

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 25, 2013

PROJECT ANALYST: Gregory F. Yakaboski

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: N-10067-12 / Bio-Medical Applications of North Carolina, Inc., d/b/a FMC St. Pauls / Relocate two dialysis stations from BMA Red Springs to FMC St. Pauls for a total of 15 dialysis stations upon completion of this project / Robeson County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC St. Pauls (FMC St. Pauls), whose parent company is Fresenius Medical Care Holdings, Inc., (FMC), proposes to relocate two dialysis stations from BMA Red Springs to FMC St. Pauls for a total of 15 dialysis stations upon completion of this project. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. In this application, the applicant proposes to relocate dialysis stations between facilities. Therefore, neither the county need nor facility need methodologies in the 2012 SMFP are applicable to this review. Additionally, Policy GEN-3 is not applicable because neither need methodology is applicable to the review. However, Policy ESRD-2 is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations* 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 to contiguous counties shall:

1. *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 North Carolina Semiannual Dialysis Report, and*
2. *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 North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate 2 existing certified dialysis stations from BMA Red Springs to FMC St. Pauls. Both facilities are located within Robeson County. Consequently, there is no change in inventory in Robeson County and the application is consistent with Policy ESRD-2 and conforming to this criterion

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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BMA proposes to relocate 2 existing certified stations from BMA Red Springs to FMC St. Pauls for a total of 15 stations at FMC St. Pauls upon completion of this project. This project is scheduled to be completed and certified June 30, 2013.

Population to be Served

In Section IV.1, page 37, the applicant identifies the population it serves, as illustrated in the table below.

County of Residence	# of In-Center Patients Dialyzing 06-30-12	Percent of Total
Robeson	46	100.0%
Total	46	100.0%

In Section III.7, page 33, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

FMC St. Pauls- Projected Patient Origin

County	Operating Year 1	Operating Year 2	County Patients as a Percent of TOTAL
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	In Center Patients	In Center Patients	Operating Year 1	Operating Year 2
Robeson	48.7	49.1	100%	100%
Total	48.7	49.1	100%	100%

On page 35, the applicant states Craig Smith, CON Section Chief, has previously indicated that patients are not partial patients, but rather are whole and that financial projections and utilization are rounded down to the whole number.

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.3(a), page 31, the applicant states that this application for the relocation of 2 existing certified dialysis stations from BMA Red Springs to FMC St. Pauls is based upon:

1. Enhancing geographic accessibility for the patients of northern Robeson County.

In Section III.3, page 31, the applicant states:

“This application is based upon enhancing the geographic accessibility for the patients residing in northern Robeson County...”

There are two BMA dialysis facilities in northern Robeson County: BMA Red Springs and FMC St. Pauls. On page 31 the applicant states that the BMA Red Springs facility has been underutilized for several years with the facility census declining as illustrated in the following table.

BMA Red Springs

SDR	Stations	Patients	Utilization
July 2008	20	58	73.0%
July 2009	18	43	60.0%
January 2010	18	43	60.0%
July 2010	18	43	60.0%
January 2011	18	44	61.0%
July 2011	18	52	72.0%
January 2012	14	32	57.1%
July 2012	14	34	60.7%
January 2013	14	33	58.9%

The historical stations, patients and utilization of FMC St. Pauls and FMC Pembroke is illustrated in the tables below.

FMC St. Pauls

SDR	Stations-	Patients	Utilization
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July 2009	10	23	58.0%
January 2010	10	22	55.0%
July 2010	10	27	68.0%
January 2011	10	31	78.0%
July 2011	10	35	88.0%
January 2012	10	38	95.0%
July 2012	10	36	90.0%
January 2013*	10	40	100.0%

*The January 2013 SDR, page 8, indicates that as of December 21, 2012 FMC St. Pauls had 13 certified stations.

FMC Pembroke

SDR	Stations-	Patients	Utilization
January 2012	13	33	0.0%
July 2012	13	39	75.0%
January 2013	13	40	76.92%

*Utilization included with BMA Red Springs, BMA Lumberton, BMA Laurinburg

Since the July 2008 SDR there has been a decline in stations and patients in the BMA Red Springs facility and the utilization has consistently been less than 80.0%. On page 31 the applicant states that *“a part of this decline is directly attributable to development of the FMC Pembroke and FMC St. Pauls dialysis facilities.”* The location of the three dialysis facilities: BMA Red Springs, FMC Pembroke and FMC St. Pauls is illustrated on a map found on page 35 of the application. The project analyst notes that FMC Pembroke and FMC St. Pauls are located on or in close proximity to major transportation corridors in contrast to the location of BMA Red Springs. The applicant notes that BMA Red Springs is underutilized as a consequence of ESRD patients in the area choosing to utilize other dialysis facilities. (See application page 31) BMA states *“It is BMA practice to support patient choice of dialysis facilities...It is also BMA practice to site dialysis stations in locations which are convenient for the ESRD patient population. This application is an effort to transfer stations to the FMC St. Pauls facility and place stations in closer proximity to a larger number of patients.”* (See application pages 31-31)

In Section III.7, pages 32-35, the applicant describes the methodology and assumptions used to project utilization at FMC St. Pauls.

The assumptions relied upon by the applicant are set forth on pages 34-36 are summarized as follows:

- As of September 30, 2012 FMC St. Pauls had 13 certified stations and 46 in-center patients for a utilization of 88.5%.
- Due to lack of patient interest FMC St. Pauls does not project to operate a third dialysis shift.

- The Robeson County Five Year Average Annual Change Rate is 0.008 [applicant mistakenly wrote 0.8% on page 34] and the applicant projects the patient population to grow at 0.008.
- Two patients are expected to transfer to the FMC St. Pauls facility upon completion of this proposed project. The projected patient transfer is documented by letters of support signed by the patients.
- The patients who have signed a letter of support all live closer to the FMC St. Pauls facility than to the facility where they are currently receiving dialysis.
- The proposed project will be completed and certified by June 30, 2013. [On page 34 the applicant states it is a four station expansion. Viewing the application in its entirety shows this to be a typo. The proposed project is for a two station expansion.]
- Operating Year 1 is from July 1, 2013 to June 30, 2014.
- Operating Year 2 is from July 1, 2014 to June 30, 2015.
- Patients are not partial patients but rather are whole. In utilization and financial projections BMA has rounded down to the whole number.

The table below illustrates the applicant's methodology and assumptions to project patient utilization.

Robeson County	In-Center
BMA begins with Robeson County patients at FMC St. Pauls as of September 30, 2012	46
BMA projects the patient population forward using the Robeson County Five Year Average Annual Change Rate for a period of three months to December 31, 2012	$[46 \times (.008/12 \times 3)] + 46 = 46.1$
BMA projects the patient population forward for six months to June 30, 2013 (this is the expected certification date of the project.)	$[46.1 \times (.008/12 \times 6)] + 46.1 = 46.3$
BMA adds two patients proposed to transfer from other BMA facilities. This is the beginning census for the project.	$46.3 + 2 = 48.3$
BMA projects the patient population from Robeson County forward for 12 months at 0.008% to June 30, 2014. This is the end of Operating Year 1.	$(48.3 \times .008) + 48.3 = 48.7$
BMA projects the patient population from Robeson County forward for another 12 months at 0.008% to June 30, 2015. This is the end of Operating Year 2.	$(48.7 \times .008) + 48.7 = 49.1$

As indicated in the table above, the applicant projects to serve 48 in-center patients in Operating Year One and 49 in-center patients in Operating Year Two. The applicant's projected patient census for the first two operating years is reasonable given the historical average annual growth rate for Robeson County, historical utilization at FMC St. Pauls, patient convenience and preference.

The applicant projects to serve 48 in-center patients or 3.2 patients per station ($48 / 15 = 3.2$) by the end of Year 1 or a 80.0% utilization rate [$48 / (4 \times 15) = 0.80$] and 49 in-center patients or 3.27 patients per station ($49 / 15 = 3.27$) by the end of Year 2 or 81.7% utilization rate [$49 / (4 \times 15) = 0.8166$] for the proposed 15 station facility. This meets the minimum requirement of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access to Services

In Section VI, page 45, the applicant states that BMA currently operates 93 facilities in 40 North Carolina Counties which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. In Section VI.1(a), page 45, the applicant provides a breakdown of the population of the FMC St. Pauls facility, as illustrated in the table below

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC St. Pauls	43.5%	39.1%	84.8%	45.7%	73.9%

In Section VI.1(c), page 46, the applicant projects that 83.1% of its patients will be covered by Medicare, Medicaid or the VA.

The applicant adequately demonstrates 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional stations and the extent to which all residents of the area are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

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BMA proposes to relocate 2 existing certified dialysis stations from BMA Red Springs to FMS St. Pauls. BMA Red Springs currently has 14 certified dialysis stations. Upon completion of the proposed project BMA Red Springs will have 12 certified dialysis stations ($14 - 2 = 12$).

In Section III.3, pages 31-32, the applicant demonstrates that the needs of the dialysis patients continuing to use the BMA Red Springs facility will be adequately addressed with by the remaining number of dialysis stations at BMA Red Springs after completion of this project.

The applicant projects a utilization rate for BMA Red Springs of 2.83 patients per stations upon completion of this proposed project. The methodology and assumptions utilized to project the utilization rate for BMA Springs are illustrated in the table below

BMA begins with the patient population at BMA Red Springs as of December 31, 2011 per the July 2012 SDR.	34
BMA projects this patient population forward for 12 months to December 31, 2012, using the Robeson County Five Year Average Annual Change Rate of 0.008%	$(34 \times .008) + 34 = 34.3$
BMA projects this population forward for six months to June 30, 2013. This is the projected certification date for this project.	$(34.3 \times .008) + 34.3 = 34.4$ [34.6]

The proposed project is scheduled to be complete and certified on June 30, 2013. In the table above, the applicant projects to serve 34 in-center patients as of June 30, 2013. This equates to 2.83 patients per station ($34 / 12 = 2.833$) by the end of Year 1 for a 70.8% utilization rate [$34 / (4 \times 12) = 0.7083$]. As a point of reference this is less than the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth.

The applicant's analysis of the effect the relocation of a total of 2 certified dialysis stations from BMA Red Springs will have on the remaining and projected dialysis patients of BMA Red Springs is reasonable and shows that the needs of the population presently served will continue to be met following the relocation of the 2 existing dialysis stations to from BMA Red Springs to FMC St. Pauls. In terms of access, the proposed relocation of 2 existing dialysis stations will improve access to dialysis services for patients who live closer to FMC St. Pauls than to their current dialysis facility while still providing sufficient dialysis stations at BMA Red Springs to serve current and projected patients. There is no indication that the reduction of dialysis stations at BMA Red Springs will have a detrimental effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly currently receiving dialysis at BMA Red Springs to obtain needed dialysis services.

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

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In Section III.9, pages 36, the applicant states the alternatives considered by BMA prior to the submission of this application, which include:

- 1) Maintain the Status Quo – Do Nothing. This alternative is not consistent with the with the projected high utilization rate at FMC St. Pauls. Do nothing would ignore the current and growing needs of the patients being served by FMC St. Pauls. Failure to develop additional stations at FMC St. Pauls would force patients to seek treatment elsewhere. Therefore, this alternative was not a viable option.
- 2) Move stations to another Robeson County facility- This was not a viable alternative as the need for additional stations at FMC St. Pauls has been demonstrated.

In Section III.9, page 36, the applicant states “*Costs are not just those costs to the facility, but also include costs to the patient, and to some degree the transportation agencies providing transportation services for the patients. BMA has considered likely alternatives to this proposal and has selected the most cost effective overall alternative.*”

The applicant adequately demonstrated the need to relocate 2 existing certified dialysis stations from BMA Red Springs to FMC St. Pauls. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, 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. d/b/a FMC St. Pauls shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls shall relocate no more than two dialysis stations from the BMA Red Springs facility to the FMC St. Pauls facility for a total of no more than 15 certified dialysis stations at FMC St. Pauls, which shall include any isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations, for a total of no more than 15 certified dialysis stations, which shall include any isolation stations.**

4. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 5. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC St. Pauls shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, pages 54-55, the applicant projects a total capital cost of \$30,550 which includes \$14,250 for water treatment equipment and \$16,300 in equipment/furniture costs. In Section IX, page 58, the applicant further states that there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated November 15, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA proposes to transfer two dialysis stations from BMA Red Springs to the BMA FMC St. Pauls dialysis facility in Robeson County. The project calls for the following capital expenditures on behalf of BMA.

Capital Expenditure: \$30,550.

As Vice President, I am authorized and do hereby authorize the transfer of two dialysis stations to FMC St. Pauls, for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$30,550 as may be needed for this project.”

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ended December 31, 2011 and 2010. As of December 31, 2011, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$204,142,000 with \$13,864,539,000 in total assets and \$8,388,027,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the proposed project.

In Section X.1, page 59, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
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Commercial Insurance	\$1,375.00
Medicare	\$234.00
Medicaid	\$137.29
VA	\$146.79
Private Pay	\$1,375.00

The applicant states on page 59 that the commercial charges above do not reflect actual reimbursement rates, and should not be taken as absolute. In addition, the applicant states that BMA has “opted in” completely to Medicare’s “Bundling” reimbursement program, which provides one basic fee for the dialysis treatment, \$234; this fee includes all ancillary services which were previously billed separately.

The applicant projects net revenue in Section X.2, page 60, of the application and operating expenses in Section X.4, page 64, of the application. The applicant projects revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Project Year 1	Project Year 2
Net Revenue	\$1,887,191	\$1,890,142
Operating Expenses	\$1,842,292	\$1,865,519
Profit	\$44,899	\$24,623

In Section VIII.9, page 57, the applicant states, “*Machine Leases are executed as the machines are needed. FMC works with a capital leasing firm to ensure the best possible rates, which are competitive with regard to financial terms, at the time the lease is executed.*” Exhibit 26 contains a sample dialysis machine lease. The applicant further states that all FMC leases are “arms length” negotiations. (See application page 57)

In Section VII.1, page 50 and Section X, pages 64-65, the applicant provides projected staffing and salaries. On page 52, the applicant states that BMA Cary will comply with all staffing requirements as stated in 42 C.F. R. Section 494 (formerly 405.2100). Staffing by shift is provided on page 53. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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BMA proposes to relocate two dialysis stations from BMA Red Springs to FMC St. Pauls for a total of 15 stations at the FMC St. Pauls dialysis facility upon completion of the proposed project. The applicant demonstrated the need to relocate 2 stations within the same county from BMA Red Springs to FMC St. Pauls based enhanced geographic accessibility, patient

letters of support, utilization of the Five Year Average Annual Growth Rate for Robeson County and the number of in-center patients it proposes to serve at both facilities. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Upon completion of the proposed project, at the end of the first operating year the facility will have 15 stations serving 48 patients which is a utilization rate of 80.0% ($48 / 15 = 3.2$; $3.2 / 4 = .8$ or 80.0%). Therefore, the applicant is conforming with the requirement in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved dialysis stations. 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 VII.1, page 50, the applicant provides the current and projected number of full-time equivalent (FTE) positions following completion of the proposed project, as illustrated in the table below:

<i>Position</i>	<i>Current # of FTEs</i>	<i>Total Positions to be Filled</i>	<i>Total FTE Positions Upon Completion</i>
<i>RN</i>	<i>1.00</i>	<i>1.00</i>	<i>2.00</i>
<i>Tech</i>	<i>4.00</i>	<i>1.00</i>	<i>5.00</i>
<i>Medical Director</i>	<i>Contract position; not an FTE of the facility</i>		
<i>Clinical Manager</i>	<i>1.00</i>	<i>0.00</i>	<i>1.00</i>
<i>Administrator</i>	<i>0.15</i>	<i>0.00</i>	<i>0.15</i>
<i>Dietitian</i>	<i>0.33</i>	<i>0.00</i>	<i>0.33</i>
<i>Social Worker</i>	<i>0.33</i>	<i>0.00</i>	<i>0.33</i>
<i>Chief Tech</i>	<i>0.15</i>	<i>0.00</i>	<i>0.15</i>
<i>Equipment Tech</i>	<i>0.40</i>	<i>0.00</i>	<i>0.40</i>
<i>In-Service</i>	<i>0.25</i>	<i>0.00</i>	<i>0.25</i>
<i>Clerical</i>	<i>1.00</i>	<i>0.00</i>	<i>1.00</i>

Analysis of the salary budgeted on pages 64-65 confirms the use of 10.61 FTE in the calculations.

In Section VII.10, page 53, the applicant provides the direct care staff for each shift offered in the facility as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:00am to 10:30am	4	4	4	4	4	4

Afternoon	10:30am to 4:00pm	4	4	4	4	4	4
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The applicant states in Section V.4 (c), page 42, that Dr. Ezra McConnell will be the Medical Director for the facility. In Exhibit 21, the applicant provides a letter from Dr. McConnell in support of the proposed project and states his willingness to continue to serve as the Medical Director for the facility. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity 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.

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In Section V.1, page 39, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, pages 16-17, Section V.1, page 39, and supplemental information. Diagnostic and evaluation services, x-ray services, blood bank services, and acute dialysis in an acute care setting will be provided by Southeastern Regional Medical Center. Transplantation services will be provided by UNC Medical Center, Duke UMC or Carolina's Medical Center. Vascular surgery will be referred to Carolina Kidney Care Vascular Access Center. The other services will be provided at the individually stated facility. Exhibits 16-18 and 20 contain documentation on service agreements to include: hospital affiliation agreements, transplant agreement, SPECTRA Lab agreement and a Home Training agreement.

The information regarding coordination of services in Section V of the application and referenced in exhibits is reasonable and credible and 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;

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In Section VI.1(a), page 45, the applicant discusses BMA's history of providing dialysis services to the underserved populations of North Carolina. The applicant states:

"...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. The patient population of the FMC St. Pauls dialysis facility is as follows:

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC St. Pauls	43.5%	39.1%	84.8%	45.7%	73.9%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 84.8% of the facility treatment reimbursement is from Medicare.

It is clear that FMC St. Pauls provides 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.”

In Section VI.1(b), page 45-46, the applicant states that historically, 79.6 % of patients at FMC St. Pauls have some or all of their services paid for by Medicare and 2.5% have some or all of their services paid for by Medicaid and an additional 1.0% are covered by the VA. The table below illustrates the current historical payor mix for the facility.

Historical Payor Source

Payor Source	In-Center
Commercial Insurance	16.7%
Medicare	79.6%
Medicaid	2.5%
VA	1.0%
Self/Indigent	0.2%
Total	100.0%

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

	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	CY2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)
Robeson	31.0%	13.2%	23.9%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by FMC St. Pauls. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina’s Network 6 were under the age of 35.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize 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 48.6% for those age 20 and younger and 31.6% 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 and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states,

“Although the ESRD population is less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”¹

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy...”

The report validates the statistical constancy reported by CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues

¹ www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf

to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6
 Includes North Carolina, South Carolina and Georgia

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

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

C

In Section VI.1(f), pages 47-48, the applicant states:

“BMA of North Carolina facilities and FMC St. Pauls 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 continue to 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 49, 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

In Section VI.1(c), page 46 the applicant states it does not anticipate any change to the future payor mix as indicated in this table.

Payor Source	In-Center
Commercial Insurance	16.7%
Medicare	79.6%
Medicaid	2.5%
VA	1.0%
Other: Self/Indigent	0.2%
Total	100.0%

As shown in the table above, the applicant projects that 83.1% of all in-center patients will have some or all of their services paid for by Medicare, Medicaid or the Veterans Administration.

In Section VI.1(d), page 47 the applicant states, *“BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”* [emphasis in original]

In Section VI.2, page 48, the applicant states the facility design provides easy access for handicapped persons and complies with the Americans with Disabilities Act (ADA) requirements. On page 49, the applicant states patients will be accepted for treatment based on medical criteria, not age or other factors.

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. 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 48, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC St. Pauls will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

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

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

C

In Section V.3, pages 40-41, the applicant states that all health related education and training programs are welcomed to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment. The facility has requested to establish a formal relationship with Robeson Community College. See Exhibit 19 for a copy of a letter from the Director of Operations, Fresenius Medical Care to the Director of the Nursing Program for Robeson Community College offering FMC St. Pauls as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.

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

C

BMA proposes to relocate two dialysis stations to enhance geographic accessibility within Robeson County from BMA Red Spring to FMC St. Pauls for a total of 12 certified dialysis stations at BMA Red Springs and 15 certified dialysis stations at FMC St. Pauls upon completion of the proposed project.

In Section V.7, pages 43-44, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states its proposal will not have any effect on competition within Robeson County. *“The patients to be served by this facility are existing dialysis patients, and future patients residing in Robeson County.”*

The applicant further states:

“At this time, there is one other provider of dialysis services operating within Robeson County: DaVita Dialysis St. Pauls. The DaVita facility uses another physician practice for referrals and Medical Director leadership. The physicians providing care at the DaVita facility do not have admitting privileges at FMC St. Pauls. The physicians providing care at FMC St. Pauls do not have admitting privileges at the DaVita St. Pauls facility. Since the physicians do not have reciprocal privileges and since each physician practice has their individual referral sources, neither group of physicians will be referring patients to the “other” facility. Consequently, this project will not change the competitive environment within Robeson County.

BMA feels that it is uniquely positioned within the dialysis industry to successfully provide services to the patients of Robeson County. This facility will have added value stemming from the strength of our relationship with Carolina Kidney Care.

...

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.

...

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives."

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that relocating two dialysis stations from BMA Red Springs to FMC St. Pauls will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- ◆ BMA adequately demonstrates the need, based on policy ESRD-2: Relocation of Dialysis Stations and enhancing geographic accessibility for patients within Robeson County, to relocate two dialysis stations from BMA Red Springs to FMC St. Pauls for a total of 15 certified dialysis stations at FMC St. Pauls upon completion of the proposed project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to FMC St. Pauls patients;
- ◆ BMA has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII, and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.

On page 20, the applicant states, *"Let there be no doubt: BMA is committed to providing quality care for all patients."*

- ◆ The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 45, the applicant states:

"It is clear that FMC St. Pauls provides 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."

The applicant provides the following table to demonstrate that the medically underserved population will have access to its services, as illustrated below.

<i>Facility</i>	<i>Medicaid/ Low Income</i>	<i>Elderly (65+)</i>	<i>Medicare</i>	<i>Women</i>	<i>Racial Minorities</i>
<i>FMC St. Pauls</i>	43.5%	39.1%	84.8%	45.7%	73.9%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 84.8% of facility treatment reimbursement is from Medicare.

The applicant states on page 22 that BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations. 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 FMC St. Pauls. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC St. Pauls has operated in compliance with all Medicare Conditions of Participation within 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:
 - (1) Utilization rates;

- C- In Section II.1, page 10, the applicant provides the utilization rate as reported in the July 2012 SDR of 90.0% with 3.6 patients per station.
- (2) Mortality rates;
- C- In Section II.1, page 10, the applicant provides the mortality rates as 13.3%, 25.8% and 5.7% for 2009, 2010 and 2011, respectively.
- (3) The number of patients that are home trained and the number of patients on home dialysis;
- NA- In Section IV.3, page 37, the applicant states, “*FMC St. Pauls does not offer home therapies. Patient who are candidates for home training are referred to BMA Lumberton.*”
- (4) The number of transplants performed or referred;
- C- In Section IV.4, page 37, the applicant states FMC St. Pauls referred 5 transplants in 2010 and 5 in 2011. No transplants were performed in 2010 and one in 2011.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section IV.5, page 37, the applicant states that FMC St. Pauls has 4 patients on the transplant waiting list.
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section IV.6, page 37, the applicant states that there were 119 total hospital admissions in 2011, 15 of which were dialysis related and 104 non-dialysis related.
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.
- C- In Section IV.7, page 38, the applicant states that there were no Hepatitis B Conversions in 2009 and 2010 and that there are currently no patients with Hepatitis B.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- FMC St. Pauls is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,
- (B) composition of the assessment/evaluation team at the transplant center,
- (C) method for periodic re-evaluation,
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.

-NA- FMC St. Pauls is an existing facility.

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

-NA- FMC St. Pauls is an existing facility.

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

-C- See Exhibit 12 for a copy of FMC St. Pauls Emergency/Disaster Manual which has policies and procedures for back-up electrical service in the event of a power outage.

(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- FMC St. Pauls is an existing facility.

(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- In Section II.1, page 12, the applicant states, “*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC St. Pauls.*”

(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 III.7, page 33-35, for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

FMC St. Pauls - Projected Patient Origin

County	Operating Year 1	Operating Year 2	County Patients as a Percent of TOTAL	
	In Center Patients	In Center Patients	Operating Year 1	Operating Year 2
Robeson	48.7	49.1	100%	100%
Total	48.7	49.1	100%	100%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.

-NA- FMC St. Pauls is an existing facility.

(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, pages 14, the applicant states, “*BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- FMC St. Pauls does not propose to establish a new End Stage Renal Disease facility.

(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- FMC St. Pauls projects utilization of 3.2 patients per station per week as of the end of the first operating year.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 14-16 and Section III.7, pages 33-35. The applicant projects an increase in its current Robeson County patient utilization using the county 5-year AACR.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) diagnostic and evaluation services;

-C- In Section II.1, page 16, the applicant states, "*Patients will be referred to Southeastern Regional Medical Center or Lumberton Radiological Associates*" for diagnostic and evaluation services.

(2) maintenance dialysis;

-C- In Section II.1, page 16, the applicant states, "*The facility will provide in-center dialysis.*"

(3) accessible self-care training;

C- In Section II.1, page 16, the applicant states, "*The facility will provide self-care training.*"

- (4) accessible follow-up program for support of patients dialyzing at home;
 - C- In Section II.1, page 16, the applicant states, "*Patients desiring to dialyze at home will be referred to the BMA Lumberton home training program.*" Exhibit 20 contains a copy of the home training center program agreement.
- (5) x-ray services;
 - C- In Section II.1, page 17, the applicant states, "*Patients in need of x-ray services will be referred to Southeastern Regional Medical Center or Lumberton Radiological Associates.*"
- (6) laboratory services;
 - C- In Section II.1, page 17, the applicant states, "*BMA provides on site laboratory services through contract with Spectra Labs.*" See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.
- (7) blood bank services;
 - C- In Section II.1, page 17, the applicant states, "*Patients in need of blood transfusion will be referred to Southeastern Regional Medical Center.*"
- (8) emergency care;
 - C- In Section II.1, page 17, the applicant states, "*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked 'crash cart' is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*"
- (9) acute dialysis in an acute care setting;
 - C- In Section II.1, page 17, the applicant states, "*Patients admitted to a hospital will be referred to Southeastern Regional Medical Center.*"
- (10) vascular surgery for dialysis treatment patients;
 - C- In Section VI.1, page 39, and supplemental information the applicant states that patients will be referred to Carolina Kidney Care Vascular Access Center.
- (11) transplantation services;

-C- In Section II.1, page 17, the applicant states, “*FMC St. Pauls has a transplant agreement with Carolina’s Medical Center, Duke UMC and UNC Medical Center.*” Exhibit 17 contains a copy of an executed transplant agreement.

(12) vocational rehabilitation counseling and services; and

-C- In Section II.1, page 17, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Division of Vocational Rehabilitation of Robeson County.*”

(13) transportation.

-C- In Section II.1, page 17, the applicant states, “*Transportation services are provided by Robeson County, Council of Governments Transit System; SEATS.*”

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

-C- In Section VII.2, page 51, the applicant states that FMC St. Pauls will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

(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- In Section II.1, page 18, the applicant states that FMC St. Pauls will provide ongoing program training for nurses and technicians in dialysis techniques, including training in facility and corporate policies and procedures; safety precautions; regulations; CPR; and in-service training on changes/developments in procedures, product line, equipment, Center for Disease Control and Prevention guidelines and OSHA compliance. See Section VII.5, pages 51, of the application, for information concerning the training and continuing education programs currently in place at FMC St. Pauls. Exhibit 14 contains copies of FMC’s Dialysis Services Training Manual which outlines its training program and Exhibit 15 contains examples of information presented as part of staff’s mandatory in-service and continuing education training.