

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012  
PROJECT ANALYST: F. Gene DePorter  
CON CHIEF: Craig R. Smith

PROJECT DESCRIPTION: Granville K-8802-12 Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC-Neuse River Add 7 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 BMA Neuse River [BMA-NR **Note:** the applicant uses BMA-NR and FMC-NR interchangeably throughout the application], currently operates 18 dialysis stations at 625 Lewis Street, Oxford, NC 27565. BMA-NR proposes to add 7 stations [after transferring 3 stations to FMS Oxford- Project # K-8775-12] for a total of 22 dialysis stations upon completion of Project # K-8775-12 and this project [# K-8802-12].

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. According to the 2012 SMFP, the county need methodology shows a deficit of three stations in Granville County. The applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology if the patients per station is 3.25+ and the utilization is

80%+. The January 2012 SDR shows FMC-NR operating with 3.89 patients per station based upon the following calculation [70 Pts. / 18 stations = 3.89]. In addition, the utilization rate as of 6/30/11 was 97.2% which exceeds the required minimum utilization standard of 80%. The applicant proposes to add new stations to an existing facility based upon applying the facility need methodology. FMC-NR is proposing to add 7 stations based upon the Facility Need Methodology shown in Table 1.

**Table 1**  
**FMC Neuse River Dialysis Facility**  
**Facility Need Methodology**

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

*Note: “Rounding” to the nearest whole number is allowed only in the step (v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.*

The calculations indicate that “the facility may apply to expand to meet the need established... up to a maximum of 10 stations.” As shown in the table above there is a need for up to 7 dialysis stations which equals the applicant’s request for 7 new dialysis stations. The application is consistent with the facility need determination for dialysis stations.

Currently, the facility has space for only four additional stations. However, BMA has a recently approved project to relocated three stations from Neuse River to FMS Oxford [Project ID # K-8775-12]. When the transfer of the three stations is complete, FMC-Neuse River will be in position to develop the seven station need identified by the Facility Need Formula application.

POLICY GEN-3 is applicable to this application. POLICY GEN-4 is not applicable because the \$15,876 capital expenditure for this project is significantly below the capital cost trigger of \$2 million, pursuant to G.S. 131E-176 (16)(b). Granville County has 34 total available dialysis stations between FMS Dialysis Services of Oxford [16 stations] and FMC Dialysis Services Neuse River [18 stations]. The approval of this project [Project # K-8802-12] will increase the Granville county dialysis station inventory to 41 dialysis stations. POLICY ESRD-2: Relocation of Dialysis Stations does not apply.

Policy GEN-3 in the 2012 SMFP is applicable to this review. Policy GEN-3 states:

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

#### Promote Safety and Quality

In Section II., page 26, the applicant describes how the proposal will promote safety and quality:

*“BMA is a high quality health care provider. The Table at II.3D provides quality indicators for the FMC Neuse River dialysis facility. In addition, BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC UltraCare certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for UltraCare certification.”*

In Section II.3, pages 33-35, the applicant describes the programs and methods it uses to insure and maintain quality care:

- Facility programs
  - 1) Quality Improvement Program;
  - 2) Staff Orientation and Training; and
  - 3) In-service Education
- Corporate programs
  - 1) Technical Audits;
  - 2) Continuous Quality Improvement
  - 3) External Surveys- DFS Certification Surveys
  - 4) Core Indicators of Quality; and
  - 5) Single Use Dialyzers

The applicant adequately demonstrates the proposal will promote safety and quality of care.

#### Maximize Healthcare Value

In Section VI.1 ( c ), page 51, the applicant states,

*“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare/Medicaid; in fact, within this application, BMA is projecting that 87.2% of the In-Center dialysis treatments will be covered by Medicare or Medicaid; an additional 4.5% are expected to be covered by the VA. Thus, 91.7% of In-Center revenue is derived from government payers.*

The applicant adequately demonstrates the proposal will maximize healthcare value.

#### Promote Equitable Access

In Section II, pages 20-23, the applicant describes how the proposal would enhance access by medically underserved groups, as follows:

*10A NCAC 2202 (b)(8) requires a commitment by BMA ‘to admit and provide 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.’ BMA provides such assurances within Section VI of this application.*

*BMA is also keenly sensitive to the second element of ‘equitable access’ - time and distance barriers. ... At this time, Wake County has 11 operational dialysis facilities one facility under development (FMC Central Raleigh). The January 2012 SDR reports that Wake County has the second largest ESRD patient population in North Carolina and that population is growing at an Average Annual Change Rate of 5.9%. As the dialysis patient population of Wake County continues to increase, the need for dialysis stations will continue to increase.*

*Over the years, BMA has sought to develop new facilities and new dialysis stations in an effort to make dialysis convenient to the patient. This application to add one dialysis station to FMC Millbrook is another example of BMA efforts to meet the needs of the ESRD patient population of Wake County....*

*As noted within Section VI of this application, 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. A patient in need of dialysis is always welcome at a BMA facility; the only requirement is proper referral from a physician.”*

*BMA FMC Neuse River patient census is comprised of the following demographics:*

**Table 2**  
**FMC-Neuse River 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>FMC Neuse River</i>	73.8%	35.9%	84.4%	42.2%	87.5%

In Section VI.2, page 52, the applicant states,

*“The design of the facility and new space is such that handicapped persons will have easy access to the facility; the facility will comply with ADA requirements. It will be constructed in compliance with applicable sections of North Carolina State Building Code, Vol. #1-General Construction, which lists minimum requirements for the handicapped applicable to institutional and residential structures. In addition, wheelchairs are always available for transporting patients who are unable to stand or walk.”*

In Section VI.7, page 48, the applicant states,

*“BMA admission policy states that ‘patients shall be accepted for treatment at BMA when such treatment is deemed indicated and appropriate according to the clinical judgment of the patients’ attending physician. No arbitrary criteria with respect to the patient’s age or magnitude of complicating medical problems are established.*

*BMA also has an AIDS policy that states ‘a diagnosis of AIDS or HIV-positive status (absent other contraindications) is not acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’”*

The applicant adequately demonstrates the proposal will promote equitable access to medically underserved groups. See Criteria (13c) for additional discussion. The application is consistent with Policy GEN-3.

(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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Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC-Neuse River [FMC-NR], whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), proposes to add seven dialysis stations to FMC-NR following the relocation of three existing dialysis stations from FMC-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 22 stations at FMC- Neuse River upon completion of both projects. The projections provided by BMA are reasonable and conservative.

### Population to be served

In Section III.7, page 37-41, 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 below). The applicant indicates the following;

As a result of this application, FMC-NR will have 22 stations. In order to

demonstrate conformity with this rule, BMA must project to serve 70.4 rounded to 71 patients at the end of Operating Year 1 [the applicant actually projects 72 in Year 1 and 74 patients in Year 2]. In Section III. 7, pages 37-40; BMA has projected that it will provide dialysis treatment for at least 72 in-center patients at the end of the first year of operation and 74 in-center patients for Year 2.

The following table identifies the expected county of origin for patients dialyzing at FMC-NR for operating years 1 and 2.

**Table 3  
FMC-Neuse River  
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	
	In-Center Patients	Home	In-Center Patients	Home	Year 1	Year 2
<i>O</i>						
Granville	51.9	2.0	52.9	3.0	72.91%	72.62%
Vance	18.0	0.0	19.1	0.0	24.38%	24.78%
Warren	1.0	0.0	1.0	0.0	1.35%	1.30%
Franklin	1.0	0.0	1.0	0.0	1.35%	1.30%
Total	72	2.0	74	3	100%	100%

The application adequately identifies the population to be served.

Projections are based upon the methodology as discussed within 10A NCAC 14C .2202 (b) (7). In Section III.8., page 41; the applicant states the following;

*“...BMA does not expect that any patient will travel more than 30 miles. The entirety of Granville and Vance Counties are within 30 miles of FMC Neuse River.”*

The last Certificate of Need activity by FMC-Neuse River was Project I.D. # K-8201-08 [Decision date 2/7/09], transfer 6 stations to FMC-Neuse River then the addition of two more dialysis stations at FMC-Neuse River Dialysis Center.

In Section III 7, page 38, the applicant states the following assumptions in support of adding 7 dialysis stations at FMC-NR;

- *“FMC-NR qualifies for up to seven additional dialysis through the Facility Need Methodology.*
- *The facility physical plant can accommodate 22 dialysis stations.*
- *The facility currently has 18 dialysis stations.*

- *On February 15, 2012, BMA filed a CON application, Project ID # K-8775-12, to transfer three dialysis stations from FMC Neuse River to FMS Oxford. Assuming that application is approved, FMC Neuse River would net to 15 stations.*
- *BMA is applying for all seven stations through the Facility Need Methodology.*
- *BMA expects the patient census of FMC Neuse River to increase commensurate with the county Five Year Average Annual Change Rate. A significant portion of the FMC Neuse River facility census resides in Vance County. BMA will therefore demonstrate growth of that patient population.*
- *BMA will project patient census of FMC-Neuse River 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). FMC Neuse River is currently serving 16 patients from Vance County. This is equivalent to 25% of the facility census. BMA is projecting that two patients from Vance County will transfer from FMC-Neuse River to FMS Oxford upon completion of that project.”*

The projections provided by BMA are reasonable and conservative.

#### Need Analysis

In Section III.3-6, page 37, the applicant states:

*“This is not an application to develop a new facility; this is an application to add seven dialysis stations to the existing facility. As a result of this application, FMC Neuse River will have 22 dialysis stations.”*

Granville County 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. The applicant states, *“It is obvious that patients are coming into Granville County for in-center dialysis services.”*

FMC-Neuse River intends to develop a home training program for peritoneal dialysis. FMC is currently providing home dialysis follow-up for several Granville County patients. The January 2012 SDR showed 10 home patients in Granville County as of June 30, 2011.

Utilization of FMC-Neuse River is projected to be the following:

Operating Year 1. (1/1/13 – 12/31/2014)

72 patients / 22 dialysis stations = 3.27 patients per station  
 $72 / (4 \times 22) = 0.818$  or 81.8%

Operating Year 2. (1/1/14-12/31/2014)

74 patients / 22 dialysis stations = 3.36 patients per station  
 $74 / (4 \times 22) = 0.841$ , or 84.1%

BMA demonstrated in Table 1 (above) 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 full year of operation [2013]. This exceeds the minimum performance standard of 3.2 patients per station. As noted in Table 2 (above) FMC-Neuse River dialysis facility currently operates with 18 stations. However, the relocation of three stations to FMS Oxford will result in down sizing the FMC-Neuse River dialysis facility to 15 stations to serve 70 patients for a utilization rate of 4.7 patients per station.

**Table 4**  
**FMC 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 FMC 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: 1 TOTAL 70

In Section III 8, page 41; BMA notes that FMS Oxford is less than 4 miles NE of the FMC-Neuse River facility. Both dialysis facilities are in the town of Oxford in Granville County. The physical proximity of both facilities can help to mitigate the higher short-term utilization rates until the relocation of three stations and the addition of seven new stations is operational.

The applicant provides letters of support from physicians and dialysis patients residing in both Granville and Vance Counties. A letter from Dr. Tomasz R. Gawecki, M.D. of Durham Nephrology Associates [Exhibit 21], states the following:

*“I am writing this letter as the Medical Director of Neuse River Dialysis Center to wholeheartedly endorse the application by Fresenius Medical Care to expand the center and add four in-center hemo-dialysis stations.”*

Other physicians from the Durham Nephrology Group have stated the following;

*“Durham Nephrology Associates has been providing nephrology services to local physicians and patients for many years. We are looking forward to continuing our relationship with Fresenius, and the staff as they provide excellent care to my patients.”*

Letters of support from FMC-Neuse River patients state the following:

*“I understand that Bio-Medical Applications of North Carolina is submitting an application for a Certificate of Need to transfer three stations from BMA-Neuse River dialysis facility to the FMC Oxford facility in Oxford. I enthusiastically support the efforts of Bio-Medical Applications of North Carolina.”*

In Section II.1(b), page 13; the applicant states:

*“BMA expects that the patient census of FMC-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

FMC-Neuse River to FMS Oxford then follow closely with this Certificate of Need application (March 15-delivery/April 1, 2012 beginning of review cycle) for seven additional stations at the FMC-Neuse River dialysis facility. Therefore, the application is conforming with 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 three existing certified dialysis stations from FMC-Neuse River to FMS Oxford for a total of 19 dialysis stations at FMS Oxford and 15 stations remaining at FMC-Neuse River, upon completion of this project. In Section III, pages 36 and 39, the applicant provides the following activity profile:

- FMS Dialysis Services of Oxford- 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 3.20 persons per station.
- FMC-Neuse River Dialysis Services- As of June 30, 2011, FMC-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.

Table 5 identifies the county of residence for the patients at FMS-Oxford and FMC-Neuse River as of December 31, 2011.

**Table 5**  
**FMS-Oxford Dialysis and FMC-Neuse River Dialysis Facilities**  
**Patient Origin as of December 31, 2011**

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

*“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[December 31, 2012.]”*

The applicant demonstrates that the needs of the population presently served at FMC-Neuse River dialysis will continue to be adequately met following the relocation of three stations to FMS Oxford and the subsequent addition of seven stations at FMC-Neuse River. Therefore, the application is conforming with 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.

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In Section III 9, page 42, 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 a suitable alternative.”*

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

The applicant concludes that transferring three dialysis stations to FMS Oxford and then developing seven stations at FMC-Neuse River is the most effective and least costly alternative. The application is conforming with 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 these criteria and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC-Neuse River 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 FMC-Neuse River shall develop and operate no more than seven additional**

**dialysis stations for a total of 22 stations upon completion of Project K-8775-12 [Relocate 3 dialysis stations from BMA Neuse River to FMS Oxford], which shall include any home hemodialysis or isolation stations.**

- 3. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC-Neuse River shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations which shall include any home hemodialysis and isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc., (BMA) d/b/a FMC-Neuse River 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.

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In Section VIII.1, page 58, the applicant projects that the total capital cost will be \$15,876, including \$1,800 for water treatment equipment, \$2,500 for patient chairs, \$7,376 for patient TVs and \$4,200 for facility automation equipment. The site and Dialysis machines will be leased [Reference Exhibit 25-Lease Agreement between Oxford Enterprises, LLC and Bio-Medical Applications of North Carolina, Inc and FMC Dialysis Services Neuse River]. In Section IX, page 62, 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 March 15, 2012, in which he states:

*“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc. and Bio-Medical Applications of North Carolina, Inc.*

*BMA is submitting a Certificate of Need Application to add seven dialysis stations for a total of 22 stations upon completion of this project and CON Project ID # K-8775-12 transfer three stations to FMS Oxford. The project calls for the following capital expenditures on behalf of BMA.*

*Capital Expenditure: \$15,876*

*As Vice President, I am authorized and do hereby authorize addition of seven new stations for a total capital cost of \$15,876. Further, I am authorized and do hereby authorize and commit cash reserves for the capital costs of \$15,876 for the project.”*

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

In Section X. 1, page 63, the applicant provides the dialysis facility’s allowable charges per treatment for In-Center and Home-PD reimbursement as follows:

**Table 6  
FMC Neuse River Charge per Treatment  
By Payer**

<b>Payer</b>	<b>In-Center</b>	<b>Home-PD</b>
Commercial Insurance	\$1,375.00	\$550.20
Medicare	\$234.00	\$234.00
Medicaid	\$137.29	\$137.29
VA	\$146.79	\$147.85
Private Pay	\$1,375.00	\$550.20

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 63 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, the 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 64, 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 70 patients. The facility projected to end the year with 70 patients. BMA calculates the average number of patients for the year as 70. BMA multiplied 70 X 156 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 70.0 In-Center patients, ending the year with 72.0 In-Center patients. BMA calculates the average number of In-Center for the first year of operations 70.9 patients  $[70.0 + 72.0] / 2 = 72.9$  (72.9 appears to be a typographical error. The number should be 70.9 or 71 patients). BMA rounds down and multiplies 70 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 72.0 In-Center patients ending the year with 74.0 In-Center patients. BMA calculates the average number of In-Center patients for the second year of operations to be 72.9 patients  $[72.0 + 74.0] / 2 = 72.9$ . BMA rounded down and multiplied 72 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 6.5%.”*

Section X, pages 63-67, the applicant provides the assumptions used in preparation of the *pro forma*, including the number of projected treatments. Table 6 provides financial performance indicators for this project.

**Table 7**  
**Bio-Medical Applications of North Carolina d/b/a FMC-Neuse River**  
**Current and Projected Financial Performance**  
**Revenue, Deductions, Net Revenue and Total Operating Costs**

<b>Financial Performance</b>	<b>Current Operating Year</b>	<b>Year 1 Operating Revenue</b>	<b>Yr. 2. Operating Revenue</b>
Gross Patient Service Revenue	\$3,419,954	\$3,464,766	\$3,568,159
Deductions from Revenue	\$ 463,173	\$ 463,173	\$ 476,407
Net Revenue	\$2,956,781	\$3,001,593	\$3,091,753
Total Operating Costs	\$2,764,491	\$2,854,123	\$2,949,275

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. Following the relocation of three stations from BMA Neuse River to FMS Oxford a CON application will be delivered to the Certificate of Need office on March 15, 2012 for the review cycle beginning April 1, 2012 for 7 stations for BMA Neuse River. The April 2012 CON application is based upon the results of applying the Facility Need Methodology to Neuse River Dialysis. The applicant indicates that the Neuse River facility can house 22 dialysis stations.

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 but more likely two patients actually completing a transfer to FMS Oxford. The balancing 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 while improving 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 55, the applicant provides current and projected staffing at the same levels for FMC Neuse River. These numbers are illustrated in the following table;

**Table 8**  
**FMC Neuse River Current and Projected Staffing**

	# of Current (FTE) Positions	# of Projected (FTE) Positions
RN	3.00	3.00
Tech.	7.00	7.00
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>13.98</b>	<b>13.98</b>

In Section VII 4, pages 56, the applicant states that it does not anticipate 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 45, 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. Tomasz R. Gawecki, MD commits to serve as Medical Director for FMC Neuse River. Exhibit 21 contains letters of support from additional 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. Section V.2, (d); the applicant states the following:

*“BMA will add home dialysis training and support for peritoneal dialysis to the FMC Neuse River facility. However, until the program is certified, patients who desire to perform home dialysis will be trained and followed by the FMC West Pettigrew Home Training Clinic. Patients who are candidates for home dialysis will be referred by their attending nephrologist to the Home Training Clinic at the FMC West Pettigrew facility. FMC Neuse River will provide back-up hemodialysis treatments to any home patient in need of temporary hemodialysis.”*

- (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 50, the applicant states;

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. BMA currently operates 86 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 FMC Neuse River facility to be comprised of the following:*

*It is clear that FMC Neuse River 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.*

*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, (b) and (C) page 51, the applicant provides the current and projected payer mix for FMC Neuse River, as shown in the following table:

**Table 9  
FMC Neuse River Payer Mix  
Current and Projected Payer Mix**

<b>IC Payor Source</b>	<b>12/31/2011 Percent of IC Total</b>	<b>12/31/2012 Percent of IC Total</b>	<b>12/31/2012 Percent of Home Total</b>
Private Pay	0.0%	0.0%	0.0%
Commercial Insurance	8.2%	8.2%	0.0%
Medicare	83.1%	83.1%	100.0%
Medicaid	4.1%	4.1%	0.0%
Medicare/Medicaid	0.0%	0.0%	0.0%
Medicare Commercial	0.0%	0.0%	0.0%
State Kidney Program	0.0%	0.0%	0.0%
VA	4.5%	4.5%	0.0%
Other- Self Pay/Indigent	0.0%	0.0%	0.0%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

As shown in the table above, 91.7% of FMC Neuse River in-center patients have some or all of their services paid for by Medicare, Medicaid and VA [83.1% Medicare plus 4.1% Medicaid and VA 4.5%]. The applicant projects future payer mix to remain the same as the payer mix for CY January 1, 2011 to December 31, 2011. BMA projections for the Home Payer mix are based upon BMA experience in FMC Neuse River and other small home programs across the state.

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 was obtained on April 10, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

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

<b>County</b>	<b>Total # of Medicaid Eligible as % of</b>	<b>Total # of Medicaid Eligible Age 21 and older</b>	<b>% Uninsured CY 08-09 (Estimate by</b>
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	<b>Total Population</b>	<b>as % of Total Population</b>	<b>Cecil G. Sheps Center)</b>
Granville	6.3%	3.2%	18.4%
Vance	13.4%	7.4%	22.8%
Statewide	6.7%	3.60%	19.7%

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

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 & (Name of Facility).

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible's 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 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. The applicant demonstrates that medically underserved populations currently have adequate access to services available at the FMC Neuse River 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 52, 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. Table 11 illustrates the applicant's projected payer mix.

C

**Table 11**  
**FMC Neuse River Projected Payer Mix**

<b>Payer</b>	<b>Percent of Total</b>
Commercial Insurance	8.2%
Medicare	83.1%
Medicaid	4.1%
VA	4.5%
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 53, the applicant states:

*“Those nephrologists who apply for and receive medical staff privileges will admit patients with ESRD to the facility. FMC Neuse River 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 47, the applicant references a letter [Exhibit 19] from Mr. Swann, FMC Director of Market Development and Certificate of Need sent to the College of Nursing, at Vance-Granville Community College inviting the Director of Nursing Education Services to consider the FMC Neuse River Facility for inclusion in their clinical rotations. This letter also seeks to establish a formal agreement regarding clinical rotations through FMC Neuse River for Health Occupation students. Such agreements are standard operating procedure between Fresenius Medical Care and local institutions training future healthcare professionals. 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 19 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 FMC Neuse River discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those 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 FMC Neuse River dialysis services in Granville County. This determination is based on the information in the application, and the following;

- The applicant adequately demonstrates the need to add seven dialysis stations at FMC Neuse River 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 pps. The applicant indicates that total costs associated with adding seven stations is \$2,268/station for a total of \$15,876 for the seven stations determined through use of the Facility Need Methodology. There is no initial start-up or operating costs associated with the seven additional stations. However, the applicant did not provide a cost-benefit analysis to document the cost and benefits to patients, facility, transportation agencies or others,
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations as shown as follows:

**Table 12**  
**FMC Neuse River 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>FMC Neuse River</i>	73.8%	35.9%	84.4%	42.2%	87.5%

The information provided by the applicant in those sections referenced, is reasonable and credible and adequately demonstrates that Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Neuse River, in so far as it relates to the relocation of three stations from FMC Neuse River to FMS Oxford [for a total of 19 stations at

FMS Oxford] and the addition of seven stations at FMC Neuse River for a total of 22 dialysis stations], will have a positive impact on both dialysis facilities by balancing the number of stations at each facility, improving access to services, the quality of the patient-provider experience and the cost-effectiveness of aspects of the service delivery model, release the pressure build up as both facilities perform beyond minimum operating standards.

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 is 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 FMC Neuse River 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.*
- NA- The applicant does not propose a new facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See 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 41, the applicant states that FMC Neuse River projects to serve 72.0 in-center patients by the end of the first operating year, for a utilization of 3.36 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 37-38, the applicant provides 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.