

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 5, 2015

Findings Date: June 5, 2015

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: K-11006-15

Facility: FMS Oxford

FID #: 041025

County: Granville

Applicant(s): Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Oxford

Project: Add four dialysis stations for a total of 23 certified stations upon completion

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 FMS Oxford [FMS Oxford] proposes to add four dialysis stations for a total of 23 certified dialysis stations upon completion of the project.

Need Determination

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Granville County; therefore, based on the county need methodology, there is no need for additional stations in Granville 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 FMS Oxford in the January 2015 SDR is 3.53 patients per station. This utilization rate was calculated based on 67 in-center dialysis patients and 19 certified dialysis stations as of June 30, 2014 (67 patients / 19 stations = 3.53 patients per station). Application of the facility need methodology indicates four 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 6/30/14		88.16%
Certified Stations		19
Pending Stations		0
Total Existing and Pending Stations		19
In-Center Patients as of 6/30/14 (SDR2)		67
In-Center Patients as of 12/31/13 (SDR1)		62
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.1613
(ii)	Divide the result of step (i) by 12	0.0134
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.0806
(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	72.4032
(v)	Divide the result of step (iv) by 3.2 patients per station	22.6260
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	4

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

Policies

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2015 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 67, 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, Section VI, pages 41-46, 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, page 20, Section V.7, page 41, 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 January 2015 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, FMS Oxford, proposes to add four dialysis stations to its existing facility for a total of 23 certified dialysis stations upon completion of the project. In Section IV.1, page 35, the applicant states that of the 67 in-center patients served at FMS Oxford as of December 31, 2014, 52 patients were Granville County residents, 13 were Vance County residents, and two patients were Franklin County residents.

Population to be Served

In Section III.7, page 32, the applicant provides the projected patient origin for FMS Oxford 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
Granville	65.7	71.0	81.41%	82.56%
Franklin	2.0	2.0	2.48%	2.33%
Vance	13.0	13.0	16.11%	15.11%
Total	80.7	86.0	100.00%	100.00%

The applicant adequately identified the population FMS Oxford 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 2015 SMFP utilizing data from the January 2015 SDR, and it proposes to add four dialysis stations to FMS Oxford for a total of 23 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 December 31, 2014, FMS Oxford was providing dialysis treatment for 67 in-center patients. Of the 67 patients, 52 were residents of Granville County, 13 patients were residents of Vance County, and 2 patients were residents of Franklin County.
3. FMS Oxford assumes the Granville County ESRD in-center patient population utilizing the facility will increase at 8.1% per year, which is equal to the Granville County Five Year Average Annual Change Rate as reported in the January 2015 SDR. On page 31, the applicant states,

“As of December 31, 2014, BMA was serving two Franklin County residents and 13 Vance County residents at FMS Oxford. BMA assumes that these patients are dialyzing at FMS Oxford by choice, and that these patients will continue to dialyze at the facility. However, BMA will not demonstrate any growth in this segment of the patient population. These patients are added to the projected census at appropriate points in time.”

Projected Utilization

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

	In-Center
BMA begins with the facility census of Granville County in-center residents as of December 31, 2014.	52 patients
The census of Granville County patients is increased by 8.1% for one year to December 31, 2015.	$(52 \times 0.081) + 52 = 56.2$
The census of Granville County patients is increased by 8.1% for one year to December 31, 2016, which is the projected completion date for the project.	$(56.2 \times 0.081) + 56.2 = 60.8$
BMA adds 15 patients residing in Franklin and Vance counties to project the total beginning census for the project.	$60.8 + 15 = 75.8$
The census of Granville County patients is again increased by 8.1% for one year to December 31, 2017.	$(60.8 \times 0.081) + 60.8 = 65.7$
BMA adds 15 patients residing in Franklin and Vance counties to project the total ending census for Operating Year 1.	$65.7 + 15 = 80.7$
The census of Granville County patients is again increased by 8.1% for one year to December 31, 2018.	$(65.7 \times 0.081) + 65.7 = 71.0$
BMA adds 15 patients residing in Franklin and Vance counties to project the total ending census for Operating Year 2.	$71.0 + 15 = 86.0$

The applicant projects to serve 80 in-center patients or 3.5 patients per station ($80/23 = 3.5$) by the end of Operating Year 1 and 86 in-center patients or 3.7 patients per station ($86/23 = 3.7$) by the end of Operating Year 2 for the proposed 23-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 July 2014 and the January 2015 SDR indicate that FMS Oxford operated at a utilization rate of 82 percent and 88 percent, respectively. In this application, the applicant assumes a projected annual rate of growth of 8.1 percent for the Granville County in-center patient census at FMS Oxford, which is consistent with the Granville 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 42, the applicant states that each of BMA's 101 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 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 four additional stations at FMS Oxford, 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 Granville County, or the demand for ESRD services at FMS Oxford, in particular.
- 2) The applicant could have relocated stations from FMC Neuse River, the only other ESRD facility in Granville County, but rejected this alternative because there is sufficient demand at that other facility to support the need for those existing stations.

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 FMS Oxford 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 FMS Oxford shall materially comply with all representations made in the certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Oxford shall develop and operate no more than four additional dialysis stations for a total of no more than 23 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 FMS Oxford shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 23 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Oxford 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 \$26,000 in 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.

Exhibit 24 includes a letter dated March 15, 2015 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 FMS Oxford facility. FMS Oxford will have a total of 23 dialysis stations upon

completion of this project. ... 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 \$26,000 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, 2013 and 2012. As of December 31, 2013, FMC and Subsidiaries had cash and cash equivalents totaling \$276 million with \$16.6 billion in total assets and \$7.7 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 55, the applicant projects the following charge per treatment for each payment source:

Payer	In-Center Charge
Commercial	\$1,425.00
Medicare	\$239.02
Medicaid	\$140.23
VA	\$231.12
State Kidney Program	\$100.00
Private Pay	\$1,425.00

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

In Section X.2, page 56, and X.4, page 62, the applicant reported projected revenues and expenses as follows:

FMS Oxford		
	Operating Year 1 CY2017	Operating Year 2 CY2018
Total Net Revenue	\$4,191,303	\$4,473,585
Total Operating Costs	\$3,268,488	\$3,452,015
Net Profit	\$922,815	\$1,021,570

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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FMS Oxford proposes to add four in-center dialysis stations for a total of 23 dialysis stations upon project completion. FMS Oxford was serving 67 patients weekly on 19 stations, which is 3.5 patients per station or 88% of capacity, as of June 30, 2014. 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 30-32 of the application. The growth projections are based on a projected 8.1% average annual growth rate in the number of Granville County dialysis patients at the FMS Oxford facility. At the end of Operating Year Two, FMS Oxford projects the utilization will be 3.7 in-center patients per station (86 patients / 23 dialysis stations = 3.7), which is 93% of capacity.

The applicant operates two dialysis centers in Granville County. There are no other providers of dialysis services in Granville County.

Granville County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
FMC Neuse River	22	76.14%	3.04
FMS Oxford	19	88.16%	3.52

Source: January 2015 SDR, Table A.

As shown in the table above, one of the two Granville County dialysis facilities is operating above 80% utilization (3.2 patients per station), and both of the Granville facilities are operating above 75% utilization (3.0 patients per station).

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 FMS Oxford, as provided by the applicant in Section VII.1, page 47:

FMS Oxford			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	3.00	1.00	4.00
Patient Care Technician	5.00	2.00	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	0.50	0.00	0.50
Social Worker	0.50	0.00	0.50
Chief Tech.	0.15	0.00	0.15
Equipment Tech.	0.50	0.00	0.50
In-Service	0.20	0.00	0.20
Clerical	1.00	0.00	1.00
Total	12.00	3.00	15.00

As shown in the above table, the applicant proposes to employ a total of 15 full-time equivalent (FTE) positions to staff FMS Oxford upon completion of the proposed project. In Section V.4, page 40, the applicant states that Charles Cooperberg, M.D., a nephrologist with Durham Nephrology Associates, will serve as medical director of the facility. Exhibit 21 contains a letter from Dr. Cooperberg stating his intention to continue as the medical director for FMS Oxford.

In Section VII.10, page 49, the applicant provides the following table showing the projected number of direct care staff for each shift offered at FMS Oxford after the addition of the four dialysis stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am to 12:00 pm	6	6	6	6	6	6
Afternoon	12:00 pm to 5:00 pm	6	6	6	6	6	6
Evening	N/A						

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 37, 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 43, the applicant reports that 85.3% of the in-center patients who received treatments at FMS Oxford 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	10.55%
Medicare	77.58%
Medicaid	0.21%
VA	2.76%
Self/Indigent	1.40%
Medicare/Commercial Insurance	7.50%
Total	100.00%

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 Granville 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) *
Granville County	15%	6.3%	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:

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

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

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:

² www.usrds.org/adr.aspx

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 44, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section VI.6 (a), page 45, 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

C

In Section VI.1(c), page 43, the applicant provides the projected payment source for the proposed services at FMS Oxford, which is shown below:

Payment Source	In-Center
Commercial Insurance	10.55%
Medicare	77.58%
Medicaid	0.21%
VA	2.76%
Self/Indigent	1.40%
Medicare/Commercial Insurance	7.50%
Total	100.0%

The applicant projects no change from the current payment source for in-center dialysis services, which is 85.3% 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 45, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMS Oxford 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 FMS Oxford 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 Vance-Granville 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.

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FMS Oxford proposes to add four in-center dialysis stations for a total of 23 dialysis stations upon project completion. The applicant operates two dialysis centers in Granville County. There are no other providers of dialysis services in Granville County.

Granville County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
FMC Neuse River	22	76.14%	3.04
FMS Oxford	19	88.16%	3.52

Source: January 2015 SDR, Table A.

As shown in the table above, one of the two Granville County dialysis facilities is operating above 80% utilization (3.2 patients per station), and both of the Granville facilities are operating above 75% utilization (3.0 patients per station).

In Section V.7, page 41, 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 effect on the competitive climate in Granville County. According to the January 2015 SDR there were two dialysis facilities operating within Granville County; both are operated by Fresenius. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at the 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 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

In Section I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 88% utilization rate as of June 30, 2014.

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

-C- In Section IV.2, page 35, the applicant reports 2012, 2013 and 2014 facility mortality rates of 16.2%, 18.8% and 14.0%, 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 35, the applicant states that FMS Oxford does not operate a home dialysis program.

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

-C- In Section IV.4, page 35 the applicant states FMS Oxford referred 7 patients for transplant evaluation in 2014, and had one patient receive a transplant in 2014.

.2202(a)(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 35, the applicant states that FMS Oxford 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 36, the applicant reports a total of 101 hospital admissions in 2013; 93 were non-dialysis related and 8 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 II.1, page 11, 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- FMS Oxford 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- FMS Oxford 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- FMS Oxford 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- FMS Oxford 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 48 and XI.6(g), page 67.

.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 32, FMS Oxford 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- FMS Oxford 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- FMS Oxford 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 80 in-center patients by the end of Operating Year 1, which is 3.5 patients per station ($80 / 23 = 3.5$). 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 Granville Medical Center or Duke Regional Hospital. See Section V.1, page 37.
- .2204(2) *Maintenance dialysis;*
- C- Provided at FMS Oxford. See Section V.1, page 37.
- .2204(3) *Accessible self-care training;*
- C- Provided by referral to FMC Neuse River. See Section V.2(d), page 38.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- Provided by referral to FMC Neuse River. See Section V.2(d), page 38.

- .2204(5) *X-ray services;*
-C- These services are provided by Granville Medical Center or Duke Regional Hospital. See Section V.1, page 37.
- .2204(6) *Laboratory services;*
-C- Provided by SPECTRA Laboratories, Inc. See Section V.1, page 37, and Exhibit 15.
- .2204(7) *Blood bank services;*
-C- Provided by Granville Medical Center. See Section V.1, page 37.
- .2204(8) *Emergency care;*
-C- Provided by FMS Oxford facility staff and the hospitals. See Section V.1, page 37.
- .2204(9) *Acute dialysis in an acute care setting;*
-C- Provided by Duke Regional Hospital. See Section V.1, page 37.
- .2204(10) *Vascular surgery for dialysis treatment patients*
-C- Provided by Duke Regional Hospital Vascular Radiology, Triangle Interventional Radiology, Duke Medical Center, and Regional Surgical Associates. See Section V.1, page 37.
- .2204(11) *Transplantation services;*
-C- Provided by Duke University Medical Center. See Section V.1, page 37.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
-C- Provided by referral to Granville County Vocational Rehabilitation. See Section V.1, page 37.
- .2204(13) *Transportation*
-C- Provided by KARTS. See Section V.1, page 37.

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 47, the applicant provides the proposed staffing. In Section VII.2, page 48, 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 48, and Exhibits 9 and 10.