton 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 BMA services, as illustrated below.

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
BMA Lumberton	13.6%	28.8%	67.2%	57.6%	68.0%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 67.2% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI.1(a), page 57, 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 BMA Lumberton. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Lumberton 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 80.8% or 3.23 patients per station ( $97 / 30 = 3.5$ ). See Exhibit 30.
- (2) Mortality rates;  
-C- In Section II.1, page 11, the applicant states the mortality rates were 22.1%, 15.2% and 13.0% in 2010, 2011 and 2012, respectively.
- (3) The number of patients that are home trained and the number of patients on home dialysis;  
-C- In Section II.3, page 12, the applicant states it currently has nine home trained patients at the time the application was filed.
- (4) The number of transplants performed or referred;  
-C- In Section II.1, page 12, the applicant states BMA Lumberton referred six transplants in 2011 and eight in 2012. Six transplants were actually performed in 2011 and three in 2012.
- (5) The number of patients currently on the transplant waiting list;  
-C- In Section II.1, page 12, the applicant states BMA Lumberton has four 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 269 hospital admissions in 2012, 52 of which were dialysis related and 217 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- BMA Lumberton 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- BMA Lumberton is an existing facility.

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

-NA- BMA Lumberton 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 BMA Lumberton.

*(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- BMA Lumberton 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 BMA Lumberton.”

(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 - 17, and Section III.7, pages 42 - 46, 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 PERCENT OF TOTAL	
	IN-CTR	PD	HOME HEMO	IN-CTR	PD	HOME HEMO	YEAR 1	YEAR 2
Robeson	107.4	12.6	3.156	110.2	13.0	3.24	94.6%	94.8%
Bladen	6	0	0	6	0	0	4.6%	4.5%
Columbus	1	0	0	1	0	0	0.8%	0.7%
Total	114.4	12.6	3.156	117.2	13.0	3.24	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- BMA Lumberton 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 18, 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.”

*(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- BMA Lumberton 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- BMA Lumberton projects utilization of 86.4%, with 3.45 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 19 - 21, and Section III.7, pages 42 - 46. 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 19 - 21, and Section III.7, pages 42 - 46. 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 24, the applicant states, “Patients will be referred to Southeastern Regional Medical Center.”

*(2) maintenance dialysis;*

-C- In Section II.1, page 24, the applicant states, “The facility will provide in-center dialysis.”

*(3) accessible self-care training;*

-C- In Section II.1, page 24, 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 home training department.*”
- (5) *x-ray services;*
- C- In Section II.1, page 24, the applicant states, “*Patients will be referred to Southeastern Regional Medical Center.*”
- (6) *laboratory services;*
- C- In Section II.1, page 24, 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 24, 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 24, 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, 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.*”
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section II.1, page 25, 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 25, the applicant refers to Exhibit 17, in which it provides a copy of an existing transplantation agreement with East Carolina University School of Medicine / Pitt County Memorial Hospital.
- (12) *vocational rehabilitation counseling and services; and*
- C- In Section II.1, page 25, 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 25, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 63, 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 25, and Section VII.5, page 63, 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.