

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

FINDINGS: June 1, 2012

PROJECT ANALYST: Gene DePorter

CON CHIEF: Craig Smith

PROJECT I.D. NUMBER: Wake J-8791-12 Bio-Medical Applications of North Carolina d/b/a Fresenius Medical Care Millbrook- Findings June 1, 2012

FID # 041024

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 [BMA] of North Carolina, Inc. d/b/a FMC Millbrook [FMC-M], whose parent company is Fresenius Medical Care Holdings, Inc. The applicant proposes to add one dialysis station to its existing dialysis facility located at 3411 West Millbrook Road, Raleigh, North Carolina, for a total of 17 dialysis stations upon completion of this project.

The 2012 State Medical Facilities Plan [2012 SMFP] provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations [Reference 2012 SMFP-Chapter 14, pages 364-366]. According to the January 2012 SDR, the county need methodology shows there is no need for dialysis stations or an additional facility in Wake County. However, the applicant is also eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Millbrook in the January 2012 SDR is 3.25 patients per station and 81.25% utilization. The patient per station and percent utilization exceed the minimum

standards of 3.2 and 80% utilization. The utilization rate was calculated based on 52 in-center dialysis patients and 16 certified dialysis stations as of January 30, 2012 [52 patients/16 stations = 3.25 patients per station]. The January 2012 Semiannual Dialysis Report [SDR] indicates a total of 16 certified dialysis stations at FMC Millbrook as of June 30, 2011. Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

Table 1
FMC Millbrook
 ESRD Facility Need Methodology
 Semiannual Dialysis Facility Need

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		81.25%
Certified Stations		16
Pending Stations		0
Total Existing and Pending Stations		16
In-Center Patients as of 6/30/11 (SDR2)		52
In-Center Patients as of 12/31/10 (SDR1)		43
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.4186
(ii)	Divide the result of step (i) by 12	0.0349
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2012 SDR (6/30/11) until the end of calendar year 12/31/2011 (6 months)	0.2093
(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	62.8837
(v)	Divide the result of step (iv) by 3.2 patients per station	19.6512
	and subtract the number of certified and pending stations as recorded in SDR2 [27] to determine the number of stations needed	4

Step (c) of the facility need methodology, page 366 of the 2012 SMFP, states; “*The facility may apply to expand to meet the need established... up to a maximum of 10 stations.*” As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is four. The applicant proposes to add one station. The application is consistent with the facility need determination for dialysis stations.

The last certificate of need action for this applicant was Project ID # J-8416-09 which resulted in 16 certified stations [reference Exhibit 1] at the completion of that project. Wake County has the second largest ESRD population in the state.

Policy GEN-3 in the 2012 SMFP is applicable to this review. Policy GEN-3 states:

“A certificate of need 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 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 certificate of need 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 certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II.1, page 18, the applicant describes how the proposal will promote safety and quality as follows:

“BMA is a high quality health care provider. The Table at II.3D provides quality indicators for the FMC Millbrook dialysis facility. The Core Indicators Project is an initiative of the Centers for Medicare and Medicaid Services (CMS) to develop clinical indicators for assessing the quality dialysis treatment outcomes. FMC, as a major function of its CQI program, has established goals that are more stringent than the national averages for the indicators.

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 Section II.3, pages 25-28, the applicant has identified the following programs it uses to insure and maintain quality care:

- 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

- 3) External Surveys- DFS Certification Surveys
- 4) Core Indicators of Quality; and
- 5) Single Use Dialyzers

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

Maximize Healthcare Value

In Section II.1, page 19, 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 76.9% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 3.0% are expected to be covered by the VA. Thus, 79.9% of In-Center revenue is derived from government payers.

In Section X.4, the applicant shows provisions for bad debt and charity care projections. For years one and two FMC Millbrook has budgeted \$72,997 and \$79,721 respectively for bad debt and charity care.

The applicant adequately demonstrates the proposal will maximize healthcare value.

Promote Equitable Access

In Section II, pages 20-23, the applicant describes how the proposal would enhance access by medically underserved groups, as follows:

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, BMA operates 11 dialysis facilities in Wake County with an additional facility under development (FMC Central Raleigh). The January 2012 SDR reports that Wake County has the second largest ESRD patient population in North Carolina and that population is growing at an Average Annual Change Rate of 5.9%. As the dialysis patient population of Wake 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 convenient to the patient. This application to add one dialysis station to FMC Millbrook is another example of BMA efforts to meet the needs of the ESRD patient population of Wake County.

As noted within Section VI.1. (a), page 42 of this application, BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ...Each of our facilities has a patient population which includes low-income person, racial and ethnic minorities, women, handicapped persons, elderly, and other traditionally underserved persons (reference Table 8). A patient in need of dialysis is always welcome at a BMA facility; the only requirement is proper referral from a physician.”

In Section VI.2, page 44, 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 will be constructed in compliance with Section XIIX of the North Carolina applicable State Building Code, Vol. 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, page 46, the applicant states,

“BMA 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 an acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’”

The applicant adequately demonstrates the proposal will promote equitable access to medically underserved groups. See Criteria (13c) for additional discussion. The application is consistent with Policy GEN-3.

POLICY GEN-4: Energy Efficiency and Sustainability for Health Service Facilities of the 2012 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.”

There is no capital cost associated with this project. Therefore, Policy GEN-4 is not applicable. 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

The January 2012 SDR indicates a total of 16 certified dialysis stations at FMC Millbrook as of June 30, 2011. In this application, the applicant will add one dialysis station for a total of 17 stations upon completion of the project.

In application Section III, page 31 the applicant identifies the population it proposes to serve during the first two operating years following project completion, as illustrated in the following table:

Table 2
FMC Millbrook-In-Center Patient Projections
Operating Years 1 and 2

County	Operating YR 1 CY2013	Operating YR 2 CY2014	County Patients as a Percentage of Total	
			Year 1	Year 2
Wake	59.0	62.0	100.0%	100.0%
Total	59.0	62.0	100.0%	100.0%

In Section III.7, pages 30-31, the applicant states the following:

“BMA assumes that the patient population of FMC Millbrook residing in Wake County will continue to increase at the same rate as the Wake County Five Year Average Annual Change Rate as published in the January 2012 SDR: that rate is 5.9%. The following table illustrates the methodology:

<i>BMA begins with Wake County patients dialyzing at FMC Millbrook as of December 31, 2011.</i>	53
---	----

<i>The portion of the census is increased by the Wake County Five Year Average Annual Change Rate for one year to December 31, 2012.</i>	$(53 \times 0.059) + 53 = 56.1$
<i>BMA Projects the Wake County patient population of FMC Millbrook forward for 12 months to December 31, 2013. This is the end of Operating Year 1.</i>	$(56.1 \times 0.059) + 56.1 = 59.4$
<i>BMA Projects the Wake County patient population of FMC Millbrook forward for 12 months to December 31, 2014. This is the end of Operating Year 2.</i>	$(59.4 \times 0.059) + 59.4 = 62.9$

In the table on page 31, the applicant projects that FMC Millbrook will serve 59.4 in-center patients at the end of Operating Year 1 (December 31, 2013). Consequently, the applicant projects it will serve 3.47 patients per station per week [59 patients/17 stations = 3.47 patients per station]. This exceeds the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding historical growth which is expected to continue in the future. Therefore, the applicant adequately demonstrates the need for one additional station.

In addition, BMA’s projected utilization calculation for project years one and two, end census is rounded down to the whole number. Utilization at FMC Millbrook is expected to be the following:

Operating Year One

59 patients dialyzing on 17 stations = 3.47 patients per station
 $59 / (4 \times 17) = 0.868$ or 86.8% by 12/31/2013.

Operating Year Two

62 patients dialyzing on 17 stations = 3.65 patients per station
 $62 / (4 \times 17) = 0.912$ or 91.2% by 12/31/2014.

In summary, the applicant adequately indentified the population to be served and demonstrated need for one additional station at FMC Millbrook based on the population it proposes to serve. 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, page 32 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services. The application is conforming to the facility need methodology for additional stations and with applicable SMFP policies. See Criterion (1) for discussion. Further, the applicant adequately demonstrated the need for one additional station 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 (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .2200 for discussion. The applicant adequately demonstrates that this project is its least costly and most effective alternative to meet the need for an additional dialysis station at this facility. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Millbrook shall materially comply with all representations made in its certificate of need application.
 2. Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Millbrook shall develop and operate no more than one additional dialysis station for a total of no more than 17 stations, which shall include any home hemodialysis or isolation stations upon completion of this project.
 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Millbrook shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station for a total of 17 stations, which shall include any home hemodialysis and isolation stations.
 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Millbrook shall not offer or develop home training.
 5. Prior to issuance of the certificate of need, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Millbrook shall acknowledge in writing to the Certificate of Need Section acceptance of and agreement to comply with all conditions stated herein.
- (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 IX, page 53, the applicant states that there are no projected start-up expenses, initial operating expenses, or working capital needs. In Section VIII.7 (b), page 51 of the application, the applicant states:

“Exhibit 10 is a copy of the most recent FMC audited financial reports. The 2010 Consolidated Balance Sheet reflects more than \$163 million in cash, and current assets exceeding \$2.7 billion. It is obvious that FMC has the resources necessary for this project.”

In Section VIII.5, page 51 of the application, the applicant states:

“This project does not require any capital cost on behalf of BMA. Please refer to Exhibit 24 for letter of commitment from Mark Fawcett, Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc.”

In a letter provided in Exhibit 24, Mr. Fawcett wrote:

“BMA proposes to add one dialysis station to FMC Millbrook for a total of 17 dialysis stations upon completion of this project. As Vice President, I am authorized and do hereby authorize the addition of one dialysis station. The project does not require any capital expenditures on behalf of BMA.”

The applicant adequately demonstrates availability of sufficient funds for the capital needs of the project.

The rates in the following table were provided by the applicant in application Section X.1, page 54 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services, as shown in the following table.

**Table 4
 Medicare/Medicaid Rates**

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

In the revenue and expense statements in Sections X, pages 55-58, the applicant projects that revenues will exceed operating costs in each of the first two years of operation. The following table illustrates projected revenues and expenses during the first two years after project completion.

**Table 5
 Revenue, Costs and Profit**

	Operating Year 1 CY2013	Operating Year 2 CY2014
Total Net Revenue	\$3,202,146	\$3,434,113

Total Operating Costs	\$2,663,243	\$2,831,765
Net Profit	\$ 538,903	\$ 602,348

Section X.3, page 55 contains the assumptions used to project revenues.

“Current Operating Year: Current year treatment numbers are derived from the information within Section III.7. The calculations begin with the census as of December 31, 2011; the in-center facility census was 53 patients. The calculations produce a projected census of 56.1 patients for December 31, 2012. Thus, BMA calculates the average number of patients for the current year to be 54.6 patients: $(53 + 56.1)/2 = 54.6$. BMA rounded down and multiplied 54 by 156 annual treatments (3 treatments per week, multiplied by 52 weeks is the industry standard) to produce the number of available treatments for the year. This number is reduced by an allowance for missed treatments of 6.5%, to produce the number of expected treatments for the year.

Operating Year 1: BMA has projected to begin the first year of operations with 56.1 In-Center patients, ending the year with 59.4 In-Center patients. BMA calculates the average number of In-Center patients for the first year of operations 57.8 patients $(56.1 + 59.4)/2 = 57.8$ BMA rounds down and multiplies 57 by 156 annual treatments to produce the projected number of treatments for Operating Year 1. This figure is then reduced by the allowance for missed treatments, again 6.5%.

Operating Year 2: BMA has projected to begin the second year of operations with 59.4 In-Center patients, ending the year with 62.9 In-Center patients. BMA calculates the average number of In-Center patients for the second year of operations to be 61.2 patients $[59.4 + 62.9] / 2 = 61.2$. BMA rounded down and multiplied 61 by 156 annual treatments to produce the projected number of treatments for Operating Year 2. That product is then reduced by the allowance for missed treatments, again 6.54%.”

Table 6
Bio-Medical Applications of North Carolina d/b/a FMS Oxford
Current and Projected
Revenue, Deductions from Revenue, Operating Costs and Difference

Cash Flow	Current Year Operating Revenue	Year 1 Operating Revenue	Yr. 2. Operating Revenue
Gross Patient Service Revenue	\$2,722,582	\$2,862,370	\$2,911,595
Contractual Allowances	\$ 303,220	\$ 318,381	\$ 323,435
Net Revenue	\$2,419,362	\$2,543,989	\$2,588,160
Total Operating Costs	\$2,119,791	\$2,347,750	\$2,403,639
Difference	\$ 299,571	\$ 196,239	\$ 184,521

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 63-67, for the applicant’s assumptions.

In summary, the applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. 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

The applicant proposes to add one dialysis station to the existing FMC Millbrook facility for a total 17 dialysis stations upon completion of this project. The methodology used by the applicant to determine the number of new stations that are needed to serve the facility's projected number of patients is consistent with the facility need methodology in the 2012 State Medical Facilities Plan and the January 2012 SDR. See Criterion (1) and (3) for discussion. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently the application is conforming to this criterion.

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

C

In Section VII.1, page 47, the applicant provides the current and projected staffing for FMC Millbrook as shown in the following table:

**Table 7
 FMC Millbrook Current and Projected Staffing**

	# of Current (FTE) Positions	# of Projected (FTE) Positions	# of (FTE) Positions to Be Filled
RN	2.00	2.50	0.50
Tech.	5.00	5.75	0.75
Clinical Manager	1.00	1.00	
Administrator	0.20	0.20	
Dietitian	0.33	0.33	
Social Worker	0.33	0.33	
Medical Records	0.35	0.35	
Chief Tech	0.10	0.10	
Equipment Tech	0.20	0.20	
In-Service	0.15	0.15	
Clerical	0.35	0.35	
Total	9.66	10.91	1.25

The applicant indicates a total of 9.66 FTE current positions and projected staffing of 10.91 for total additional staff of 1.25 upon project completion. The applicant indicates in Section VII.4, page 48; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in application Section VII and the estimated

annual salaries and revenues are reasonable and credible. The applicant anticipates no difficulty in recruiting staff. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. 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 application Section V.1, page 35, the applicant lists providers of the necessary ancillary and support services. Exhibit 16 contains a copy of an “*Transplant Services Agreement*” between UNC Health Care and FMC Millbrook. Duke University Medical Center and FMC Millbrook have an agreement in place for “*Transplant Center Evaluation Services.*” Section V.4 (b), pages 39-40 contains two tables listing physicians a) physicians by specialty that support this application and b) those physicians who have expressed a willingness to provide medical coverage for ESRD patients. Exhibit 21 contains a letter from Dr. Phillip Timmons, M.D. who is and will continue to serve, as the Medical Director for the facility. The information provided in Section V is reasonable and credible and supports a finding of conformity with this criterion. See also 10A NCAC 14C .2200 in these findings.

- (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(a), Page 42, the applicant states the following;

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. BMA currently operates 76 facilities in 40 North Carolina Counties (includes our affiliations with RRI facilities); in addition BMA has ten facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly or traditionally underserved persons. The patient population of the facility is comprised of the following:

**Table 8
 FMC Millbrook Patient Profile**

Facility	Medicaid/Lo w Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>FMC Millbrook</i>	<i>15.1%</i>	<i>47.2%</i>	<i>81.1%</i>	<i>34.0%</i>	<i>60.4%</i>

“It is clear that BMA provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved...For example, Medicare represented 79.7% of North Carolina Dialysis Treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of BMA facility treatments in FY 2011, low income and medically underserved persons will continue to have access to all services provided by BMA.”

The facility will conform to the North Carolina 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.”

As shown in the following table, 79.9% [70.8% Medicare, 6.1% Medicaid and 3.0% VA = 79.9%] of FMC Millbrook current in-center patients have some or all of their care paid for by Medicare or Medicaid. The applicant demonstrated that medically underserved populations currently have adequate access to dialysis services provided at FMC Millbrook. Therefore, the application is conforming to this criterion.

In Section VI.1.(b), page 43 the applicant provides the current and projected payer mix for FMC Millbrook. The applicant projects no change in reimbursement, between current and projected payer mix, as shown in the following table:

Table 9
FMC Millbrook
Current Payor Mix

Payor Source	Current Percent of Total
Private	0.0%
Commercial Insurance	20.1%
Medicare	70.8%
Medicaid	6.1%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	3.0%
Other: Self Pay/Indigent	0.0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2009 and CY 2005, respectively. The data in the table were obtained on April 10, 2012. More current

data, particularly with regard to the estimated uninsured percentages, was not available.

Table 10
Percent of Medicaid Eligible
By County and State

County	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligible Age 21 and older as % of Total Population	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center)
Wake	3.35%	1.7%	10%
Statewide	6.71%	3.6%	17%

Source: www.ncdhhs.gov/dema-Medicaid Eligible-Wake County June 2010.

The majority of Medicaid eligible is 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 services offered by the applicant.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible who actually utilizes 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 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer 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 applicant demonstrates that medically underserved populations currently have adequate access to services available at the FMC Millbrook dialysis facility. 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;

In application Section VI.1 (f), page 44, the applicant states, “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.*” In Section VI.6 (a), page 45, the applicant states, “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” 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 application Section VI.1 (b) and (c), page 42-43, the applicant states, “*The next table represents the BMA projection for future reimbursement. This table is based upon recent historical performance for the facility. BMA is not projecting any change in reimbursement. BMA will accept Medicaid patients at FMC Millbrook with proper referral.*” The following table from Section VI.1(c) projected payer mix for the proposed dialysis services is the same as the facility’s current payer mix.

Table 11
FMC Millbrook
Projected Payer Mix

Payer Source	Projected % of Total Patients
Medicare	70.8%
Medicaid	6.1%
Commercial Insurance	20.1%
Other: Self/Indigent	0.0%
VA	3.0%
Total	100.0%

As shown in the above table, 79.9% [70.8% Medicare + 6.1% Medicaid + 3.0% VA = 79.9%] of the FMC Millbrook’s in-center patients will have some or all of their care paid for by Medicare or Medicaid. The applicant demonstrated that medically underserved populations will have adequate access to the proposed dialysis 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 (a), page 45, the applicant states, “*FMC Millbrook has an open policy, which means that any Nephrologist may apply to admit patients at the facility.*” Further, in Section VI.5 (b), page 45, the applicant states, “*... all patients will be admitted to the facility through one of the Nephrologists on the staff of FMC*”

Millbrook. Referrals for treatment will continue to come from Wake Med [sic] Hospital, and practicing physicians in the area as patients demonstrate a need for nephrology physician services.” The information provided 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 application Section V.3 (a), page 37, the applicant states:

“Exhibit 19 contains a letter to Wake Technical Community College inviting the school to include FMC Millbrook as a clinical rotation site for the Health Occupations students. This type of agreement is typical for all BMA facilities. Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.

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

The information provided in application Section V 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, III, V, VI and VII. In particular, see Section II, pages 19-21, in which FMC Millbrook discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Wake County. This determination is based on the information in the application, and the following:

- In Section VIII, page 50; the applicant indicates that there are no costs associated with adding the one station, as determined through use of the Facility Need Methodology. Currently, the addition of one dialysis station at FMC Millbrook will relieve the current utilization and patients per station pressure of 81.25% and 3.25 respectively. The applicant states that this proposal is a cost effective alternative to meet the need to enhance capacity as opposed to demand curve growth exceeding capacity.
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

- Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Millbrook, addition of one station for a total of 17 dialysis stations upon project completion, is a cost-effective alternative to meet the need to enhance access and position the facility for near-term growth in dialysis stations [see Criteria (1), (3), (4) (5) and (12) 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].
- The applicant adequately demonstrates that the proposal is cost-effective [see Criterion (5) for additional discussion].

In Section V.7, page 41 the applicant offers the following comments on competition;

- *'This proposal will not have an effect on competition in Wake County. The patients to be serviced by this facility are existing and future patients residing in Wake County. Another provider, DaVita, operates a dialysis facility in Wake Forest. The DaVita Wake Forest facility is approximately 20 miles from the FMC Millbrook Facility. In addition, there are other BMA facilities closer to the DaVita facility. Consequently the facility is not likely to be serving patients who might otherwise choose to receive dialysis treatment at the DaVita location. The DaVita facility will not be operated the same as the BMA facility. The DaVita facility will have its own medical director.*
- *BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their*

treatments. In this application BMA projects that 76.9% of the In-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.

- *...BMA is the only national provider of dialysis services which has eliminated the re-use conception facilities and provide every patient a new dialyzer at each treatment. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and (b) that once the project is completed, all staff members work towards the clinical and financial success of the facility. This facility will be no different.”*

Therefore, the application is conforming to this criterion.

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

C

The applicant currently provides dialysis services at Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Millbrook. According to 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 (as of 4/2/2012) and there were no incidents resulting in a determination of immediate jeopardy during 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, 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 APPLICANT

(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 II, 1, Page 10, Section III 7, page 30, and the January 2012 SDR.*
- .2202(a)(2) Mortality rates;*
 - C- See Section IV.2, page 33.*
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*
 - C- See Section IV.3, page 33.*
- .2202(a)(4) The number of transplants performed or referred;*
 - C- See Section IV.4, page 33.*
- .2202(a)(5) The number of patients currently on the transplant waiting list;*
 - C- See Section IV.5, page 33.*
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
 - C- See Section IV.6, page 33.*
- .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 34.*

(b) An applicant that proposed develop a new facility, to 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- FMC Millbrook 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- FMC Millbrook 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- FMC Millbrook 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 62 and Exhibit 12 regarding back-up capabilities.
- .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- FMC Millbrook 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 II.1, page 9, Section XI.6 (g), page 62 and Exhibits 11 and 12.
- .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 30-31, and discussion in Criterion (3).
- .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- FMC Millbrook 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 II.1, page 13.

.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 week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
-NA- FMC Millbrook 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.*
-C- In Section III.7, pages 30-35 the applicant projects to serve 59 in-center patients by the end of Year 1, which are 3.47 patients per station per week [59 / 17 = 3.47]. Further, the applicant projects to serve 63 in-center patients by the end of Year 2, which are 3.65 patients per station per week [62 / 17 = 3.65]. See Criterion (3) for discussion.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
-C- In Section III.7, pages 30-31, the applicant provided the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion.

.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 35.
- .2204(2) *Maintenance dialysis;*
-C- See Section V.1, page 35.
- .2204(3) *Accessible self-care training;*
-C- See Section V.1, page 35.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
-C- See Section V.1 (d), page 35.
- .2204(5) *X-ray services;*
-C- See Section V.1, page 35.
- .2204(6) *Laboratory services;*
-C- See Section V.1, page 35.
- .2204(7) *Blood bank services;*
-C- See Section V.1, page 35.
- .2204(8) *Emergency care;*
-C- See Section V.1, page 35.

- .2204(9) *Acute dialysis in an acute care setting;*
-C- See Section V.1, page 35.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
-C- See Section V.1, page 35.
- .2204(11) *Transplantation services;*
-C- See Section V.1, page 35.
- .2204(12) *Vocational rehabilitation counseling and services; and*
-C- See Section V.1, page 35.
- .2204(13) *Transportation*
-C- See Section V.1, page 35.

.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 494 (formerly 405.2100)*
-C- See Section VII.1 and VII.2, page 47-49.
- .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 48 and Exhibits 14 and 15.