

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: July 19, 2012
PROJECT ANALYST: Gloria C. Hale
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8794-12/ Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston/ Add three dialysis stations for a total of 20 certified stations upon completion of this project / Gaston 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. (BMA) d/b/a FMC South Gaston, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add three dialysis stations for a total of 20 certified 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 new dialysis stations. According to the January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of two dialysis stations in Gaston County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for FMC South Gaston in the January 2012 SDR is 3.35 patients per station. This utilization rate was calculated based on 57 in-center dialysis patients and 17 certified dialysis stations. (57 patients / 17 stations = 3.3529 patients per station).

Application of the facility need methodology indicates three additional stations are needed for this facility, as illustrated in the following table.

Required SDR Utilization	80%
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Center Utilization Rate as of 6/30/11		83.8%
Certified Stations		17
Pending Stations		0
Total Existing and Pending Stations		17
In-Center Patients as of 6/30/11 (SDR2)		57
In-Center Patients as of 12/31/10 (SDR1)		50
Difference (SDR2 - SDR1)		7
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.2800
(ii)	Divide the result of Step (i) by 12	0.0233
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the Jan 2012 SDR (6/30/11) until the end of calendar year 2011 (6 months)	0.1398
(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	64.9686
(v)	Divide the result of Step (iv) by 3.2 patients per station	20.3027
	and subtract the number of certified and pending stations as recorded in SDR2 [17] to determine the number of stations needed	3

See page 366 SMFP 2012

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations. Step (C) of the facility need methodology states, *“The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.”* The applicant proposes to add three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 40, of 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 17, 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 Section II.3, pages 24-25, the applicant states:

“FMC South Gaston will have a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method of review is patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation. Other audits include Patient Satisfaction Surveys and chart audits. CQI membership includes the Medical Director, Area Manager, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing the improvement opportunities.”

In Section II.3, pages 25-26, the applicant indicates:

There is an ongoing Clinical Review Program and a Continuous Quality Improvement Program. Regional teams in each of FMC’s regions monitor quality improvement, regulatory compliance, systems education and technical proficiency in each of their facilities. Continuous follow-up is done by the Regional Quality Manager on all reports of clinical variance, mortality reviews, and other QI issues identified at QI committee meetings.

Furthermore, FMC states that as a major function of its CQI program, it has established goals that are more stringent than national averages for quality indicators adopted by CMS from the National Kidney Foundation and its committees.

See Exhibit 13 for copies of the CQI Theory.

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

Promote Equitable Access

In Section VI.1, page 39, the applicant indicates:

BMA facilities provide services to all persons in need of dialysis, *“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.”* FMC South Gaston’s patient population consists of 7.9% Medicaid/Low Income, 20.6% Elderly (65+), 71.4% Medicare, 34.9% Women, and 65.1% Racial Minorities.

In Section VI.1, page 41, the applicant indicates:

FMC South Gaston will *“continue to treat all patients the same regardless of race or handicap status”* and that it will be accessible to handicapped persons in compliance with ADA requirements.

Further, in Section VI.1, page 43, the applicant indicates:

It has an AIDS policy which specifically prohibits refusal to accept a referral for services due to a diagnosis of AIDS or HIV-positive status.

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section II.1, page 19, the applicant states:

“BMA is projecting a capital expenditure \$14,375. 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 transfer [sic] of stations in an effort to bring dialysis treatment close to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other governmental payor sources. For example, within this application, BMA projects that 81.5% of the treatments are covered by Medicare and Medicaid,

and an additional 5.4% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. See criterion (3) and (13) for additional discussion. The application is consistent with the facility need determination in the January 2012 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

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The applicant, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston, proposes to add three dialysis stations for a total of 20 certified stations upon completion of this project.

Population to be Served

In Section II.1, page 15, 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.

FMC South Gaston	Operating Year 1 Jan 1 to Dec 31, 2013	Operating Year 2 Jan 1 to Dec 31, 2014	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Operating Year 1	Operating Year 2
Gaston County	66.7	69.8	97.1%	97.2%
York County (SC)	2.0	2.0	2.9%	2.8%
Total	68.7	71.8	100.0%	100.0%

The applicant adequately identified the population to be served.

Need Analysis

In Section III.2, pages 28-31, the applicant:

BMA cites the January 2012 Semiannual Dialysis Report and provides a table, included on page 2 of these findings, demonstrating facility need utilizing the ESRD Facility Need Methodology. The final step of the table demonstrates a need for three additional dialysis stations. In addition, in the table above, BMA identifies the expected county of origin for the patients expected to be dialyzing at FMC South Gaston during Operating Years 1 and 2 of the project. BMA demonstrates that the facility is serving patients from Gaston County and York County (SC).

Assumptions:

“Within this application, BMA will demonstrate growth of the Gaston County patient population only. BMA assumes that patients from York County will continue to dialyze at FMC South Gaston as a function of patient choice; however, BMA will not project growth of these portions of the patient population as there are dialysis facilities in each of these counties.

Within the application, BMA projects the Gaston County ESRD patient population to continue to grow commensurate with the Gaston County Five Year Average Annual Change Rate as published in the January 2012 SDR; that rate is 4.6.

The following table illustrates the methodology:

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FMC South Gaston	In-Center
BMA begins with Gaston County patients dialyzing at FMC South Gaston as of December 31, 2011.	61
The portion of the census is increased by the Gaston County Five Year Average Annual Change Rate for one year to December 31, 2012.	$(61 \times 0.046) + 61 = 63.8$
BMA adds the two patients from York County, SC. This is the projected beginning census for this project.	$63.8 + 2 = 65.8$
BMA projects growth of the Gaston County patient population for 12 months to December 31, 2013.	$(63.8 \times .046) + 63.82 = 66.7$
BMA adds the two patients from York County, SC. This is the projected ending census for Operating Year 1.	$66.7 + 2 = 68.7$
BMA projects growth of the Gaston County patient population for 12 months to December 31, 2014. This is the end of Operating Year 1 [sic]*	$(66.7 \times .046) + 66.7 = 69.8$
BMA adds the two patients from York County, SC. This is the projected ending census for Operating Year 2.	$69.8 + 2 = 71.8$

*Actually Operating Year 2

The applicant projects to serve 68 in-center patients or 3.4 patients per station ($68/20=3.4$) by the end of Year 1 and 71 in-center patients or 3.6 patients per station ($71/20=3.6$) by the end of Year 2 for the proposed 20 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for three additional stations. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of

low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

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In Section III.8, page 31, the applicant states that they had considered alternatives to the project, including having applied for fewer stations. However, having utilized the Facility Need Methodology, they demonstrated that they qualified for three additional stations and that these are needed to meet the needs of the growing patient population of the FMC South Gaston facility. Further, BMA has concluded that *“there are no suitable alternatives to this project other than a decision to not apply.”* The applicant adequately demonstrated the need for three additional stations based on the continued growth of Gaston County and the facility’s projected utilization. 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 is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston 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 South Gaston shall develop no more than three additional stations for a total of no more than 20 stations, which shall include any home hemodialysis training or isolation stations.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of 20 dialysis stations which shall include any isolation stations.**
4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**

- 5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston 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.**

It should be noted that the applicant applied for and received a certificate of need to relocate five dialysis stations to FMC South Gaston in 2009, for a total of no more than 17 dialysis stations. The certificate of need contained the following conditions,

1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston shall materially comply with all representations made in its certificate of need application.
 2. Bio-Medical Applications of North Carolina, Inc. shall relocate no more than five dialysis stations from the BMA Gastonia facility which shall include any home hemodialysis or isolation stations.
 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston shall install plumbing and electrical wiring through the walls for no more than five additional dialysis stations for a total of no more than 17 dialysis stations, which shall include any home hemodialysis and isolation stations.
 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC South Gaston 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.2, page 48, the applicant states that funding for the project will be provided by corporate Accumulated Reserves.

Exhibit 24 includes a letter of commitment dated March 15, 2012 from the Vice President and Assistant Treasurer, Fresenius Medical Care Holdings, Inc., which states:

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

BMA proposes to add three dialysis stations to FMC South Gaston for a total of 20 dialysis stations upon completion of this project. The project calls for the following capital expenditures on behalf of BMA. Capital Expenditure \$14,375.

Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$14,375 as may be needed for this project.”

In Exhibit 10, the applicant provides the audited financial statements for FMC Holdings, Inc., Consolidated Balance Sheet for 2009 and 2010. In addition, the applicant provides a copy of the Auditor’s letter. As of December 31, 2010, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$163,292,000 with \$12,017,618,000 in total assets and \$6,561,629,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the proposed project.

The Medicare/Medicaid rates in Section X.1 of the application are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. This is depicted in the following table.

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

The applicant projects net revenue in Section X.2 of the application and operating costs in Section X.4 of the application. The applicant’s projected revenue in excess of expenses in each of the first two operating years following completion of the project is illustrated in the following table.

	Project Year 1	Project Year 2
Net Revenue	\$3,205,376	\$3,356,787
Operating Costs	\$2,600,050	\$2,897,296
Profit	\$605,326	\$459,491

Source: Application pages 53 and 56

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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.

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FMC South Gaston operates six days a week with patients dialyzing three times per week. The facility operates two shifts per day, serving the same patients on Mondays, Wednesdays, and Fridays, and others on Tuesdays, Thursdays, and Saturdays. Therefore, four patients can be served per station. The State Health Care Coordinating Council requires that ESRD facilities have at least 10 stations, serving at least 32 patients per week at 3.2 patients per station for a utilization of 80% ($32/10 = 3.2$; $3.2/4 = 80\%$). The applicant proposes to add three dialysis stations to FMC South Gaston for a total of 20 stations upon completion of the proposed project. The applicant adequately demonstrated the need for three additional stations based on the number of in-center patients it proposes to serve. As of December 31, 2011, the 17 station facility was operating at 90% capacity ($61/17 = 3.59$; $3.59/4 = 90\%$). Upon completion of this project, the facility will have 20 stations serving 68 patients (end of year 1) which is an occupancy rate of 85% ($68/20 = 3.4$; $3.4/4 = 85\%$).

The applicant adequately demonstrated that the proposal would 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.

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In Section VII.1, page 44, the applicant provides the current number of full-time equivalent positions and projects that an additional 1.00 FTE will be added to FMC South Gaston following completion of the proposed project, as illustrated in the following table.

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
RN	1.75	1.00	2.75
Tech	5.00	0.00	5.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position – Not an FTE of facility		
Admin. (FMC Area Manager)	0.30	0.00	0.30
Dietitian	0.35	0.00	0.35
Social Worker	0.50	0.00	0.50
Other (Specify)	0.00	0.00	0.00
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.40	0.00	0.40
In-Service	0.10	0.00	0.10
Clerical	1.00	0.00	1.00
Total	10.50	1.00	11.50

A letter of endorsement from Paul Cheifetz, MD, Medical Director, FMC South Gaston, is provided in Exhibit 21 of the application.

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 Application Section IV.1, page 34, the applicant lists the providers of the necessary ancillary and support services. The information regarding coordination of services in Section IV.1, page 34, of the application and referenced in exhibits 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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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 2010 and CY 2009, respectively. The data in the table was obtained on June 11, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008 (Estimate by Cecil G. Sheps Center)
	(% of statewide Medicaid Eligibles)		
Gaston	3%	9.0%	19.0%
Statewide	17%	7.0%	19.7%

Data for FMC South Gaston is not available on the DMA web site.

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 services offered by FMC South Gaston.

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 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.

In Section II.1, page 20, the applicant states, "*BMA has a long history of providing dialysis services to all segments of the population, regardless of*

race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations.”

In Section VI.1. (a), page 39, the applicant further states, “*Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*”

The FMC South Gaston facility is comprised of the following:

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC South Gaston</i>	<i>7.9%</i>	<i>20.6%</i>	<i>71.4%</i>	<i>34.9%</i>	<i>65.1%</i>

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.8% [sic] of the facility treatment reimbursement is from Medicare.

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.”

In Section VI.1(c), page 40, the applicant projects future reimbursements based on the recent historical performance of the BMA Gastonia facility. Medicare or Medicaid reimbursement, either in whole or in part, account for 81.4% percent of the facility’s reimbursements. The table below illustrates the historical payor mix for the BMA Gastonia facility.

Historical Payor Source

Payor Source	In-Center
Commercial Insurance	11.6%
Medicare	76.7%
Medicaid	4.7%
VA	5.4%
Other: Self/Indigent	1.5%
Total	100.0%

The applicant demonstrated that it provides adequate access to medically underserved populations. 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;

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In Section VI.1 (f), page 41, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will continue to treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6 (a), page 42, 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 Section VI.1 (a), page 39, the applicant states,

“BMA of North Carolina has 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. Low income and medically underinsured persons will continue to have access to all services provided by BMA.” On page 40, BMA provides the following projection for future reimbursements:

<i>In-Center Payor Source</i>	<i>%</i>
<i>Private Pay</i>	<i>0.0%</i>
<i>Commercial Insurance</i>	<i>11.6%</i>

<i>Medicare</i>	76.7%
<i>Medicaid</i>	4.7%
<i>Medicare/Medicaid</i>	0.0%
<i>Medicare/Commercial</i>	0.0%
<i>State Kidney Program</i>	0.0%
<i>VA</i>	5.4%
<i>Other: Self/Indigent</i>	1.5%
<i>Total</i>	100.0%

As shown in the table above, the applicant projects that 81.4% of all in-center patients will be paid for by Medicare or Medicaid.

The applicant demonstrated that it will provide adequate access to elderly and medically underserved populations. 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.

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In Section VI.5 (a), page 42, the applicant states:

“Those Nephrologist [sic] who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC South Gaston will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospitals.”

The applicant further states,

“Referrals for treatment will continue to come from local area hospitals, and practicing physicians in the area as patients demonstrate a need for nephrology physician services. The nephrologists identified as willing to refer patients to the center (V.4.a) have established relationships in the medical community of Gaston County.”

The applicant adequately demonstrated that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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The applicant has an agreement with Gaston College, through its Associate Degree Nursing Program, to utilize the FMC South Gaston facility as a site for student and faculty clinical experience. Further, the applicant states that, *“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 applicant adequately demonstrated that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

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

C

See Sections II, V, and VI. In particular, see Section V.7, page 38, in which BMA discusses the impact of the proposed project on competition in the service area 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 Gaston County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to add three dialysis stations for a total of 20 certified dialysis stations. The applicant also demonstrated that the proposed project is a cost-effective alternative;
- ◆ 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.

In Section VI.1, page 39, the applicant provides the following table to demonstrate that the medically underserved population will have access to its serves, as illustrated below.

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC South Gaston</i>	7.9%	20.6%	71.4%	34.9%	65.1%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.8% [sic] of facility treatment reimbursement is from Medicare.

Therefore, the application is conforming to this criterion.

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

C

The applicant currently provides dialysis services at FMC South Gaston. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC South Gaston has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and

Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANTS

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) Utilization rates;

-C- In Section II.1, page 10, and Section III.7, page 34, the applicant provides the utilization rate as reported in the January 2012 SDR of 83.82% with 57 patients dialyzing on 17 station stations. This is a per station utilization of 3.35.

(2) Mortality rates;

-C- In Section II.1, page 10 and Section IV.2, page 32, the applicant provides the mortality rates illustrated below.

<i>FMC South Gaston</i>	<i>Beginning In-Center and Home Patients</i>	<i>Ending In-Center and Home Patients</i>	<i>Average</i>	<i>Deaths</i>	<i>% Gross Mortality</i>
<i>2009</i>	<i>36</i>	<i>34</i>	<i>35</i>	<i>0</i>	<i>0.0%</i>
<i>2010</i>	<i>34</i>	<i>50</i>	<i>42</i>	<i>9</i>	<i>21.4%</i>
<i>2011</i>	<i>50</i>	<i>63</i>	<i>56.5</i>	<i>8</i>	<i>14.2%</i>

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

-NA-

(4) The number of transplants performed or referred;

-C- In Section II.1, page 10, the applicant provides the number of transplants performed and referred by FMC South Gaston, as illustrated in the following table.

<i>FMC South Gaston</i>	<i>Transplants Referred</i>	<i>Transplants Performed</i>

	2010	2011	2010	2011
	9	14	1	0

- (5) The number of patients currently on the transplant waiting list;
- C- In Section II.1, page 10 the applicant states, “*FMC South Gaston has five (5) patients on the transplant waiting list.*” The applicant also indicates this in tabular form in Section IV.5, page 32.
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section II.1, page 10 and Section IV.6, page 33, the applicant states in 2011 that there were 99 hospital admissions of which 4 were dialysis related and 95 that were non-dialysis related.
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.
- C- In Section II.1, page 11 and Section IV.7, page 33, the applicant states in 2010 and 2011 that there were no patients at the facility with Hepatitis B Conversions, however there was one current patient with Hepatitis B, an infectious disease.

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

- (1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.
- NA- FMC South Gaston is an existing facility.
- (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 South Gaston is an existing facility.

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

-NA- FMC South Gaston is an existing facility.

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

-C- See Exhibit 12 for a copy of National Medical Care, Inc. and its affiliates' Emergency/Disaster Manual which has policies and procedures for back-up electrical service in the event of a power outage.

(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 South Gaston is an existing facility.

(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

-C- In Section II.1, page 12, the applicant states, "*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC South Gaston.*"

(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 II.1, page 12 and Section III.7, page 30, and Criterion (3).

(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 South Gaston is an existing facility.

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

-C- In Section II.1, page 13, the applicant states, *“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- FMC South Gaston does not propose to establish a new End Stage Renal Disease facility.

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

-C- Section II.1, pages 14-16, and Section III.7, pages 30-31, provide the assumptions used by the applicant in determining its utilization for the FMC South Gaston which convey an expected utilization of 3.4 patients per station per week as of the end of the first operating year with the additional stations ($68/20 = 3.4$).

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

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 15-16, and Section III.7, pages 30 -31.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

- (1) diagnostic and evaluation services;

- C- In Section II.2, page 22, the applicant states that EKG's will be performed on site when needed and laboratory samples will be obtained on site. Laboratory samples will be sent to Spectra East, which is under contract, to obtain over night results. In addition, the applicant states, "*STAT laboratory tests will be sent to the local hospitals.*" Evaluations for transplant candidacy will be performed within 60 days of admission. All follow up procedures pertaining to transplant candidacy will be performed on site and coordinated with the transplant agency. Other diagnostic evaluation services are available from Gaston Memorial Hospital, Gaston Radiology or a diagnostic center of patient choice as depicted in Section V.1., page 34. See Exhibit 16 for a copy of the hospital agreement with Gaston Memorial Hospital.

- (2) maintenance dialysis;

- C- The applicant states in Section II.2, page 21, "*Staff assisted hemo-dialysis will be provided under the direction of a full-time Clinical Manager.*"

- (3) accessible self-care training;

- C- In Section II.2, page 22 the applicant states, "*Each patient is continually assessed for appropriateness regarding home training candidacy. Patients who wish to perform dialysis at home, and have both the capability and supportive home environment, will be referred to the Home Training Facility within BMA Gastonia. There the patient will be trained in either peritoneal dialysis (CAPD or CCPD) or Hemodialysis.*" Exhibit 20 contains a copy of the home training center program agreement.

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

- C- In Section II.2, page 22, the applicant states that follow-up care will be provided to those patients dialyzing at home, specifically,
"*Visits to the home will be made by the Home Training Social Worker and a Home Training Nurse to determine on-going compatibility and adaptability to the home environment. Back-up dialysis treatments, lab work, EPO injections and antibiotic therapy are also provided.*"

In Section V.2., page 36, the applicant states,

“Home patients will receive benefit from the services offered to home patients by the BMA Gastonia facility. These services include home visitation, assistance with problems that patients have with catheters, diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician. See Exhibit 20 for a copy of the home training center program agreement.

(5) x-ray services;

-C- In Section V.1, page 34, the applicant states that x-ray services will be provided at Gaston Memorial Hospital or a diagnostic center of the patient’s choice.

(6) laboratory services;

-C- In Section II.2, page 22, the applicant states that laboratory services are provided by Spectra East under contract. See Exhibit 18 for the laboratory services agreement with Spectra Laboratories, Inc.

(7) blood bank services;

-C- In Section V.1, page 34, the applicant depicts the availability of blood bank services at Gaston Memorial Hospital as indicated in a table that lists all of the services available to the facility’s patients. Exhibit 16 contains a signed affiliation agreement with Gaston Memorial Hospital.

(8) emergency care;

-C- In Section II.2, page 21, the applicant states, *“FMC South Gaston will maintain a fully equipped, mobile emergency cart with medications, oxygen and suction capabilities. All dialysis chairs will be mobile to facilitate access to patients in need of emergency care. All BMA direct care staff will be certified in CPR. Both patients and staff will take part in disaster drills on a quarterly basis. Each patient, when capable, will be instructed on emergency procedures and how to turn off the dialysis machine should an emergency occur. Local EMS services are available to transport patients to a local hospital when necessary.”* Exhibit 14 contains a copy of FMCNA Dialysis Services Training Manual. According to the manual’s table of contents, the topic, Emergency Situations, can be found on page 2 and the sample orientation schedule indicates that emergency equipment use is covered during week 1, day two of orientation.

(9) acute dialysis in an acute care setting;

- C- Acute dialysis in an acute care setting will be provided at Gaston Memorial Hospital. See Exhibit 16 for a copy of the hospital agreement with Gaston Memorial Hospital.
- (10) vascular surgery for dialysis treatment patients;
- C- In Section V.1, page 34, the applicant indicates that vascular surgery is available from Metrolina Nephrology Access Center; Carolina Surgery, Gastonia Surgical Associates, Dr. David Draughn, as depicted in a table provided.
- (11) transplantation services;
- C- In Section V.2 (c), page 35, the applicant states, "*Transplant Agreements with Carolinas Medical Center is [sic] included at Exhibit 17.*"
- (12) vocational rehabilitation counseling and services; and
- C- In Section V.1., page 34, the applicant indicates that vocational rehabilitation counseling and services available upon referral to the NC Division of Vocational Rehabilitation, located at 965 Roberts Drive, Gastonia, as listed in a table.
- (13) transportation.
- C- In Section V.1, page 34, the applicant indicates that transportation services will be provided by Gaston County Access / City Paratransit, as listed in a table.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

- (a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.
 - C- In Section VII.1, page 44, the applicant provides the following current and projected number of FTE for FMC South Gaston following completion of the proposed project, as illustrated in the following table:

Position	Current # of FTEs	Projected # of New FTEs	Total # of FTEs
RN	1.75	1.00	2.75
Tech	5.00	0.00	5.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position – Not an FTE of facility		
Admin. (FMC Area Manager)	0.30	0.00	0.30
Dietitian	0.35	0.00	0.35
Social Worker	0.50	0.00	0.50
Other (Specify)	0.00	0.00	0.00
Chief Tech	0.10	0.00	0.10
Equipment Tech	0.40	0.00	0.40
In-Service	0.10	0.00	0.10
Clerical	1.00	0.00	1.00
Total	10.50	1.00	11.50

The applicant adequately demonstrates that its proposed number of FTEs will meet the staffing requirements as stated in 42 C.F.R., Section 405.2100.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- In Section VII.5, page 45, the applicant states,

“Each new employee will be required to successfully complete an eight-week training program. Employees will be carefully and thoroughly trained in the clinical aspects of their job including facility and corporate policies and procedures. Staff will also be trained in safety precautions for themselves and patients, and in regulations to assure Occupational, Safety and Health Administration compliance. Each employee will be trained in CPR and required to maintain CPR certification. Exhibit 14 contains copies of FMCNA Dialysis Services Training Manual which outlines its training program. The contents section of the manual includes the topic of Hemodialysis.

In addition, in Section II.3, page 25, the applicant states,

“FMC South Gaston will offer in-service education programs for all employees. Each employee will be required to attend a minimum number of programs annually. See Exhibit 15 for details of on-going training.”