

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 19, 2017

Findings Date: May 19, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: K-11308-17

Facility: FMS Dialysis Services of Oxford

FID #: 041025

County: Granville

Applicant(s): Bio-Medical Applications of North Carolina, Inc.

Project: Add two dialysis stations for a total of 25 dialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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. (BMA) d/b/a FMS Dialysis Services of Oxford (FMS Oxford) proposes to add two dialysis stations for a total of 25 certified dialysis stations upon project completion.

Need Determination

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The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of one dialysis station in Granville County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 2017 SDR is 3.3043 patients per station per week, or 82.61% ($3.3043 / 4 \text{ patients per station} = 0.82607$). This utilization rate was calculated based on 76 in-center dialysis patients and 23 certified dialysis stations ($76 \text{ patients} / 23 \text{ stations} = 3.3043 \text{ patients per station per week}$).

Application of the facility need methodology indicates 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 6/30/16		82.61%
Certified Stations		23
Pending Stations		0
Total Existing and Pending Stations		23
In-Center Patients as of 6/30/16 (SDR2)		76
In-Center Patients as of 12/31/15 (SDR1)		71
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 12/31/15	0.1408
(ii)	Divide the result of step (i) by 12	0.0117
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0704
(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	81.3521
(v)	Divide the result of step (iv) by 3.2 patients per station	25.4225
	and subtract the number of certified and pending stations to determine the number of stations needed	2

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

Policies

There is one policy in the 2017 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 12, and Section O, pages 54-58. 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 B.4, page 13, Section C, page 19, Section L, pages 47-51, 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 B.4, pages 13-14, Section C, pages 17-19, Section N, page 53, 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.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 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.

C

The applicant proposes to add two dialysis station for a total of 25 certified dialysis stations at FMS Oxford upon project completion.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as "*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*" Thus, the service area is Granville County. Facilities may serve residents of counties not included in their service area.

In Section C, page 21, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by FMS Oxford, as shown below:

FMS Oxford Dialysis Patients as of 12/31/2016	
COUNTY	IC PATIENTS
Granville	63
Franklin	1
Vance	12
Virginia	1
Total	77

In Section C-1, page 17, the applicant provides the projected patient origin for FMS Oxford for the first two years of operation following project completion, as follows:

	FMS OXFORD			
	OPERATING YEAR 1 CY2018	OPERATING YEAR 2 CY2019	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER	
	IN-CENTER	IN-CENTER	YEAR 1	YEAR 2
Granville	69.6	73.1	83.3%	83.9%
Franklin	1.0	1.0	1.2%	1.1%
Vance	12.0	12.0	14.4%	13.8%
Virginia	1.0	1.0	1.2%	1.1%
TOTAL	83.6	87.1	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 17-18. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add two dialysis stations to the existing FMS Oxford facility for a total of 25 certified dialysis upon project completion. In Section B.2, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the January 2017 SDR. In Section C.1, pages 17-18, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s patients who reside in Granville County have increased at a rate commensurate with the Five-Year Average Annual Change Rate for Granville County, which is 5.1%. Although there are 12 Vance County patients dialyzing at FMS Oxfords, the applicant does not project an increase in its Vance County patient population which represents approximately 14 percent of FMS Oxford’s patient population. Additionally, the applicant does not project growth of its patients residing in Franklin County or Virginia; those existing patients were added to the projected Granville County patients at appropriate points in the methodology.

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Operating Year 1 (OY1) = Calendar Year (CY) 2018
OY2 = CY2019

Projected Utilization

In Section C, page 18, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Granville County patients dialyzing at FMS Oxford as of December 31, 2016.	63
Project the Granville County patient population forward for one year to December 31, 2017.	$(63 \times .051) + 63 = 66.2$
Project the Granville County patient population forward one year to December 31, 2018.	$(66.2 \times .051) + 66.2 = 69.5$
OY1: Add 12 patients from Vance County and 1 patient from Franklin County and 1 patient from Virginia for a total of 14 patients. This is the projected census for OY 1.	$69.5 + 14 = 83.6$
Project the Granville County patient population forward one year to December 31, 2019.	$(69.5 \times .051) + 69.5 = 73.0$
OY2: Add 12 patients from Vance County and 1 patient from Franklin County and 1 patient from Virginia for a total of 14 patients. This is the projected census for OY 2.	$73 + 14 = 87.0$

On page 19, the applicant states it rounded the patient population down. Thus, the applicant projects that FMS Oxford will serve a total of 83 in-center patients at the end of OY1 for a utilization rate of 83% or 3.32 patients per station per week ($83 \text{ patients} / 25 \text{ stations} = 3.32 / 4 = 0.83$ or 83%). The projected utilization of 3.32 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization for the in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

On page 18 of the application, the applicant states FMS Oxford does not currently provide home hemodialysis (HH) or peritoneal dialysis (PD) training nor does the applicant propose adding a home training program in the proposed application. On page 38, the application states HH and PD training will continue to be provided, for those patients who desire this service, at FMC Neuse River.

Access

In Section L-1(a), pages 47-48, the applicant states that each of BMA’s 108 facilities in 42 North Carolina Counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other traditionally underserved persons. In Section L-7, page 51, the applicant provides the historical payor mix (CY 2016) for FMS Oxford, as illustrated below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.73%
Medicare	69.86%
Medicaid	4.33%
Commercial Insurance	9.04%
Medicare / Commercial	12.59%
Misc. (VA)	3.44%
Total	100.0%

On page 48, the applicant projects that 85.21% of its patients will be Medicare or Medicaid recipients. 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, adequately demonstrates the need that population has for the proposed in-center stations and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section E-1, page 24, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates given the historical growth rate of the facility. Failure to develop additional stations could result in restricting patient admissions. Therefore, this alternative was rejected.
2. Apply for Fewer Stations - Application of the facility need methodology indicated a need for an additional two stations based on the continued growing need for dialysis services at FMS Oxford. Therefore, this alternative was rejected.
3. Relocate Stations from FMC Neuse River facility - The applicant states the facility operated at 75.0% utilization as of December 31, 2016, which is higher than the rate reported in the January SDR. Therefore, this alternative was rejected.

The applicant states the project as proposed in the application would ensure that the facility addresses the issues of growth and access to dialysis services by its patients. Therefore, the applicant believes that adding two dialysis stations at FMS Oxford is the most effective alternative to meet the identified need.

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 this proposal is the least costly or most effective alternative to meet the identified 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 Dialysis Services of Oxford shall materially comply with all representations made in the certificate of need application as conditioned.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Dialysis Services of Oxford shall develop and operate no more than two additional dialysis stations at FMS Dialysis Services of Oxford for a total of no more than 25 certified dialysis stations which shall include any isolation or home hemodialysis training stations upon project completion.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Dialysis Services of Oxford shall install plumbing and electrical wiring through the walls for no more**

than two additional dialysis stations, which shall include any isolation or home hemodialysis training stations.

4. Prior to the issuance of the certificate of need Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Dialysis Services of Oxford shall provide documentation that FMS Oxford will accommodate the clinical needs of health professional training programs in its area.

5. Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Dialysis Services of 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.

C

The applicant proposes to add two dialysis stations for a total of 25 certified dialysis stations at FMS Oxford upon project completion.

Capital and Working Capital Costs

In Section F, page 26, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Dialysis machines	\$6,000
Water treatment equipment	\$1,500
Total	\$7,500

In Section F, page 29, the applicant states that there are no working capital needs for the proposed project since FMS Oxford is an existing facility.

Availability of Funds

In Section F, page 27, the applicant states that accumulated reserves will be used to finance the proposed project. Exhibit F-1 contains a letter dated March 15, 2017, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), the parent company of BMA, which authorizes and commits cash reserves for the project capital costs of \$7,500 for development of this project. Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249.3 million in cash and cash equivalents as of December

31, 2015, \$19.3 in total assets and \$10.1 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

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

Financial Feasibility

In Section R, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown below in the table.

FMS Oxford		
	Operating Year 1 CY2018	Operating Year 2 CY2019
Total Treatments*	12,004	12,597
Total Gross Revenues (Charges)	\$47,871,952	\$50,236,836
Total Net Revenue	\$3,766,975	\$3,953,064
Total Operating Expenses (Costs)	\$2,834,506	\$2,941,159
Net Income	\$932,469	\$1,011,905

*Adjusted by the applicant for missed treatments.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the project is based on reasonable projections of costs and charges. 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.

The applicant proposes to add two dialysis stations for a total of 25 certified dialysis stations at FMS Oxford upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Granville County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are two dialysis facilities in Granville County, as follows:

**Granville County Dialysis Facilities
as of June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
FMC Dialysis Services Neuse River	Fresenius Medical Care	74	Oxford	25	0	74.00%
FMS Dialysis Services of Oxford	Fresenius Medical Care	76	Oxford	23	0	82.61%

As shown in the table above both the facilities in Granville County are operated by Fresenius Medical Care. Based on the most recent SDR, FMC Dialysis Services Neuse River (FMC Neuse River) operated at 74.0% and FMS Oxford operated at 82.61% of capacity as of June 30, 2016. Thus, both of the dialysis facilities are reasonably well utilized.

In Section C, pages 17-18, the applicant demonstrates that FMS Oxford will serve a total of 83 in-center patients at the end of OY1 for a utilization rate of 83% or 3.32 patients per station (83 patients / 25 stations = 3.32 / 4 = .83 or 83%). The projected utilization of 3.32 patients per station per week for OY1 exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add two additional stations at FMS Oxford based on the number of in-center patients it projects to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis services in Granville County. Consequently, the application is conforming to this criterion.

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

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In Section H, page 35, the applicant provides current and projected staffing in full time equivalents (FTEs) for FMS Oxford, as shown in the table below.

POSITION	CURRENT # FTEs	# FTEs POSITIONS ADDED/ DELETED	PROJECTED # FTEs
Registered Nurse	2.00	1.00	3.00
Technician (PCT))	6.00	1.00	7.00
Clinical Manager	1.00		1.00
Administrator	0.15		0.15
Dietician	1.00		1.00
Social Worker	1.00		1.00
Chief Tech	0.15		0.15
Equipment Tech	1.00		1.00
In-Service	0.15		0.15
Clerical	1.00		1.00
Total	13.45	2.00	15.45

In Section H, page 37, the applicant provides the projected direct care staff for FMS Oxford in OY2. In Section I, page 39, the applicant identifies Dr. Charles Cooperberg as the Medical Director of the facility. In Exhibit I-5, the applicant provides a signed letter from Dr. Cooperberg of Durham Nephrology Associates, PA supporting the project and confirming his commitment to serve as Medical Director. In Section H, page 36, the applicant describes the methods used to recruit and fill vacant or new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed 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.

C

In Section I, page 38, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 39-40. Exhibits I-2 through I-4, respectively, contain copies of agreements for Spectra laboratories services, Granville Medical Center, and UNC Hospitals

Center for Transplant Care for transplant services. The information in Section I and Exhibits I-2, I-3 and I-4 is reasonable and adequately supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

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

NA

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

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

C

In Section L, page 51, the applicant reports that 86.78% of the patients who received treatments at FMS Oxford had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated in the table below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	0.73%
Medicare	69.86%
Medicaid	4.33%
Commercial Insurance	9.04%
Medicare / Commercial	12.59%
Misc. (VA)	3.44%
Total	100.0%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Granville	15%	49%	42%	16%	15%	17%
Vance	16%	53%	59%	27%	19%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28¹. The ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions' Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015 Annual Report, submitted in November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*² percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina and total Network data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

¹http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

²<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 and 2015						
	2014 Patients and Percentages*				2015 Patients and Percentages**	
	NC Patients	NC Percentage	Total Network 6 Patients	Total Network 6 Percentage	Total Network 6 Patients	Total Network 6 Percentage
Age						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
Gender						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
Race						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

**2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3, page 50, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.”

In Section L.6, page 50, the applicant states that there have been no patient civil rights complaints filed against any BMA North Carolina facilities in the past five years.

The application is conforming to this criterion.

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

C

In Section L.1, page 47, the applicant states:

“It is BMA [sic] policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 48, the applicant projects that 85.21% of all in-center patients will have all or part of their services paid for by Medicare and or Medicaid.

**FMS Oxford
Projected Payor Mix OY2**

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.63%
Medicare	69.74%
Medicaid	3.27%
Commercial Insurance	9.67%
Medicare / Commercial	12.20%
Misc. (VA)	3.51%
Total	100.00%

The applicant adequately demonstrates that medically underserved populations will have 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 L.4, page 50, 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 has an open policy, which means that any Nephrologist may apply to admit patient to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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.

CA

In Section M.1, page 52, the applicant states that FMS Oxford offered the facility as a site for clinical rotations for Vance-Granville Technical Community College’s nursing students. However, Exhibit M.I contains a copy of a letter from Fresenius Kidney Care to the Nursing Department Chair of Wake Technical Community College and not Vance-Granville Technical Community College documenting the offer. Therefore, prior to the issuance of the certificate of need the applicant shall provide documentation that FMS Oxford will accommodate the clinical needs of health professional training programs in its area. See Criterion 4, Condition #2 of these findings.

- (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

The applicant proposes to add two dialysis stations for a total of 25 certified dialysis stations at FMS Oxford upon project completion.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Granville County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are two dialysis facilities in Granville County, as follows:

**Granville County Dialysis Facilities
as of June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
FMC Dialysis Services Neuse River	Fresenius Medical Care	74	Oxford	25	0	74.00%
FMS Dialysis Services	Fresenius	76	Oxford	23	0	82.61%

of Oxford	Medical Care					
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As shown in the table above both the facilities in Granville County are operated by Fresenius Medical Care. Based on the most recent SDR, FMC Dialysis Services Neuse River (FMC Neuse River) operated at 74.0% and FMS Oxford operated with 82.61% of capacity as of June 30, 2016. Thus, all of the dialysis facilities are reasonably well utilized.

In Section N, page 53, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“BMA does not expect this proposal to have effect on the competitive climate in Granville County. BMA does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMS Oxford facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Granville County five year average annual change rate of 5.10% as published within the January 2016 SDR.”

See also Sections C, F, G, H, L and P where the applicant discusses cost-effectiveness, quality and access.

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

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section B, pages 12-14, Section O, pages 54-56, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, pages 57-58, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity only the two facilities listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Rocky Mount	1/25/2017	Yes	3/1/2017
RAI West College	3/15/2016	Yes	4/11/2016

Based on a review of this certificate of need application and publicly available information, 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 criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

FMS Dialysis Services of Oxford

K-11308-17

Page 22

.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 C, pages 17-18, the applicant demonstrates that FMS Oxford will serve a total of 83 in-center patients at the end of OY1 for a utilization rate of 83% or 3.32 patients per station per week ($83 \text{ patients} / 25 \text{ stations} = 3.32 / 4 = .83$ or 83%). The discussion regarding analysis of need 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 C.1, pages 17-18, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.