

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS  
C = Conforming  
CA = Conditional  
NC = Nonconforming  
NA = Not Applicable

DECISION DATE: January 23, 2012  
PROJECT ANALYST: Gregory F. Yakaboski  
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: Project I.D. #N-8751-11 / Bio-Medical Applications of North Carolina, Inc., d/b/a FMC St. Pauls / Add 4 dialysis stations to the existing facility for a total of 14 stations upon completion of this project / 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 St. Pauls ("FMC St. Pauls") proposes to add four dialysis stations to the existing facility for a total of 14 stations upon project completion. The project is scheduled for completion December 31, 2012.

The 2011 State Medical Facilities Plan (2011 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2011 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC St. Pauls in the July 2010 SDR is 3.50 patients per station. This utilization rate was calculated based on 35 in-center dialysis patients and 10 certified dialysis stations as of December 31, 2010 (35 patients / 10 stations = 3.5 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/10		88.0%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 12/31/10 (SDR2)		35
In-Center Patients as of 6/30/10 (SDR1)		31
Difference (SDR2 - SDR1)		4
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/10	0.2581
(ii)	Divide the result of Step (i) by 12	0.0215
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2011 SDR (12/31/10) until the end of calendar year 2011 (12 months)	0.2581
(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	44.0323
(v)	Divide the result of Step (iv) by 3.2 patients per station	13.7601
	and subtract the number of certified and pending stations as recorded in SDR2 [20] to determine the number of stations needed	4

Step C of the facility need methodology states *“The facility may apply to expand to meet the need established in (2)(B)(v) [Step (v) in the table above], up to a maximum of ten stations.”* Based on the facility need methodology for dialysis stations, the number of stations needed is four and the applicant proposes to add no more than four new stations.

Therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2011 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 application Section II.1, page 21, the applicant states:

*“BMA is a high quality health care provider.*

...

*In addition, 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.”*

In application Section II.3, pages 28-30, the applicant describes the methods it uses to ensure and maintain quality of care which include the following:

*Facility programs*

- 1) Quality Improvement Program;*
- 2) Staff Orientation and Training; and*
- 3) In-service Education*

*Corporate programs*

- 1) Technical Audits;*
- 2) Continuous Quality Improvement*

*External Surveys - DFS Certification Surveys  
Core Indicators of Quality; and  
Single Use Dialyzers”*

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

**Promote Equitable Access**

In Section II.1, page 22, 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 81.8% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 10.6% are expected to be covered by VA. Thus, 86.2% of the In-Center revenue is derived from government payors.*

*10A NCAC 2202 (b)(8) requires a commitment by BMA ‘to admit and provide 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.’ BMA provides such assurances within Section VI of this application.*

...

*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. The July 2011 SDR reports that Robeson County ESRD patient population is growing at an Average Annual Rate of 1.9%. As the dialysis patient population of Robeson County continues to increase, the need for dialysis stations will continue to increase. Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis more convenient to the patient. This application to add four dialysis stations to FMC St. Pauls is another example of BMA efforts to meet the needs of the ESRD patient population of Robeson County. BMA is planning to add four stations so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this area of Robeson County.”*

In application Section VI.1 (a), page 43, 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.*

*BMA of St. Pauls and BMA of North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare represented 80.3% of North*

*Carolina dialysis treatments in BMA facilities in FY 2010. Medicaid treatments represented an additional 4.3% of treatments in BMA facilities for FY 2010. Low income and medically underinsured persons will continue to have access to all services provided by BMA.*

*The facility will conform to the North Carolina State Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies."*

In Section VI.2, page 46, the applicant states,

*"The design of the facility is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It was constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk."*

In Section VI.7, pages 46-47, the applicant states,

*"BMA's admission policy states that 'patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients' attending physician. No arbitrary criteria with respect to the patient's age or magnitude of complicating medical problems are established.'*

*BMA also has an AIDS policy that states 'a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.'*

*Please see Exhibit 9 for a copy of policy/procedure."*

The applicant adequately demonstrates that medically underserved groups will have equitable access to the proposed services.

### **Maximize Healthcare Value**

In Section II.1, page 22, the applicant states,

*"BMA is projecting a capital expenditure of \$17,776 for this project. This expenditure is necessary in the normal course of business. BMA is not seeking State or Federal monies to develop the facility; BMA is not seeking charitable contributions to develop this facility. 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 close to the patient homes. ...”*

In Section III.9, pages 35, the applicant states

*“Expansion via Facility Need Methodology is the best option for sustaining service to the patients of this area. Costs are not just those costs to the facility, but also include costs to the patient, and to some degree the transportation agencies providing transportation services for the patients. BMA has considered likely alternatives to this proposal and has selected the most cost effective overall alternative.”*

The applicant adequately demonstrates the 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.

Policy Gen-4: Energy Efficiency and Sustainability for Health Service Facilities of the 2011 SMFP states *“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.”* The capital cost of the proposed project is \$17,776. Therefore, Policy Gen-4 is not applicable.

The application is consistent with Policy GEN-3 and is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

## C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls proposes to add four dialysis stations to the existing facility for a total of 14 stations upon project completion.

### **Population to be Served**

In Section IV.1, page 36, the applicant identifies the patient population it currently serves, as illustrated in the table below.

County	In-Center patients
Robeson	38
<b>Total</b>	<b>38</b>

In Section III.7, pages 33-34, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

County	Year 1		Year 2		County Patients as a Percent of Total	
	Home Dialysis	In-Center	Home Dialysis	In-Center	Year 1	Year 2
Robeson	0	45	0	46	100.0%	100.0%
<b>Total</b>	<b>0</b>	<b>45</b>	<b>0</b>	<b>46</b>	<b>100.0%</b>	<b>100.0%</b>

In Section III.7, page 34, the applicant states that “*Facility station utilization rates are calculated using whole patients; BMA has rounded down to the whole patient...*” The applicant adequately identified the population to be served.

**Need Analysis**

The applicant projects to serve 45 in-center patients or 3.21 patients per station ( $45/14 = 3.21$ ) by the end of Year 1 and 46 in-center patients or 3.29 patients per station ( $46/14 = 3.285$ ) by the end of Year 2 for the proposed 14-station facility. This exceeds the minimum of 3.2 patients per station per week as required by rule 10A NCAC 14C .2203(b).

The assumptions and methodology used to project the in-center utilization are provided in Section III.7, pages 32-34. On page 32, the applicant details the assumptions and methodology utilized to project utilization.

*“ Assumptions:*

1. *FMC St. Pauls is currently operating at 95% capacity with a census of 38 patients dialyzing on 10 certified dialysis stations. BMA does not project to operate a third dialysis shift at FMC St. Pauls due to a lack of patient interest.*
2. *BMA assumes that the patient population of FMC St. Pauls will increase at a rate commensurate with the Robeson County Five Year Average Annual Change Rate as published in the July 2011 SDR. That rate is: 1.9%.*
3. *FMC St. Pauls qualifies for additional stations using the Facility Need Methodology. The facility need calculations are included in response to III.2 above.*
4. *BMA has included 4 letters of support from patients dialyzing in other BMA facilities in Robeson and Cumberland County. Each of these patients resides closer to the FMC St. Pauls facility than to their current dialysis facility. BMA conservatively*

*projects that six patients will actually transfer to the facility upon completion of this expansion project.*

5. *BMA projects that this four station expansion will be completed and certified by December 31, 2012. Operating Year 1 is the period from January 1, 2013 through December 31, 2013. Operating Year 2 is the period from January 1, 2014 through December 31, 2014.*

*Methodology:*

*BMA will project growth of the Robeson County patient population at FMC St. Pauls by using the Robeson County Five Year Average Annual Change Rate."*

The table below illustrates the applicant's assumptions and methodology used to project utilization, as provided on page 34.

	<i>In-Center</i>
<i>BMA begins with the Robeson County patients at FMC St. Pauls as of June 30, 2011.</i>	38
<i>This patient population is projected forward for six months using the Robeson County Five Year Average Annual Change Rate to produce a calculated census of Robeson County patients for December 31, 2011.</i>	$[38 \times (0.019/12 \times 6)] + 38 = 38.4$
<i>This calculated census is projected forward for 12 months to December 31, 2011. This is the expected certification date of this project.</i>	$(38.4 \times .019) + 38.4 = 39.1$
<i>At this point, BMA adds six patients from other BMA facilities; this is the beginning census for this project.</i>	$39.1 + 6 = 45.1$
<i>BMA projects the calculated census of Robeson County patients forward for one year to December 31, 2013. This is the end of the Operating Year 1.</i>	$(45.1 \times .019) + 45.1 = 45.9$
<i>BMA again projects the calculated census of Robeson County patients forward for one year to December 31, 2014. This is the end of Operating Year 2.</i>	$(45.9 \times .019) + 45.9 = 46.8$

...

*Facility station utilization rates are calculated using whole patients; BMA has rounded down to the whole patient for each of the following calculations. BMA offers the following projections of facility in-center station utilization rates ...*

*Operating Year 1: 45 patients dialyzing on 14 stations = 3.21 patients per station  
 $45 / (4 \times 14) = 0.804$  or 80.4%"*

On page 34 the applicant provides a calculation for Operating Year 2 using figures which are not based on the table above. The correct calculations for Operating Year 2 are set forth below.



Operating Year 2: 46 patients dialyzing on 14 stations = 3.29 patients per station  
 $46 / (4 \times 14) = 0.821$  or 82.1%.\

However, while the applicant projects six patients transferring from other BMA facilities the applicant only provided documented support for four BMA patients to transfer from other BMA facilities. Therefore the calculations in the table above, which are based on six patients transferring, are not supported. The calculations are redone below based on four patients transferring from other BMA facilities to the FMC St. Pauls facility as follows:

At this point, BMA adds four patients from other BMA facilities; this is the beginning census for this project.	$39.1 + 4 = 43.1$
BMA projects the calculated census of Robeson County patients forward for one year to December 31, 2013. This is the end of the Operating Year 1.	$(43.1 \times .019) + 43.1 = 43.9$
BMA again projects the calculated census of Robeson County patients forward for one year to December 31, 2014. This is the end of Operating Year 2.	$(43.9 \times .019) + 43.9 = 44.7$

There are 10 existing dialysis stations and the applicant is requesting 4 additional stations which would result in a total of 14 dialysis stations at FMC St. Pauls. The number of projected in-center patients is 43. Dividing 43 by the 14 projected dialysis stations results in 3.07 patients per station which is below the required 3.2 patients per station. One of the projected additional stations must be disallowed to achieve the required 3.2 patients per station ( $43 / 13$  stations = 3.307 or 3.31 patients per station). The applicant has only identified and documented a need for three additional stations at FMC St. Pauls.

In summary, the applicant adequately identified the population to be served and demonstrated the need for the three additional dialysis stations at FMC St. Pauls based on the population it proposes to serve. Therefore, the application is conforming to this criterion for a total of 14 ESRD stations inclusive of one isolation station.

- (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, page 35, the applicant discusses the alternatives it considered to meet the need for the proposed services. The application is conforming to the facility need methodology for additional stations. See Criterion (1) for discussion. Further, the applicant demonstrated the need for four additional stations based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrated that the proposal to add four dialysis stations is its least costly or most effective alternative. Consequently, the application is conforming to this criterion subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls shall materially comply with all representations made in its certificate of need application as amended by the conditions of approval.**
  - 2. Upon completion of this project, Bio-Medical Applications North Carolina, Inc. d/b/a FMC St. Pauls shall add 3 dialysis stations and be certified for no more than 13 dialysis stations, which shall include any home hemodialysis and isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of 13 operating stations, which shall include any home hemodialysis and isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls 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.

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In Section VIII.1, page 51, the applicant states the capital cost is projected to be \$17,776. In Section IX, page 55, the applicant states that there will be no start-up costs or initial operating expenses.

In Section VIII, pages 52-53, the applicant states it will fund the capital costs of the project with accumulated reserves of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. Exhibit 24 contains a letter, dated September 15, 2011, from the Vice President of Fresenius Medical Care Holdings, Inc. which states:

*“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA proposes to add four dialysis stations to the FMC St. Pauls dialysis facility in Robeson County.*

...

*As Vice President, I am authorized and do hereby authorize the addition of four dialysis stations, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$17,776 as may be needed for this project.”*

Exhibit 10 contains the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries which show \$163,292,000 cash and cash equivalents and more than \$2.7 billion current assets as of December 31, 2010. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section X, pages 56-63, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 56, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming with 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.

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The applicant proposes to add four dialysis stations to the existing FMC St. Pauls facility for a total of 14 dialysis stations upon completion of this project. The applicant adequately demonstrates the need to add four stations based on the number of in-center patients it proposes to serve. See Section III.7, pages 31-33, Section III.9, page 35, and Section V.7, page 42. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved

health service capabilities or facilities. Consequently, the application is conforming with 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.

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In Section VII.1, page 47, the applicant states it will add 1.5 full-time equivalent (FTE) positions as a result of this project. Exhibit 21 contains a letter from Ezra Lee McConnell, III, MD stating that he is the current Medical Director and will continue to serve in this capacity upon completion of the project. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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.

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In Section V.1, page 38, the applicant lists the providers of the necessary ancillary and support services, and illustrates how the project will be coordinated with the existing health care system. The information provided in Section V and Exhibit 18 is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (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;

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In Section VI.1.(b), pages 43-44, the applicant provides the following current payor mix for in-center patients.

Payor	In-Center Patients
Commercial Insurance	18.2%
Medicare	79.3%
Medicaid	2.5%
<b>Total</b>	<b>100.0%</b>

In Section VI.1(c), page 44, the applicant states that the payor mix for the proposed service is a function of historic experience.

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 as of CY2008-2009. The data in the table was obtained January 14, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Robeson	31%	13.2%	23.9%
Statewide	17%	6.7%	19.7%

\*Source: DMA Website: <http://www.ncdhhs.gov/dma/pub/index.htm>

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 to be offered at FMC St. Pauls.

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

health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of January 14, 2012 no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' 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.

The applicants demonstrated that medically underserved populations currently have adequate access to FMC St. Pauls's existing services. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.1(f) page 45, the applicant states "*BMA of North Carolina facilities and FMC St. Pauls do not have any obligation to provide uncompensated care or community service under any federal regulations.*" In Section VI.6(a), page 46, the applicant states "*There have been no Civil Rights complaints lodged against FMC St. Pauls or any BMA North Carolina facilities in the past five years.*" Therefore, the application is conforming with 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 44, the applicant provides the projected payor mix for in-center dialysis patients.

Payor	In-Center Patients
Commercial Insurance	18.2%
Medicare	79.3%
Medicaid	2.5%
<b>Total</b>	<b>100.0%</b>

The applicant projects 81.8 % of its in-center patients will have some or all of their care paid for by Medicare or Medicaid (79.3 percent Medicare plus 2.5 percent Medicaid). The applicant demonstrates that it will provide adequate access to medically underserved populations. Therefore, the application is conforming with 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 46, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity with 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(a), page 39 the applicant states "*Exhibit 19 contains a letter from Shelley Brown, Director of Operations, requesting to establish a Health Occupations Agreement with Robeson Community College.*" The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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



C

See Sections II.6, II.7, III.1, III.2, III.3, III.6, III.7, V.7, VI, VII, and XI.7. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the FMC St. Pauls addition of four dialysis stations for a total of 14 stations upon project completion would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The addition of four dialysis stations to FMC St. Pauls is needed to meet the needs of the increasing dialysis population in the area. The proposal is a cost-effective alternative to meet the need and to improve access to the proposed services. [see Criteria (1), (3), (4) and (5) for additional discussion];
- The applicant has and will continue to provide quality services [see Criteria (7), (8) and (20) for additional discussion];
- The applicant has and will continue to provide adequate access to medically underserved populations [see Criterion (13) for additional discussion].

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant currently provides dialysis services as Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy 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.

CA

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

**.2202 INFORMATION REQUIRED OF APPLICANTS**

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

- .2202(a)(1) Utilization Rates;*  
-C- See Section III.2, page 31, the July 2011 SDR and Section III.7, pages 32-34.
- .2202(a)(2) Mortality rates;*  
-C- See Section IV.2, page 36.
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*  
-NA- FMC St. Pauls does not offer home therapies. Patients who are candidate for home training are referred to BMA Lumberton. See Section IV., page 36.
- .2202(a)(4) The number of transplants performed or referred;*  
-C- See Section IV.4, page 36.
- .2202(a)(5) The number of patients currently on the transplant waiting list;*  
-C- See Section IV.5, page 36.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- See Section IV.6, page 36.
- .2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*  
-C- See Section IV.7, page 37.

*(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

- .2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*  
-NA- Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls is an existing facility.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
  - (B) *composition of the assessment/evaluation team at the transplant center,*
  - (C) *method for periodic re-evaluation,*
  - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
  - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Section XI.6(f), page 66, and Exhibit 12.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
- C- See Section VII. 1-2, pages 48-49, and Section XI.6(g), page 66.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 32-34.

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

-NA- Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls is an existing facility.

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

-C- See Section VI.1(d), page 45.

### **.2203 PERFORMANCE STANDARDS**

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-CA- In Section III.7, pages 32-34, the applicant projects to serve 45 in-center patients or 3.21 patients per station [ $45 / 14 = 3.21$ ] by the end of Year 1 for the proposed 14-station facility. However, as discussed in Criterion (3) the applicant only documented the need for 3 additional stations which would result in a 13 station facility. See conditions in Criterion (4).

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-CA- In Section III.7, pages 32-34, the applicant provided the assumptions and methodology used to project utilization of the additional station. See Criterion (3) for discussion. However, as discussed in Criterion (3) the applicant only documented the need for 3 additional stations which would result in a 13 station facility. See conditions in Criterion (4).

**.2204 SCOPE OF SERVICES**

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

- .2204(1) *Diagnostic and evaluation services;*  
-C- See Section V.1, page 38.
- .2204(2) *Maintenance dialysis;*  
-C- See Section V.1, page 38.
- .2204(3) *Accessible self-care training;*  
-C- See Section V.1, page 38.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*  
-C- See Section V.1, page 38.
- .2204(5) *X-ray services;*  
-C- See Section V.1, page 38.
- .2204(6) *Laboratory services;*  
-C- See Section V.1, page 38 and Exhibit 18.
- .2204(7) *Blood bank services;*  
-C- See Section V.1, page 38.
- .2204(8) *Emergency care;*  
-C- See Section V.1, page 38.
- .2204(9) *Acute dialysis in an acute care setting;*  
-C- See Section V.1, page 38.
- .2204(10) *Vascular surgery for dialysis treatment patients;*  
-C- See Section V.1, page 38.
- .2204(11) *Transplantation services;*  
-C- See Section V.1, page 38.
- .2204(12) *Vocational rehabilitation counseling and services;*  
-C- See Section V.1, page 38.
- .2204(13) *Transportation*  
-C- See Section V.1, page 38.

**.2205 STAFFING AND STAFF TRAINING**

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*  
-C- See Sections VII.1 & 2, pages 48-9, and VII.10, page 50.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*  
-C- See Section VII.5, page 49, and Exhibits 14 and 15.