

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 18, 2012  
PROJECT ANALYST: F. Gene DePorter  
CON CHIEF: Craig R. Smith

PROJECT DESCRIPTION: Granville K-8775-12 FMS Oxford Relocate Three Dialysis Stations From BMA Neuse River for a Total of 19 Dialysis Stations

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMS Oxford, whose parent company is Fresenius Medical Care Holdings, Inc. (FMCH), proposes to relocate three existing certified dialysis stations from BMA Neuse River to FMS Oxford for a total of 19 dialysis stations at FMS Oxford upon completion of the project. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. Therefore, neither of the two need methodologies in the 2012 State Medical Facilities Plan (2012 SMFP) is applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a new institutional health service for which there is a need determination in the 2012 SMFP. However, Policy ESRD-2 is applicable to this review.

Policy ESRD-2 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:*

- (A) *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and*
- (B) *Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.”*

The applicant proposes to relocate three existing dialysis stations within Granville County. Consequently, there is no change in the Granville County inventory. Therefore, the application is consistent with Policy ESRD-2 and 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

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMS Oxford, whose parent company is Fresenius Medical Care Holdings, Inc. (FMCH), proposes to relocate three existing dialysis stations from BMA Neuse River (City of Oxford/Granville County) to FMS Oxford (City of Oxford/Granville County) for a total of 19 dialysis stations at FMS Oxford and 15 stations remaining at BMA Neuse River upon completion of this project. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations.

### Population to be Served

In Section II. (7), pages 12-14, the applicant projects the number of in-center dialysis patients to be served in the first two years of operation following project completion (Reference Table 1 below).

In Section II. Assumptions 1-4 and Patient Origin, pages 12-13; the applicant states the following;

- “1. The FMS *Oxford* census as of December 31, 2011 was 59 dialysis patients. BMA has informed the patients who reside in Vance County that the FMS *Oxford* facility is actually closer and may be a more convenient setting for their dialysis treatments. In fact several patients residing in Vance County have expressed an interest in transferring to the FMS *Oxford* facility upon completion of this project.

*BMA includes letters of support from six patients. BMA will conservatively project that only two of these patients will actually transfer.*

2. *BMA will project patient census of FMS Oxford to increase at a rate commensurate with the Granville (1.9%) or Vance (5.8%) County Five Year Average Annual Change Rate (as may be appropriate). FMS Oxford is currently serving 12 patients from Vance County. This is equivalent to 20.3% of the facility census.*
3. *The project is schedule for completion by December 31, 2012. Operating Year one is the period from January 1, 2013 through December 31, 2013. Operating Year 2 is the period from January 1, 2014 to December 31, 2014.*
4. *BMA does project that the patient from Franklin County, currently dialyzing at FMS Oxford, to continue at FMS Oxford until January 1, 2014. BMA suggests that this patient is dialyzing at FMS Oxford by choice. BMA further suggests that this patient may desire to transfer to another facility in Franklin County on or after December 31, 2013. Thus, this patient is not reflected in patient projections for Operating Year 2 of this project.”*

**Table 1  
 FMS Oxford  
 Projected Dialysis Patient Origin**

County	Operating Year 1 In-Center Patients 1/1/13-12/31/13	Operating Year 2 In-Center Patients 1/1/14-12/31/14	County Patients as a Percent of TOTAL	
			Year 1	Year 2
Granville	47.8	48.7	74.34%	75.00%
Vance	15.5	16.5	24.11%	25.35%
Franklin	1.0	0.0	1.55%	0.00%
Total	64.3	65.1	100%	100%

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.3 (a), (b), and (c) pages 33-35, the applicant states:

*“The BMA Neuse River facility qualifies for up to seven additional dialysis stations via the Facility Need Methodology. The facility is currently certified for 18 dialysis stations. The facility physical plant capacity is only 22 dialysis stations. Thus BMA Neuse River has room for only four more dialysis stations.*

*The FMS Oxford facility did not qualify for additional stations by way of the Facility Need Methodology. The January 2012 SDR reported the facility utilization rate was only 79.69% with 51 patients dialyzing on 16 stations. However, a single patient*

more would have resulted in a utilization rate in excess of 80% and qualification for up to three additional dialysis stations.

Granville County only has two dialysis facilities with a combined total of 34 dialysis stations. The January 2012 SDR indicates that Granville County has a deficit of three dialysis stations. More importantly the SDR indicates that Granville County has an ESRD patient population of 126 patients as of June 30, 2011. Of those, 10 patients were home dialysis patients. When considering the home patient population, one can conclude that there were 116 in-center dialysis patients in Granville County as of June 30, 2011. Yet, the SDR reports that the two BMA dialysis facilities were serving 121 in-center patients as of June 30, 2011. More, importantly BMA records indicate that the two facilities were serving 123 in-center patients as of December 31, 2011. It is obvious that patients are coming into Granville County for in-center dialysis services.

The following table details the Facility Need Methodology for the BMA Neuse River facility.

**Table 2**  
**BMA Neuse River Dialysis Facility**  
**Facility Need Methodology**

Required SDR Utilization		80%
Facility Utilization Rate as of January 2012 SDR		97.2%
Certified Stations		18
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>18</b>
In-Center Patients as of the previous report (SDR 1)		61
In-Center Patients as of the current report (SDR 2)		70
<b>Step</b>	<b>Description</b>	<b>Result</b>
	Difference (SDR2 – SDR1)	9
(i)	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of (SDR 1)	0.2951
(ii)	Divide the result of step (i) by 12	0.0246
(iii)	Multiply the result of step (ii) by 6, (the number of months from June 30, 2011 until December 31, 2011) for the January 2012 SDR.	0.1476
(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	80.3279
(v)	Divide the result of step (iv) by 3.2 patients per station	7.1025
	and subtract the number of certified and pending stations as recorded in SDR2 [18] to determine the number of stations needed	7

*The calculations indicate that the facility can apply for up to seven additional dialysis stations. However, as noted the facility only has space for four additional stations. Given the county deficit and the fact that the BMA facilities in Granville County are providing treatment for patients from other counties, BMA concludes that it is in the best interest of the patient population choosing to dialyze at BMA facilities in Granville County to create additional space at BMA Neuse River by transferring three stations to FMS Oxford. This transfer application coupled with the Facility Need Methodology will allow BMA Neuse River to apply for seven additional stations in the March CON application cycle (review begins April 2, 2012).”*

BMA demonstrated in Section II. (7) Assumptions on page 13 of the application, that FMS Oxford will be serving 64 in-center patients with 19 stations for a utilization rate of 3.37 patients per station by the end of the first federal fiscal year of 2013. This exceeds the minimum performance standard of 3.2 patients per station.

As noted in Table 2 (page 5 above) BMA Neuse River dialysis facility is currently certified for 18 stations. However, the relocation of three stations to FMS Oxford will result in down-sizing the BMA Neuse River dialysis facility to 15 stations to serve 70 patients for a utilization rate of 4.7 patients per station. Table 3 illustrates the BMA Neuse River patient origin through December 31, 2012.

**Table 3  
 BMA Neuse River Current and Projected Dialysis Patient Origin**

County	In-center Patients 12/31/2011	Methodology Narrative	In-center Patients 12/31/2012
Granville	50	BMA begins with the BMA Neuse River in-center patient base as of 12/31/2011.	Granville: 50 patients Vance: 18 patients
Vance	18	BMA projects both county patient volumes forward for 12 months to 12/31/2012,	Granville: (50 X .019 [5Y AARC]) + 50 = 51.0 Vance: (18 X .058 [5Y AARC]) +18 = 19.0
Warren Franklin	1 1	At 12/31/2012, BMA adds 2 patients, one each from Warren and Franklin Counties and subtracts two from Vance who are transferring to FMS Oxford.	Granville: 51 Vance: 19-2= 17 Warren: 1 Franklin: <u>1</u> TOTAL 70

In Section III 6, page 37; BMA notes that FMS Oxford is less than 4 miles NE of the BMA Neuse River facility. Both dialysis facilities are in the town of Oxford in Granville County.

In Section III 8, page 40, the applicant indicates that 100% of dialysis center patients will be within 30 miles of either facility. The applicant acknowledges that the BMA Neuse

River utilization will be too high after down sizing to 15 stations. The applicant indicates that this circumstance will be mitigated by it's filing of a Certificate of Need application on March 15, 2012 to add 7 stations to the Neuse River facility.

The applicant provides 6 letters of support from physicians and 29 letters of support from dialysis patients residing in both Granville and Vance Counties. The letters, in part, state the following:

*“Patients on dialysis have many hardships, especially arranging transportation three days per week. The BMA dialysis facilities in Oxford make it more convenient for me and are closer to my home than if I had to travel to Durham or any other surrounding counties.”*

In Section II.1, Assumption 2, page 19; the applicant states:

*“BMA assumes that the patient population of FMS Oxford and BMA Neuse River will increase at a rate commensurate with the Five Year Average Annual Change Rate for Granville (1.9%) and Vance (5.8%) county, as published in the January 2012 SDR.*

BMA projects that FMS Oxford will serve 64 in-center patients by the end of Year One or 3.37 patients per station [ $64 / 19 = 3.37$ ], and 65 in-center patients by the end of Year Two or 3.42 patients per station [ $65 / 19 = 3.42$ ]. The projected utilization rate is 84% at the end of Year One [ $3.37 / 4.0 = 0.8425$ ] and 86% in Year Two [ $3.42 / 4.0 = 0.86$ ]. Projected utilization at FMS Oxford is based on reasonable and supported assumptions.

In summary, the applicant adequately identified the population proposed to be served and demonstrated the need to relocate three existing dialysis stations from BMA Neuse River to FMS Oxford then follow closely with a Certificate Need application (March 15-delivery/April 1, 2012 beginning of review cycle) for additional stations at the BMA Neuse River dialysis facility. 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.

## C

BMA proposes to relocate three existing certified dialysis stations from BMA Neuse River to FMS Oxford for a total of 19 dialysis stations at FMS Oxford and 15 stations remaining at BMA Neuse River, upon completion of this project. In Section III, pages 35 and 39, the applicant provides the following operating profile:

- FMS Oxford Dialysis Services- As of June 30, 2011, FMS Oxford was operating with 16 certified dialysis stations. According to the January 2012 SDR, Table A; the facility was operating at 79.69% utilization with 51 patients and 3.1875 persons for stations.
- BMA Neuse River Dialysis Services- As of June 30, 2011, BMA Neuse River dialysis was certified for 18 dialysis stations. According to the January 2012 SDR, Table A; the facility was operating at 97.22% utilization with 70 patients and 3.89 patients per station.

The following table identifies the county of residence for the patients at FMS Oxford and BMA Neuse River as of September 30, 2010:

**Table 4**  
**Patient Origin**  
**FMS Oxford Dialysis and BMA Neuse River Dialysis Facilities**  
**As of December 31, 2011**

FMS Oxford Census December 31, 2011	# Pts Dialyzing In-Center	BMA Neuse River Census December 31, 2011	# Pts Dialyzing In-Center
Granville	46	Granville	50
Vance	12	Vance	18
Franklin	0	Franklin	0
Warren	0	Person	0
TOTAL	58	TOTAL	68

*“In addressing the needs of patients continuing to dialyze at BMA Neuse River subsequent to the transfer of three stations to FMS Oxford, BMA will project growth of the FMS Oxford patient population to the projected date of project completion and certification of the project at FMS Oxford facility: December 31, 2012.”*

Section III.7, page 37-38, Assumptions, the applicant states the following;

*“The FMS Oxford census on December 31, 2011 was 59 dialysis patients. BMA has informed the patients who reside in Vance County that the FMS Oxford facility is actually closer and may be a more convenient setting for their dialysis treatments. In fact, several patients residing in Vance County have expressed an interest in transferring to the FMS Oxford facility upon completion of this project. BMA includes letters of support (reference Exhibit 22) from six patients. BMA will conservatively project that only two of these patients will actually transfer. This should not be read to suggest that BMA will restrict transfers, rather, this should be reads that BMA is offering a very conservative of the future patient population for FMS Oxford.”*

Exhibit 22 contains 29 letters of support from current patients dialyzing at FMS Oxford, 17 of 46 (37%) of patient letters of support are from Granville County dialysis patients and 8 of 12 (67%) of patient letters of support are from Vance County dialysis patients. In total, 25 of 58 (43%) dialysis patients from Granville submitted letters of support.

The applicant demonstrates that the needs of the population presently served at BMA Neuse River dialysis will continue to be adequately met following the relocation of three stations to FMS Oxford. Therefore, the application is conforming to this criterion.

- (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 III 9, pages 40-41, the applicant indicates the following in reference to alternatives considered;

*“a) BMA could have chosen not to pursue this transfer and expansion of this facility. However, this option is not consistent with the growth of the patient population in the county. This is not suitable alternative.”*

*b) BMA evaluated the possibility of applying to transfer fewer stations to the facility. However, as demonstrated by the need discussion, the facility will need three additional stations. Additionally, the proposed utilization rates indicate, the facility is expected to be operating above 80% utilization by the end of the first year of this project.*

*c) BMA considered development of a third dialysis facility for Granville County by relocating a total of 10 dialysis stations (would require stations from both BMA Neuse River and FMS Oxford) to a new location in the county. BMA is not able to identify a suitably sized patient location which would warrant a third facility within the county at this time.”*

The applicant concludes that transferring three dialysis stations to FMS Oxford is the most effective and least costly alternative. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (13), (14), (18a), (20), and the Criteria and Standards for End State Renal Disease Services, promulgated in 10A NCAC 14C .2200. Therefore, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS Oxford shall materially comply with all representations made in its certificate of need application.**



2. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS Oxford shall be certified for no more than 19 dialysis stations, which shall include any home hemodialysis or isolation stations.**
  3. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS Oxford shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations which shall include any home hemodialysis and isolation stations.**
  4. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS Oxford shall not develop or offer home dialysis services as a part of this project.**
  5. **After certification of three stations relocated to FMS Oxford, BMA Neuse River shall take the steps necessary to decertify three dialysis stations for a total of no more than 15 stations at BMA Neuse River.**
  6. **Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMS Oxford shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 57, the applicant projects the total capital cost will be \$11,607, including \$1,875 for Patient chairs, \$5,532 for Patient TVs, and \$4,200 Facility Automation Equipment. In Section IX, page 61, the applicant states that there are no start-up or initial operating expenses. Exhibit 24 contains a letter signed by Mr. Mark Fawcett, Vice President of Fresenius Medical Care Holdings, Inc. dated February 15, 2012, 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 proposes to relocate three dialysis stations from BMA Neuse River to the FMS Oxford dialysis facility. The project calls for the following capital expenditures on behalf of BMA.*

*Capital Expenditure: \$11,607*

*As Vice President, I am authorized and do hereby authorize the relocation of these three stations to FMS Oxford for the capital costs of \$ 11,607.”*

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

In Section X, page 62, the applicant provides the dialysis facility’s allowable charge per treatment for each payment source as follows:

**Table 5  
FMS Oxford Charge per Treatment  
By Payer**

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

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X, page 62 the applicant states the following in reference to implementation of the Medicare “Bundling” reimbursement program;

*“This program is to be phased in over a period of three years. Providers have an opportunity to “opt” in for 100% participation beginning January 1, 2011. FMCNA, parent company of BMA has opted in completely.*

*The Bundling program will provide one basic fee for the dialysis treatment; this fee includes all ancillary services which were previously billed separately. As a consequence of this, the basic rate for Medicare reimbursement is \$234.00 per treatment. Medicare will provide additional reimbursement for some co-morbid conditions; however, for CON application purposes, BMA will use only the base rate of \$234.00. This will necessarily result in slightly lower Medicare reimbursement projections; however, the complexity of the Medicare “kickers” is driven by patient specific data and does not lend itself to the reporting format of the CON application; \$234.00 is the minimum by Medicare.*

*BMA has historically projected additional revenues for ancillary services provided with each dialysis treatment. Financial projections included in this application will reflect those same additional revenues except for the Medicare treatment volumes. The Medicare treatment volumes have been subtracted from the total number of treatments within the ancillary projections.*

*At the time this application is prepared, no direction has been provided for other government payers such as Medicaid or VA. BMA will continue to reflect the*

*Medicaid and VA treatments within its ancillary projections until such time as guidance is provided.”*

In Section X. 3, page 63, the applicant states the following assumptions used to project revenue for Year 1 and Year 2. The applicant also provides current year revenue and expenses and shows that current and projected revenue exceeds expenses across three years.

**“Current Operating Year:** *Current year treatment numbers are derived from the information within Section III.7. BMA began calculations with the December 31, 2011 census of 59 patients. The facility projected to end the year with 62.3 patients. BMA calculates the average for the year as 60.8  $(59 + 62.6)/2 = 60.8$ . BMA has rounded down and multiplied 60 by 156 annual treatments (3 treatments per week, multiplied by 52 weeks) to produce the number of available or scheduled treatments for the year. That number is reduced by the number of missed treatments of 6.5%, to produce the number of expected treatments for the year.*

**Operating Year 1:** *BMA has projected to begin the first year of operations with 62.6 In-Center patients, ending the year with 64.3 In-Center patients. BMA calculates the average number of In-Center for the first year of operations 63.4 patients  $(62.6 + 64.3)/2 = 63.1$  BMA rounds down and multiplies 63 by 156 annual treatments to produce the projected number of treatments for Operating Year 1. That product is then reduced by the allowance of missed treatments, again 6.5%.*

**Operating Year 2:** *BMA has projected to begin the second year of operations with 64.3 In-Center patients ending the year with 65.1 In-Center patients. BMA calculates the average number of In-Center patients for the second year of operations to be 64.7 patients  $[64.3 + 65.1] / 2 = 64.7$ . BMA rounded down and multiplied 64 by 156 annual treatments to produce the projected number of treatments for Operating Year 2. That product is then reduced by the allowance for missed treatments, again 6.54%.”*

**Table 6  
 Bio-Medical Applications of North Carolina d/b/a FMS Oxford  
 Current and Projected  
 Revenue, Deductions from Revenue, Operating Costs and Difference**

Cash Flow	Current Year Operating Revenue	Year 1 Operating Revenue	Yr. 2. Operating Revenue
Gross Patient Service Revenue	\$2,722,582	\$2,862,370	\$2,911,595

Contractual Allowances	\$ 303,220	\$ 318,381	\$ 323,435
Net Revenue	\$2,419,362	\$2,543,989	\$2,588,160
Total Operating Costs	\$2,119,791	\$2,347,750	\$2,403,639
Difference	\$ 299,571	\$ 196,239	\$ 184,521

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 63-67, for the applicant’s assumptions.

In summary, the applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. Therefore, the application is conforming with 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.

C

BMA proposes to relocate three existing certified dialysis stations from BMA Neuse River to FMS Oxford for a total of 19 stations at FMS Oxford upon project completion. The applicant indicates that the BMA Neuse River facility is currently operating at 97.22% and 3.89 patients per station with 18 stations available prior to relocating three to FMS Oxford. The applicant proposes to minimally “stress” the facility to achieve a short term solution. BMA Neuse River has filed a CON on March 15, 2012 for the review cycle beginning April 1, 2012 to add 7 stations at BMA Neuse River, based on the Facility Need Methodology. The applicant indicates that the Neuse River facility has a capacity for 22 dialysis stations, if three stations are relocated to FMS Oxford.

The applicant adequately demonstrates the need to relocate three stations to FMS Oxford. BMA has secured letters of support (reference Exhibit 22) from existing FMS Oxford patients with six expressing interest in possible transfer to FMS Oxford. The equalizing of dialysis stations between FMS Oxford and BMA Neuse River [both located on opposite sides of the town of Oxford] will serve to improve access, relieve the high utilization pressure at Neuse River dialysis and improve utilization at the FMS Oxford facility.

Therefore, the applicant adequately demonstrates that the proposed project would not result in unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming with 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.

C

In Section VII.1, page 54, the applicant provides current and projected staffing for FMS Oxford upon project completion, as illustrated in the following table:

**Table 7**  
**FMS Oxford Projected Staffing**

	# of Current (FTE) Positions	# of Projected (FTE) Positions
RN	2.00	3.50
Tech.	4.00	6.50
Clinical Manager	1.00	1.00
Administrator	0.18	0.18
Dietitian	0.30	0.30
Social Worker	0.30	0.30
Chief Tech	0.18	0.18
Equipment Tech	0.30	0.30
In-Service	0.22	0.22
Clerical	1.00	1.00
<b>Total</b>	<b>10.45</b>	<b>13.48</b>

The applicant indicates a total of 10.45 FTE current positions and projected staffing of 13.48 for total additional staff of 3.03 upon project completion. The applicant states on page 55 that it does not expect any difficulty in recruiting staff. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. Therefore, the application is conforming with this criterion.

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

C

In Section V.1, page 44, the applicant lists the providers of the necessary ancillary and support services. On pages 45-48 the applicant describes how the facility will coordinate services with the existing health care system. Exhibit 21 contains a letter in which Dr. Charles Cooperberg, MD commits to serve as Medical Director for FMS Oxford. Exhibit 21 contains letters of support from physicians. The applicants adequately demonstrate that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming 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 VI.1 (a), page 49, the applicant states,

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. BMA currently operates 88 facilities in 43 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has eight facilities under development or pending CON approval. Each of our facilities has a patient population which includes*

*low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. BMA projects the patient population of FMS Oxford facility to be comprised of the following:*

*It is clear that FMS Oxford projects to provide service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*

**Table 8**  
**FMS Oxford Patient Profile**

<b>Facility</b>	<b>Medicaid/Low Income</b>	<b>Elderly (65 +)</b>	<b>Medicare</b>	<b>Women</b>	<b>Racial Minorities</b>
<i>FMS Oxford</i>	45.8%	47.5%	96.6%	49.2%	89.8%

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 90.74% of the facility treatment reimbursement is from Medicare.*

*BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, race or ethnic background, gender, handicap, age or any other grouping/category or basis of being an underserved person. For example Medicare represented 79.7% of North Carolina Dialysis Treatments in BMA facilities in FY 2011. Medicaid treatments represented an additional 4.8% of treatments in BMA facilities for FY 2011, low income and medical underinsured persons will continue to have access to all services provided by BMA.*

*The facility will conform to the North Carolina Building Code, the National Fire Protection Association 101 Life Safety Code, the Americans with Disabilities Act, ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies.”*

In Section VI.1, page 50, the applicant provides the current and projected payer mix for FMS Oxford, as shown in the following table:

**Table 9**  
**FMS Oxford Payor Mix**  
**Current and Projected**

<b>Payor Source</b>	<b>Percent of Total</b>
Commercial Insurance	6.3%
Medicare	86.9%
Medicaid	3.3%
VA	3.5%

Total	100.00%
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As shown in the table above, 93.7% of FMS Oxford in-center patients have some or all of their services paid for by Medicare or Medicaid [86.9% Medicare, 3.3% Medicaid and 3.5% VA]. The applicant projects future payer mix to remain the same as the payer mix for CY January 1, 2011 to December 31, 2011.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2009 and CY 2005, respectively. The data in the table were obtained on March 3, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

**Table 10**  
**Percent of Medicaid Eligible**  
**and Percent Uninsured by County**

County	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligible Age 21 and older as % of Total Population	% Uninsured CY 2005 (Estimate by Cecil G. Sheps Center)
Granville	6.30%	3.23%	18.4%
Vance	13.42%	8.10%	22.8%
Statewide	6.71%	3.60%	19.7%

Source: [www.ncdhhs.gov/dema-Medicaid](http://www.ncdhhs.gov/dema-Medicaid) Eligible-Granville and Vance Counties June 2010.

The majority of Medicaid eligible is 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 the applicant.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible who actually utilizes health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to



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

*"FMS Oxford will have an open policy, which means that any Nephrologists may apply to admit patients at the facility."*

The applicant demonstrates that medically underserved populations currently have adequate access to services available at the FMS Oxford dialysis facility. 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 VI.1 (f), page 51, the applicant states:

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

In Section VI.6 (a), page 62, the applicant states:

*"There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years."*

The application is conforming to this criterion.

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

C

**Table 11**  
**FMS Oxford Projected Payer Mix**

	Percent
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Payer	of Total
Commercial Insurance	6.3%
Medicare	86.9%
Medicaid	3.3%
VA	3.5%
Total	100.00%

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 (a), page 52, the applicant states:

*“Those nephrologists who apply for and receive medical staff privileges will admit patients with ESRD to the facility. FMS Oxford will have an open policy, which means that any nephrologists may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospitals.”*

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

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

C

In Section V.3 (a), page 46, the applicant states:

*“Exhibit 20 contains a letter from Sheila Abbott, RN, Clinical Manager, Oxford Dialysis to Vance-Granville Community College inviting the director of nursing education services (Erica Jastrow) to consider the FMS Oxford facility for inclusion in their clinical rotations of nursing students. Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.”*

The information provided in Section V.3 (a) and Exhibit 20 is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.

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

### C

See Sections II, III, V, VI and VII. In particular, see Section II, pages 19-22, in which FMS Oxford discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. This application will not have any effect on competition within Granville County. This proposal will certainly not adversely effect quality, but rather enhance the quality of the ESRD patients' lives. The information provided by the applicant in these sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Granville County.

- *FMS Oxford has projected that the facility will be comprised of the following demographics [as shown earlier in these findings]:”*

This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add 3 dialysis stations at FMS Oxford to relieve the current utilization pressure of 101.04% and the patients per station [pps] rate of 4.04. Both of these numbers exceed the minimum standards of 80% utilization and 3.2 patients per station. The applicant states that this proposal is a cost effective alternative to meet the need to enhance capacity when compared to the construction of a replacement facility. However, there is no cost benefit analysis provided by the applicant to document the cost benefits to patients, the facility, transportation agencies or others.
  
- The applicant has and will continue to provide quality services; as referenced in Section II., pages 23-26 wherein the applicant specifically notes the following in reference to safety and quality, equitable access, and maximizing healthcare value for the resources expended;
  - *“Safety and Quality-BMA is a high quality healthcare provider. ...BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attend ‘UltraCare’ certification. ...this is an ongoing process aimed at*

*encouraging all staff, vendors, physicians and patients to be apart of the quality care program.”* The applicant has and will continue to provide quality services,

- *“Equitable Access-The State Health Coordinating Council, and specifically, the Quality, Access, and Value Work Group have identified three basic principles which govern the development of the SMFP and to which the applicant subscribes; namely ameliorate economic barriers and mitigate time and distance barriers.”*

Bio-Medical Applications of North Carolina, Inc., d/b/a FMS Oxford relocation of three stations from BMA Neuse River to FMS Oxford for a total of 19 dialysis stations is needed to balance patient use among these two Oxford dialysis facilities. The proposal is a cost-effective alternative to meet the need to enhance access and position BMA Neuse River for near-term growth in dialysis stations while serving the following the FMS Oxford dialysis center patient profile;

FMS Oxford Patient Profile

Facility	Medicaid/Low Income	Elderly (65 +)	Medicare	Women	Racial Minorities
FMS Oxford	45.8%	47.5%	96.6%	49.2%	89.8%

**Note:** The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 90.74% of the facility treatment reimbursement is from Medicare.

*“Maximizing Healthcare Value for Resources Expended-The projected capital expenditure for this project is \$11,607. BMA, through its parent company, FMC is taking on the financial burden to complete this transfer of stations in an effort to bring dialysis treatment closer to patient homes.*

- The applicant has and will continue to provide adequate access to medically underserved populations. Bio-Medical Applications of North Carolina, Inc., d/b/a FMS Oxford’s relocation of three stations from BMA Neuse River to FMS Oxford for a total of 19 dialysis stations would have a positive impact on cost-effectiveness, quality and access to the proposed services because. Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

The applicant currently provides dialysis services at several facilities in North Carolina. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of

immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

### C

The application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as promulgated in 10A NCAC 14C .Section .2200. The specific criteria are discussed below.

#### **.2202 INFORMATION REQUIRED OF APPLICANT**

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

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

-C- See Section II.1, 10A NCAC 14C .2202 page 10, Section III.7, page 37, Section IV.1, page 50.

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

-C- See Section II.1, page 9 and Section IV.2, page 42.

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

-NA- In Section II. (3), page 10, the applicant states that FMS Oxford does not have a home training program.

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

-C- See Section II. (4), page 10.

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

-C- See Section II. (5), page 10.

*.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- See Section II (6), page 11.

*.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- See Section II (7), page 11.

*(b) An applicant that proposed 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- The applicant does not propose a new facility.

*.2202(b)(2) For new facilities, a letter of intent to sign 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 for transplantation, and

(E) signatures of the duly authorized persons representing the facilities and the agency providing the services.

-NA- The applicant does not propose a new facility.

*.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- The applicant does not propose a new or replacement facility.

*.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- In Exhibit 12, the applicant provided power failure procedures as required by this rule.

*.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.*

- The applicant does not propose a new facility.

- NA-
- .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 Section II (6), page 12, Section VII, 2. page 55, and Section XI (g), page 70.
- .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- See Section II. (6), page 12.
- .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- The applicant does not propose a new 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 rate for such services.*
- C- In Section II.1, 10A NCAC 14C .2202 (b) (9), page 14, the applicant states that it will admit and provide services as required by this rule.

### **.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- The applicant does not propose a new 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 III, page 38, the applicant states that FMS Oxford projects to serve 64.3 in-center patients by the end of the first operating year, for a utilization of 3.34 patients per station. See Criterion (3) for discussion.

- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*  
-C- In Section III.7, page 37, the applicant provided the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion.

#### **.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- See Section V.1, page 44.
- .2204(2) *Maintenance dialysis;*  
-C- See Section V.1 (e), page 44.
- .2204(3) *Accessible self-care training;*  
-C- See Section V.1 (d), page 44.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*  
-C- See Section II. (d)(2), page 44.
- .2204(5) *X-ray services;*  
-C- See Section V.1 (g), page 44.
- .2204(6) *Laboratory services;*  
-C- See Section V.1 (h), page 44.
- .2204(7) *Blood bank services;*  
-C- See Section V.1(i), page 44.
- .2204(8) *Emergency care;*  
-C- See Section V.1 (b), page 44.
- .2204(9) *Acute dialysis in an acute care setting;*  
-C- See Section V.1 (a), page 44.
- .2204(10) *Vascular surgery for dialysis treatment patients;*  
-C- See Section V.1 (p), page 44.
- .2204(11) *Transplantation services;*  
-C- See Section V.1 (f), page 44.
- .2204(12) *Vocational rehabilitation counseling and services;*  
-C- See Section V.1 (o), page 44.
- .2204(13) *Transportation*  
-C- See Section V.1 (q), page 44.



**.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- See Sections VII, pages 54-56, and Exhibits 13 and 14.
- .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, pages 54-56, and Exhibits 13 and 14.