

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: January 22, 2015

PROJECT ANALYST: Mike McKillip

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10343-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake / Add three dialysis stations for a total of 14 certified stations upon completion of this project and Project I.D. # K-10099-13 / Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake [FMC Eastern Wake] proposes to add three dialysis stations for a total of 14 certified dialysis stations upon completion of this project and Project I.D. # K-10099-13, relocate three dialysis stations to FMC Tar River (Franklin County).

Need Determination

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 July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 12 dialysis stations in Wake County; therefore, based on the county need methodology, there is no need for additional stations in Wake 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 Eastern Wake in the July 2014 SDR is 3.79 patients per station. This utilization rate was calculated based on 53 in-center dialysis patients and 14 certified dialysis stations as of December 31, 2013 (53 patients / 14 stations = 3.79 patients per station). Application of the facility need methodology indicates three additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW - JULY SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		94.6%
Certified Stations		14
Pending Stations		0
Total Existing and Pending Stations		14
In-Center Patients as of 12/31/13 (SDR2)		53
In-Center Patients as of 6/30/13 (SDR1)		53
Step	Description	
	Difference (SDR2 - SDR1)	0
(i)	Multiply the difference by 2 for the projected net in-center Change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.0000
	(ii) Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.0000
(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	53.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	16.5625
	and subtract the number of certified and pending stations as recorded in SDR2 [14] to determine the number of stations needed	3

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.

Policies

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.”

The applicant addresses Policy GEN-3 beginning on page 18 of the application.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 4-8, Section II, pages 18-19, Section XI.6(g), page 68, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 19-20, and Section VI, pages 43-47, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section II, pages 20-21, and Section V.7, page 42, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 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 Eastern Wake, proposes to add three dialysis stations to its existing facility for a total of 14 certified dialysis stations upon completion of this project and Project I.D. # K-10099-13, relocate three dialysis stations to FMC Tar River (Franklin County). In Section IV.1, page 36, the applicant states that of the 51 in-center patients served at FMC Eastern Wake as of June 30, 2014, 43 patients were Wake County residents and eight patients were Franklin County residents.

Population to be Served

In Section III.7, page 31, the applicant provides the projected patient origin for FMC Eastern Wake for in-center patients for the first two years of operation following completion of the project as follows:

Projected Patient Origin

County	Year 1 CY2017	Year 2 CY2018	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Wake	49.5	51.5	100.0%	100.0%
Total	49.5	51.5	100.0%	100.0%

The applicant adequately identified the population FMC Eastern Wake proposes to serve.

Analysis of Need

In Section III.2, page 29, the applicant states the application is filed pursuant to the facility need methodology in the 2014 SMFP utilizing data from the July 2014 SDR, and it proposes to add three dialysis stations to FMC Eastern Wake for a total of 14 stations at that facility. The applicant used the following assumptions:

1. The project is scheduled for completion and certification of stations on December 31, 2016, projecting January 1, 2017 through December 31, 2017 as Operating Year 1, and January 1, 2018 through December 31, 2018 as Operating Year 2.
2. On June 30, 2014, FMC Eastern Wake was providing dialysis treatment for 51 in-center patients. Of the 51 patients, 43 were residents of Wake County, and eight were residents of Franklin County.
3. FMC Eastern Wake assumes the Wake County ESRD in-center patient population utilizing the facility will increase at 4.1% per year. Also, the applicant assumes that the Franklin County patients will transfer their care to FMC Tar River (Project I.D. # K-10099-13) upon completion of that project. On page 31, the applicant states,

“BMA assumes that the dialysis patient population residing in Wake County and dialyzing at FMC Eastern Wake will increase at a rate commensurate with the Wake County Five Year Average Annual Change Rate, 4.1% as published in the July 2014 SDR. ... BMA is currently serving patients from Franklin County at FMC Eastern Wake. In CON Project ID # K-10099-13, BMA assumed that the patients of Franklin County would transfer their care to the FMC Tar River facility upon completion of the that project. In this proposal, BMA continues to assume that the patients of Franklin County will transfer their care to FMC Tar River upon completion of that project. ... BMA notes that the FMC Tar River decision has been appealed by DaVita and is currently before the NC Court of Appeals. ... BMA assumes a favorable decision by the COA by the end of 2015. Absent further appeal to the NC Supreme Court, BMA assumes that the FMC Tar River project will be constructed and certified by December 16, 2016.”

Projected Utilization

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

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	In-Center
BMA begins with the facility census of Wake County in-center residents as of June 30, 2014.	43
The census of Wake County patients is increased by one half of 4.1% (2.05%) to project the census forward for six months to December 31, 2014.	$(43 \times 0.0205) + 43 = 43.9$
The census of Wake County patients is increased by 4.1% for one year to December 31, 2015.	$(43.9 \times 0.041) + 43.9 = 45.7$
The census of Wake County patients is again increased by 4.1% for one year to December 31, 2016, which is projected completion date for the project.	$(45.7 \times 0.041) + 45.7 = 47.6$
The census of Wake County patients is again increased by 4.1% for one year to December 31, 2017. This is the projected ending census for Operating Year 1.	$(47.6 \times 0.041) + 47.6 = 49.5$
The census of Wake County patients is again increased by 4.1% for one year to December 31, 2018. This is the projected ending census for Operating Year 2.	$(49.5 \times 0.041) + 49.5 = 51.5$

The applicant projects to serve 49 in-center patients or 3.5 patients per station ($49/14 = 3.5$) by the end of Operating Year 1 and 51 in-center patients or 3.6 patients per station ($51/14 = 3.6$) by the end of Operating Year 2 for the proposed 14-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). The January 2014 and the July 2014 SDR both indicate that FMC Eastern Wake operated at a utilization rate of 95 percent (3.8 patients per station). In this application, the applicant assumes a projected annual rate of growth of 4.1% for the Wake County in-center patient census at FMC Eastern Wake, which is consistent with the Wake County Five Year Average Annual Change Rate (2009-2013). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI.1(a), page 43, the applicant states that each of BMA's 102 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 86% of its in-center patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional stations at FMC Eastern Wake, and demonstrates the extent to which all residents of the area, including 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.

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.9, pages 33-35, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states that it rejected this alternative because it would not address need for a growing ESRD population in Wake County.
- 2) The applicant could have relocated stations from other facilities, but rejected this alternative because the other facilities were developed to provide localized delivery of care and because there is sufficient demand at those other facilities to support the need for those existing stations.
- 3) The applicant considered expanding a different facility, but rejected this alternative because the other facilities serve different patient populations than are served by FMC Eastern Wake.

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 Eastern Wake 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 Eastern Wake 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 Eastern Wake shall develop and operate no more than three additional dialysis stations for a total of no more than 14 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 Eastern Wake shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 14 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **The certificate of need for Project I.D. #J-10343-14 shall not be issued until the certificate of need is issued for Project I.D. #K-10099-13.**
 5. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Eastern Wake shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 51, the applicant projects no capital costs will be incurred for the proposed project. In Section IX, page 54, the applicant states there will be no start-up or initial operating expenses associated with the proposed project. In Exhibit 4, the applicant provides the audited financial statements for FMC and Subsidiaries for the years ended December 31, 2012 and 2011. 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.

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In Section X.1, page 55, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
Commercial	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
VA	\$231.12
Private Pay	\$1,425.00

The applicant states the commercial charge listed does not reflect actual reimbursement.

In Section X.2, page 57, and X.4, page 62, the applicant reported projected revenues and expenses as follows:

FMC Eastern Wake		
	Operating Year 1 CY2017	Operating Year 2 CY2018
Total Net Revenue	\$2,614,350	\$2,678,015
Total Operating Costs	\$2,259,301	\$2,321,246
Net Profit	\$355,048	\$356,770

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 Eastern Wake proposes to add three in-center dialysis stations for a total of 14 dialysis stations upon project completion. FMC Eastern Wake was serving 53 patients weekly on 14 stations, which is 3.8 patients per station or 95% of capacity, as of December 31, 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 31-34 of the application. The growth projections are based on a projected 4.1% average annual growth rate in the number of Wake County dialysis patients at the FMC Eastern Wake facility. At the end of Operating Year Two, FMC Eastern Wake projects the utilization will be 3.6 in-center patients per station (51 patients / 14 dialysis stations = 3.6), which is 91% of capacity.

The applicant operates eleven dialysis centers in Wake County. DaVita (Wake Forest Dialysis Center) is the only other provider of dialysis services in Wake County, and operates just one dialysis center, as shown in the table below.

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/13	% Utilization	Patients Per Station
BMA of Fuquay-Varina	19	86.84%	3.5
BMA of Raleigh Dialysis	43	84.88%	3.4
BMA Cary	24	87.50%	3.5
FMC Apex (BMA)	17	75.00%	3.0
FMC Central Raleigh (BMA)	15	93.33%	3.7
FMC Eastern Wake (BMA)	14	94.64%	3.8
FMC Millbrook (BMA)	17	91.18%	3.6
FMC New Hope (BMA)	36	59.03%	2.4
Southwest Wake (BMA)	31	87.90%	3.5
Wake Dialysis (BMA)	50	81.50%	3.3
Wake Forest Dialysis (DaVita)	15	98.33%	3.9
Zebulon Kidney Center (BMA)	30	82.50%	3.3

Source: July 2014 SDR, Table A.

As shown in the table above, ten of the twelve Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and eleven of the twelve facilities are operating at or above 75% utilization (3.0 patients per station).

The applicant adequately demonstrates the need to develop three 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 Eastern Wake, as provided by the applicant in Section VII.1, page 48:

FMC Eastern Wake			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	1.50	1.00	2.50
Tech.	4.00	2.00	6.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contracted Position		
Admin. (FMC Dir. Ops.)	0.15	0.00	0.15
Dietician	0.50	0.00	0.50
Social Worker	0.50	0.00	0.50
Chief Tech.	0.25	0.00	0.25
Equipment Tech.	0.60	0.00	0.60
In-Service	0.25	0.00	0.25
Clerical	1.00	0.00	1.00
Total	9.75	3.00	12.75

As shown in the above table, the applicant proposes to employ a total of 12.75 full-time equivalent (FTE) positions to staff FMC Eastern Wake upon completion of the proposed project. In Section V.4, page 40, the applicant states that Mark Rothman, M.D., a nephrologist with Wake Nephrology Associates, will serve as medical director of the facility. Exhibit 21 contains a letter from Dr. Rothman stating his intention to continue as the medical director for FMC Eastern Wake.

In Section VII.10, page 50, the applicant provides the following table showing the projected number of direct care staff for each shift offered at FMC Eastern Wake after the addition of the three dialysis stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am to 12:00 pm	5	5	5	5	5	5
Afternoon	12:00 pm to 5:00 pm	5	5	5	5	5	5
Evening	N/A	2	0	2	0	2	0

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 38, 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 his 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 44, the applicant reports that 85.6% of the in-center patients who received treatments at FMC Eastern Wake 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:

Payment Source	In-Center
Commercial Insurance	14.1%
Medicare	66.4%
Medicaid	1.3%

VA	0.3%
Medicare/Commercial Insurance	17.9%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Wake County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Wake County	10%	3.3%	18.4%
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 services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted 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 do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

¹<http://www.esrdnetwork6.org/utills/pdf/annualreport/2013%20Network%206%20Annual%20Report.pdf>

²www.usrds.org/adr.aspx

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show 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 2013 *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%
Total	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

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;

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³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 45, 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 46, 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

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In Section VI.1(c), page 44, the applicant provides the projected payment source for the proposed services at FMC Eastern Wake, which is shown below:

Payment Source	In-Center
Commercial Insurance	14.1%
Medicare	66.4%
Medicaid	1.3%
VA	0.3%
Medicare/Commercial Insurance	17.9%
Total	100.0%

The applicant projects no change from the current payment source for in-center dialysis services, which is 85.6% 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.

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In Section VI.5, page 46, 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 Eastern Wake 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 Eastern Wake 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.

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In Section V.3, page 39 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 Wake 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 Eastern Wake proposes to add three dialysis stations to the existing facility for a total of 14 stations upon completion of this project and Project I.D. # J-10099-13, FMC Tar River (Franklin County). The applicant operates eleven dialysis centers in Wake County. DaVita (Wake Forest Dialysis Center) is the only other provider of dialysis services in Wake County, and operates just one dialysis center, as shown in the table below.

Wake County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/13	% Utilization	Patients Per Station
BMA of Fuquay-Varina	19	86.84%	3.5
BMA of Raleigh Dialysis	43	84.88%	3.4
BMA Cary	24	87.50%	3.5
FMC Apex (BMA)	17	75.00%	3.0
FMC Central Raleigh (BMA)	15	93.33%	3.7
FMC Eastern Wake (BMA)	14	94.64%	3.8
FMC Millbrook (BMA)	17	91.18%	3.6
FMC New Hope (BMA)	36	59.03%	2.4
Southwest Wake (BMA)	31	87.90%	3.5
Wake Dialysis (BMA)	50	81.50%	3.3
Wake Forest Dialysis (DaVita)	15	98.33%	3.9
Zebulon Kidney Center (BMA)	30	82.50%	3.3

Source: July 2014 SDR, Table A.

As shown in the table above, ten of the twelve Wake County dialysis facilities are operating above 80% utilization (3.2 patients per station), and eleven of the twelve facilities are operating at or above 75% utilization (3.0 patients per station).

In Section V.7, page 42, 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,

“The patients to be served by this facility are existing dialysis patients, and future patients residing in Wake County. Another provider, DaVita, operates a dialysis facility in Wake Forest. The DaVita Wake Forest facility is approximately seven miles from the FMC Eastern Wake facility. However, this facility is not likely to be serving patients who might otherwise choose to receive dialysis treatment at the DaVita location. The DaVita facility is not [sic] be operated the same as the BMA facility. The DaVita facility has its own medical director.”

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 dialysis services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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

According to the files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, FMC Eastern Wake operated in compliance with the Medicare Conditions of Participation within the 18 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 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 II.1, page 10, which indicates the facility had an 95% utilization rate as of December 31, 2013.

.2202(a)(2) Mortality rates;

)

-C- In Section IV.2, page 36, the applicant reports 2011, 2012 and 2013 facility mortality rates of 14.5%, 14.6% and 6.4%, 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 36, the applicant states that FMC Eastern Wake does not operate a home dialysis program.

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

)

-C- In Section IV.4, page 36 the applicant states FMC Eastern Wake referred 9 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 36, the applicant states that FMC Eastern Wake has three 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 37, the applicant reports a total of 34 hospital admissions in 2013; 27 were non-dialysis related and 7 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 37, 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 Eastern Wake 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 Eastern Wake 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 Eastern Wake 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 Eastern Wake 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 49 and XI.6(g), page 68.
- .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 31, FMC Eastern Wake 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 Eastern Wake 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 14, 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 Eastern Wake is an existing facility.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section II.1, page 13, the applicant projects to serve 49 in-center patients by the end of Operating Year 1, which is 3.5 patients per station ($49 / 14 = 3.5$). The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 12-13 and Section III.7, pages 30-32, the applicant provides

the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

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 WakeMed and Rex Hospital. See Section V.1, page 38.

.2204(2) *Maintenance dialysis;*

-C- Provided at FMC Eastern Wake. See Section V.1, page 38.

.2204(3) *Accessible self-care training;*

-C- Provided by referral to BMA Wake. See Section V.2(d), page 39.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- Provided by referral to BMA Wake. See Section V.2(d), page 39.

.2204(5) *X-ray services;*

-C- Provided by WakeMed and Raleigh Radiology. See Section V.1, page 38.

.2204(6) *Laboratory services;*

-C- Provided by SPECTRA Laboratories, Inc. See Section V.1, page 38, and Exhibit 15.

.2204(7) *Blood bank services;*

-C- Provided by WakeMed. See Section V.1, page 38.

.2204(8) *Emergency care;*

-C- Provided by FMC Eastern Wake facility staff and the hospitals. See Section V.1, page 38.

.2204(9) *Acute dialysis in an acute care setting;*

-C- Provided by WakeMed. See Section V.1, page 38.

.2204(10) *Vascular surgery for dialysis treatment patients*

-C- Provided by Carolina Cardiovascular, Wake Surgical, North Raleigh Surgical and Carolina Surgery. See Section V.1, page 38.

.2204(11) *Transplantation services;*

-C- Provided by Duke University Medical Center and UNC Hospitals. See Section V.1, page 38.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- Provided by referral to North Carolina Division of Vocational Rehabilitation. See Section V.1, page 38.

.2204(13) *Transportation*

-C- Provided by Johnston Ambulance Services, Tri-Star Transportation, or Wake Coordinated Transportation. See Section V.1, page 38.

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 48, the applicant provides the proposed staffing. In Section VII.2, page 49, 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. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- See Section VII.5, page 49, and Exhibits 9 and 10.