

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: June 2, 2014

PROJECT ANALYST: Mike McKillip

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10258-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC West Pettigrew / Add four dialysis stations for a total of 24 certified stations upon completion of this project / Durham County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

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Bio-Medical Applications of North Carolina, Inc. d/b/a FMC West Pettigrew [FMC West Pettigrew] proposes to add four dialysis stations for a total of 24 certified dialysis stations upon completion of this project.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Durham County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for FMC West Pettigrew in the January 2014 SDR is 3.35 patients per station. This utilization rate was calculated based on 67 in-center dialysis patients and 20 certified dialysis stations as of June 30, 2013 (67 patients / 20 stations = 3.35 patients per station). Application of the facility need methodology indicates two additional stations are needed for this facility, as illustrated in the following table.

**APRIL 1 REVIEW - JANUARY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		83.8%
Certified Stations		20
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>20</b>
In-Center Patients as of 6/30/13 (SDR2)		67
In-Center Patients as of 12/31/12 (SDR1)		44
Step	Description	
(i)	Difference (SDR2 - SDR1)	23
	Multiply the difference by 2 for the projected net in-center Change	46
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	1.0455
(ii)	Divide the result of Step (i) by 12	0.0871
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.5227
(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	102.0227
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.8821
	and subtract the number of certified and pending stations as recorded in SDR2 [20] to determine the number of stations needed	12

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 12 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 only four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 38, of the 2014 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.3, page 30, the applicant states,

*“FMC West Pettigrew 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 individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing improvement opportunities.”*

See Exhibit 8 for a copy of the “Quality Assessment and Performance Improvement” policy.

In Section II.1, page 23, 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 I.13, pages 4-8, the applicant discusses the quality of services provided at FMC West Pettigrew, stating that its success in providing quality services is due to its organizational structure, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments, and other management resources as discussed below.

- Clinical Services Department
  - Serves as a clinical resource for the entire FMC network
  - Provides facilities with the best procedures and equipment available

- Assists facility managers and medical personnel with questions and concerns on clinical operations
- Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program
- Technical Services Department
  - Oversees the technical and mechanical aspects of dialysis
  - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
- Regulatory Affairs and Law Departments
  - Deals with legal and regulatory issues
  - Provides interpretation of legislation and government policy to ensure compliance
- Other Management Resources, including but not limited to:
  - Revenue Operations – draws experience through interaction with numerous Medicare intermediaries and third-party carriers
  - Accounting and Budget – tailored to ensure effective financial management of dialysis treatment centers
  - Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities
  - Human Resources – develops productivity standards, job descriptions, staff performance review, personnel policies and procedures and employee relations
  - Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care
  - Marketing and Managed Care – responsible for competitive analysis and continuous development of dialysis services
  - Health, Safety, and Risk Management – provides regulatory information used to ensure compliance in the dialysis setting and provides risk management services
  - Regional Vice Presidents – provide operational direction and monitoring of daily operations

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

Promote Equitable Access

In Section II.1, page 24, 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 64.0% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. Thus, 64.0% of the In-Center revenue is derived from government payors.”*

On page 25, the applicant states it has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, payor source, gender, or other considerations. The applicant further states, *“A patient in need of dialysis is always welcomed at a BMA facility; the only requirement is proper referral from a physician.”*

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

*“BMA is also keenly sensitive to the second element of “equitable access” – time and distance barriers. ... As the dialysis patient population of Durham County continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed.”*

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

#### Maximize Healthcare Value

In Section VIII.1, page 58, the applicant projects a capital expenditure of \$4,500, and, in Section II.1, page 25, states that BMA is not seeking State or Federal monies or charitable contributions to develop the project. Rather, the applicant states, BMA, through its parent company, FMC, *“is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close to the patient homes.”* The applicant goes on to state:

*“As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... 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 service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the January 2014 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, FMC West Pettigrew, proposes to add four dialysis stations to its existing facility for a total of 24 certified stations upon completion of this project.

**Population to be Served**

In Section III.7, page 38, the applicant provided the projected patient origin for FMC West Pettigrew for in-center patients for the first two years of operation following completion of the project as follows:

FMC West Pettigrew						
County	Operating Year 1 CY2016		Operating Year 2 CY2017		County Patients Percent of Total	
	In-center Patients	Home Dialysis Patients	In-center Patients	Home Dialysis Patients	Year 1	Year 2
Durham	64.2	19.5	68.5	20.8	77.0%	78.1%
Alamance	0.0	1.0	0.0	1.0	0.9%	0.9%
Chatham	1.0	0.0	1.0	0.0	0.9%	0.9%
Granville	1.0	1.0	1.0	1.0	1.8%	1.7%
Orange	3.0	2.0	3.0	2.0	4.6%	4.4%
Person	2.0	1.0	2.0	1.0	2.8%	2.6%
Wake	0.0	3.0	0.0	3.0	2.8%	2.6%
Madison	1.0	0.0	1.0	0.0	0.9%	0.9%
Other States	8.0	1.0	8.0	1.0	8.3%	7.9%
<b>TOTAL</b>	<b>80.2</b>	<b>28.5</b>	<b>84.5</b>	<b>29.8</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identified the population FMC West Pettigrew proposes to serve.

**Demonstration of Need**

In Section III.1-7, pages 33-36, the applicant states the application is filed pursuant to the facility need methodology in the 2014 SMFP utilizing data from the January 2014 SDR, and it proposes to add four dialysis stations to FMC West Pettigrew for a total of 24 stations at that facility. The applicant used the following assumptions:

1. The project is scheduled for completion and certification of stations on December 31, 2015, projecting January 1, 2016 through December 31, 2016 as Operating Year 1, and January 1, 2017 through December 31, 2017 as Operating Year 2.
2. On June 30, 2013, FMC West Pettigrew was providing dialysis treatment for 67 in-center patients, including 51 Durham County residents, and 16 patients who were residents of other area counties.
3. FMC West Pettigrew assumes the ESRD in-center Durham County patient population utilizing the facility will increase at 6.78% per year. On pages 36-37, the applicant states,

*“The Facility Need Methodology calculations indicate that the facility is increasing at a rate of 104.5% (see III.2, Facility Need Methodology). BMA suggests this is an aberration and the facility is not growing at this rate. ... BMA does suggest that the facility census is increasing at a rate greater than the Durham County Five Year Average Annual Change Rate. Recent trends at the facility indicate the census is increasing at a rate of 6.78%. ... Considering the two years involved in the SDR data, the facility census has increased by eight patients from 59 patients (January 2012 SDR) to 67 patients (January 2014 SDR). This growth translates to a raw change of 13.56% for the two years, or an average of 6.78% annually. Thus, based upon the recent trends, BMA will use a growth rate of 6.78%. ... BMA will only apply this growth rate to the population of Durham County residents dialyzing at the facility, as of June 30, 2013.”*

The applicant’s methodology is provided in the following table.

FMC West Pettigrew  
J-10258-14  
Page 8

	In-Center
BMA begins with the facility census of Durham County in-center residents as of June 30, 2013.	51 patients
The census is increased by 6.78% for one year to June 30, 2014.	$(51 \times 0.0678) + 51 = 54.5$
The census is increased by 6.78% for one year to June 30, 2015.	$(54.5 \times 0.0678) + 54.5 = 58.1$
The census is increased by 3.39% (half of 6.78%) for six months to December 31, 2015. This is the projected certification date for this project.	$(58.1 \times 0.0339) + 58.1 = 60.1$
BMA adds 16 patients from the other counties. This is the projected beginning census for the project.	$60.1 + 16 = 76.1$
The census of Durham County residents is again increased by 6.78% for one year to December 31, 2016.	$(60.1 \times 0.0678) + 60.1 = 64.2$
BMA adds 16 patients from the other counties. This is the projected ending census for Operating Year 1.	$64.2 + 16 = 80.2$
The census of Durham County residents is again increased by 6.78% for one year to December 31, 2017.	$(64.2 \times 0.0678) + 64.2 = 68.5$
BMA adds 16 patients from the other counties. This is the projected ending census for Operating Year 2.	$68.5 + 16 = 84.5$

The applicant projects to serve 80 in-center patients or 3.33 patients per station ( $80/24 = 3.33$ ) by the end of Operating Year 1, and 84 in-center patients or 3.5 patients per station ( $84/24 = 3.5$ ) by the end of Operating Year 2 at the proposed 24-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Between June 30, 2012 and June 30, 2013, the number of in-center patients at FMC West Pettigrew increased from 56 to 67, which is an increase of 11 patients or 20%. The applicant's projected rate of growth for in-center patient census at FMC West Pettigrew (6.78%) is well below the applicant's recent historical growth rates. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

**Access**

In Section VI.1(a), page 50, the applicant states that each of BMA's 100 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects

85% of its in-center patients will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at FMC West Pettigrew, and demonstrates all residents of the area, and, in particular, underserved groups are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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

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In Section III.9, pages 40-42, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states that FMC West Pettigrew has experienced significant growth in utilization in recent years, and projects the facility will reach 83% utilization by the end of the first operating year for the proposed project, so the applicant rejected this alternative.
- 2) The applicant could have applied for fewer stations, but rejected this alternative because it would not meet the growing demand for dialysis services at FMC West Pettigrew.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the FMC West Pettigrew proposal is the least costly or most effective alternative to meet the need. 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 West Pettigrew shall materially comply with all representations made in the certificate of need application.**

2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC West Pettigrew shall develop and operate no more than four additional dialysis stations for a total of no more than 24 certified stations upon completion of this project, which shall include any isolation or home hemodialysis stations.**
  3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC West Pettigrew shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 24 dialysis stations, which shall include any isolation or home hemodialysis stations.**
  4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC West Pettigrew shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 58, the applicant projects a capital cost of \$4,500 for the proposed project, funded through accumulated reserves. In Section IX, page 62, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated March 17, 2014 from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

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

*BMA is submitting a Certificate of Need Application to add four dialysis stations to its FMC West Pettigrew facility in Durham County. ... As Vice President, I am authorized and do hereby authorize the addition of four dialysis stations for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$4,500 as may be needed for this project."*

In Exhibit 4, the applicant provides the audited financial statements for FMC and Subsidiaries for the years ended December 31, 2011 and 2012. As of December 31, 2012, FMC and Subsidiaries had cash and cash equivalents totaling \$341 million with \$17.8 billion in total

assets and \$9.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 63, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
Commercial	\$1,425.00
Medicare	\$239.00
Medicaid	\$137.29
VA	\$146.79
Private Pay	\$1,425.00

The applicant states the commercial charge listed does not reflect actual reimbursement. The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Section X.2, page 65 and X.4, page 72, the applicant reported projected revenues and expenses as follows:

FMC West Pettigrew		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$6,010,164	\$6,181,967
Total Operating Costs	\$4,651,468	\$4,806,950
Net Profit	\$1,358,696	\$1,375,017

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) 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.

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FMC West Pettigrew proposes to add four in-center dialysis stations for a total of 24 dialysis stations upon project completion. FMC West Pettigrew was serving 67 patients weekly on 20

stations, which is 3.35 patients per station or 84% of capacity, as of June 30, 2013. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 35-39 of the application. The growth projections are based on a projected 6.78% average annual growth rate in the number of dialysis patients at the FMC West Pettigrew facility. At the end of Operating Year Two, FMC West Pettigrew projects the utilization will be 3.5 in-center patients per station (84 patients / 24 dialysis stations = 3.5), which is 88% of capacity.

The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming 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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The following table shows current and projected staffing for FMC West Pettigrew, as provided by the applicant in Section VII.1, page 55:

<b>FMC West Pettigrew</b>			
<b>Position</b>	<b>Current FTEs</b>	<b># of FTE Positions to be Added</b>	<b>Total FTE Positions</b>
RN	2.00	1.00	3.00
LPN	1.00	0.00	1.00
Tech.	6.00	1.00	7.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contracted Position		
Admin. (FMC Dir. Ops.)	0.15	0.00	0.15
Dietician	0.40	0.00	0.40
Social Worker	0.40	0.00	0.40
Home Training Nurse	3.00	0.00	3.00
Chief Tech.	0.15	0.00	0.15
Equipment Tech.	0.66	0.00	0.66
In-Service	0.20	0.00	0.20
Clerical	1.00	0.00	1.00
<b>Total</b>	<b>15.96</b>	<b>2.00</b>	<b>17.96</b>

As shown in the above table, the applicant proposes to employ a total of 17.96 full-time equivalent (FTE) positions to staff FMC West Pettigrew upon completion of the proposed

project. In Section V.4, page 47, the applicant states that Elzbieta Rybicka-Kozlowska, M.D., a nephrologist with Durham Nephrology Associates, will serve as medical director of the facility. Exhibit 21 contains a letter from Dr. Rybicka-Kozlowska stating her intention to continue as the medical director for FMC West Pettigrew.

The applicant has documented the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section V.1, page 45, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 21 contains a letter from the medical director of the facility expressing her support for the proposed project, and Exhibit 22 contains a letter of support for the project signed by existing patients of the facility. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
  - (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
  - (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
    - (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In Section VI.1(b), page 51, the applicant reports that 85% of the in-center patients who received treatments at FMC West Pettigrew had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment source of the facility:

FMC West Pettigrew In-Center Patients	
Source of Payment	Percentage

FMC West Pettigrew  
J-10258-14  
Page 15

Medicare	63.19%
Medicaid	0.77%
Medicare/Commercial	21.05%
Commercial Insurance	14.10%
VA	0.69%
Other: Self/Indigent	0.19%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Durham County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Durham County	16%	5.8%	20.1%
Statewide	17%	6.7%	19.7%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by FMC West Pettigrew. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina’s Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

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 applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*<sup>1</sup> (p. 216)

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<sup>1</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)*

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6. Table includes North Carolina statistics only.<sup>2</sup>

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>TOTAL</b>	<b>\$49.2</b>	<b>100.0%</b>

\*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

The applicant demonstrates 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;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 53, 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 applicant will treat all patients the same regardless of race or handicap status.”*

In Section VI.6 (a), page 54, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

<sup>2</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

C

In Section VI.1(c), page 51, the applicant provides the projected payor mix for the proposed services at FMC West Pettigrew, which is shown below:

FMC West Pettigrew In-Center Patients	
Source of Payment	Percentage
Medicare	63.19%
Medicaid	0.77%
Medicare/Commercial	21.05%
Commercial Insurance	14.10%
VA	0.69%
Other: Self/Indigent	0.19%
Total	100.00%

The applicant projects no change from the current payor mix for in-center dialysis services, which is 85% Medicare and Medicaid. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5, page 53, the applicant states,

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC West Pettigrew 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 hospital emergency rooms.”*

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

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

C

In Section V.3, page 46 the applicant states,

*“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.”*

Exhibit 19 contains a letter from the applicant to Durham Technical Community College inviting the school to include the facility in its clinical rotations for nursing students. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity 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

FMC West Pettigrew proposes to add four dialysis stations to the existing facility for a total of 24 stations upon completion of this project. The applicant operates four dialysis centers in Durham County. Duke University Hospital operates one dialysis facility and DVA Healthcare Renal Care, Inc. (DaVita) three dialysis facilities Durham County, as shown in the table below.

**Durham County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/2013</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
Duke Hospital Dialysis	16	75.00%	3.00
Durham Dialysis (DaVita)	24	96.88%	3.88
Durham West Dialysis (DaVita)	29	81.90%	3.28
FMC Dialysis Briggs Avenue	29	63.79%	2.55
FMC Dialysis West Pettigrew	20	83.75%	3.35
FMC South Durham Dialysis	12	83.33%	3.33
Freedom Lake Dialysis (BMA)	22	87.50%	3.50

Southpoint Dialysis (DaVita)	12	97.92%	3.92
Totals (Averages)	164	82.47%	3.30

Source: January 2014 SDR, Table A.

As shown in the table above, six of the eight Durham County dialysis facilities are operating above 80% utilization (3.2 patients per station), and seven of the eight facilities are operating at or above 75% utilization (3.0 patients per station).

In Section V.7, pages 48-49, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states,

*“BMA does not expect this proposal to have an effect on the competitive climate in Durham County. According to the January 2014 SDR there were eight dialysis facilities operating within Durham County, operated by Fresenius, DaVita Dialysis, and Duke University Hospital. Patients have many choices of where to receive dialysis. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following:

- ◆ The applicant adequately demonstrates the need to add four dialysis stations at the FMC West Pettigrew facility and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that it will continue to provide quality services; and
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

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.

According to the files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMC West Pettigrew was found out of compliance with the Medicare Conditions of Participation in a survey conducted on February 26, 2014. However, the deficiencies were corrected and the applicant was found to be in compliance on the follow up survey on March 27, 2014. 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 application is conforming to all applicable regulatory review criteria. The specific criteria are discussed below:

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

.2202(a)(1) *Utilization rates;*

-C- See Section III.1, page 34, which indicates the facility had an 84% utilization rate as of June 30, 2013.

.2202(a)(2) *Mortality rates;*

-C- In Section IV.2, page 43, the applicant reports 2011, 2012 and 2013 facility mortality rates of 7.5%, 11.0% and 16.1%, respectively.

.2202(a)(3) *The number of patients that are home trained and the number of patients on Home dialysis;*

-NA- In Section IV.3, page 43, the applicant states that FMC West Pettigrew is currently providing home dialysis care and support for 17 home dialysis patients, and the facility provided home training for 15 patients in 2013.

.2202(a)(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 43, the applicant states FMC West Pettigrew referred two

patients for transplant evaluation in 2013, and had one patient receive a transplant in 2013.

- .2202(a)(5) *The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 44, the applicant states that FMC West Pettigrew has five patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus Non-dialysis related;*  
-C- See Section IV.6, page 44, the applicant reports a total of 146 hospital admissions in 2013; 113 were non-dialysis related and 33 were dialysis-related.
- .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- In Section IV.7, page 44, the applicant reports that in 2013 there were no patients with an infectious disease, and no patients converted to infectious status in 2013.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*  
-NA- FMC West Pettigrew 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 West Pettigrew 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 West Pettigrew 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- Exhibit 12 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .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 West Pettigrew 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, water supply, and other relevant health and safety requirements.*
- C- See Sections II.1, page 12; VII.2, page 56 and XI.6(g), page 78.
- .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- In Section III.7, page 38, FMC West Pettigrew provided projected patient origin based on historical experience for the first two years of operation following completion of the project.
- .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 West Pettigrew 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 for such services.*
- C- In Section II.1, page 16, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

## **10 NCAC 14C .2203 PERFORMANCE STANDARDS**

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- FMC West Pettigrew 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 Sections II.1, page 14 and III.7, page 35, the applicant projects to serve 80 in-center patients by the end of Operating Year 1, which is 3.33 patients per station ( $80 / 24 = 3.33$ ). See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 17-20, and Section III.7, pages 35-39, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

#### **10 NCAC 14C .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- These services are provided by Duke Regional Hospital. See Section V.1, page 45.
- .2204(2) *Maintenance dialysis;*
  - C- Provided at FMC West Pettigrew. See Section V.1, page 45.
- .2204(3) *Accessible self-care training;*
  - C- Provided by FMC West Pettigrew. See Section V.1, page 45.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
  - C- Provided by FMC West Pettigrew. See Section V.1, page 45.
- .2204(5) *X-ray services;*
  - C- Provided by Duke Regional Hospital. See Section V.1, page 45.
- .2204(6) *Laboratory services;*
  - C- Provided by SPECTRA Laboratories, Inc. See Section V.1, page 45, and Exhibit 15.
- .2204(7) *Blood bank services;*
  - C- Provided by Duke Regional Hospital. See Section V.1, page 45.
- .2204(8) *Emergency care;*
  - C- Provided by FMC West Pettigrew facility staff and the hospitals. See Section V.1, page 45.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- Provided by Duke Regional Hospital. See Section V.1, page 45.
- .2204(10) *Vascular surgery for dialysis treatment patients*
  - C- Provided by Regional Vascular Associates and Duke Regional Hospital. See Section V.1, page 45.

- .2204(11) *Transplantation services;*  
-C- Provided by Duke University Medical Center. See Section V.1, page 45.
- .2204(12) *Vocational rehabilitation counseling and services; and,*  
-C- Provided by referral to Durham Vocational Rehabilitation services. See Section V.1, page 45.
- .2204(13) *Transportation*  
-C- Provided by DATA. See Section V.1, page 45.

#### **10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*  
-C- In Section VII.1, page 55, the applicant provides the proposed staffing. In Section VII.2, page 56, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- .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 56, and Exhibits 9 and 10.