

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

FINDINGS: April 28, 2014
PROJECT ANALYST: Gene DePorter
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: K-10245-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a Neuse River Dialysis Center / Add 3 dialysis stations for a total of 25 upon project completion /Granville

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 (BMA) of North Carolina, Inc. d/b/a Neuse River Dialysis Center (a/k/a BMA Neuse River or FMC Neuse River) proposes to add three dialysis stations to its existing 22-station dialysis facility located at 625 Lewis Street, Oxford for a total of 25 dialysis stations upon completion of this project.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of one dialysis station in Granville County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology if the patients per station ratio is 3.2 or greater. The January 2014 SDR shows Neuse River Dialysis Center (referred to in the SDR as FMC Services Neuse River) is operating with 3.5 patients per station [$77 / 22 = 3.50$] or 87.5% utilization [$3.50 / 4 = 0.875$]. Application of the facility need methodology indicates a need for 3 additional stations, as illustrated in the following table.

K-10245-14-Neuse River Dialysis Center
ESRD Facility Need Methodology

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		84.1%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		22
In-Center Patients as of 6/30/13 (SDR2)		77
In-Center Patients as of 12/31/12 (SDR1)		74
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.0811
(ii)	Divide the result of step (i) by 12	0.0068
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.0405
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	80.1216
(v)	Divide the result of step (iv) by 3.2 patients per station	25.0380
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	3

Based upon the calculations in the above table there is a need for 3 additional dialysis stations. Step (c) of the facility need methodology, page 364 of the 2014 SMFP, states; *“The facility may apply to expand to meet the need established... up to a maximum of 10 stations.”* The applicant is proposing to add 3 dialysis stations which is consistent with the facility need determination for dialysis stations.

POLICY GEN-3: BASIC PRINCIPLES, in the 2014 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 27, the applicant describes how this 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 facility. In addition, BMA's parent company, Fresenius Medical Care encourages all BMA facilities to attain the FMS 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 34-36 the applicant identifies the following programs and methods it uses to insure and maintain quality care:

Maintaining Quality Care Programs

Corporate Programs	Facility Programs
Technical Audits	Quality Improvement Program
Continuous Quality Improvement	Staff Orientation and Training
External Surveys-DFS Certification Surveys	In-Service Education
Core Indicators of Quality	
Single Use Dialyzers	

Exhibit 8 includes Neuse River Dialysis Center's Quality Improvement Program. The applicant adequately demonstrates the proposal will promote safety and quality of care.

Promote Equitable Access

In Section II, page 28-29, the applicant describes how the proposal will promote equitable access for 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. ... as the dialysis patient population of Granville County continues to increase the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. In this case, BMA is applying for three additional stations to meet a growing need in Granville County.

In Section VI.1 (a), page 55 the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA currently operates 100 facilities in 42 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, and other traditionally underserved persons.”

In Section VI.1 (a), page 55, the applicant projects that the facility will have the following patient demographic profile:

Neuse River Dialysis Center Patient Demographics

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
Neuse River Dialysis Center	47.3%	45.9%	78.4%	41.9%	77.0%

In Section VI.2, pages 58, 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 59 the applicant states:

“The BMA admission policy state’s [sic] 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 [an] acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’ Refer to Exhibit 11, for a copy of policy/procedure.”

The applicant adequately demonstrates how the proposal will promote equitable access to medically underserved groups.

Maximize Healthcare Value

In Section II., page 29, the applicant states:

“BMA is projecting a capital expenditure of only \$10,573 for this project. BMA is not seeking State or Federal monies to accomplish this transfer of stations; BMA is not seeking charitable contributions to accomplish this addition of stations. Rather, BMA through its parent company, FMC is taking on the financial burden to complete this addition of stations in an effort to bring dialysis treatment closer to the patient homes. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid or other government payor sources. For example, within this application, BMA projects that 84.8% of the treatments are covered by Medicare and Medicaid and an additional 5.49% are covered by VA. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, BMA must work diligently to control costs of delivery for dialysis. BMA does.”

The applicant adequately demonstrates the proposal will maximize healthcare value. Consequently, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. The application is consistent with the facility need determination in the January 2014 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

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The applicant, Neuse River Dialysis Center, proposes to add 3 dialysis stations to its existing 22-station facility at 625 Lewis Street, Oxford for a total of 25 certified stations upon completion of this project.

Population to Be Served

In Section III. 7, page 40, the applicant identifies the in-center dialysis patient population it served as of June 30, 2013 as 59 Granville County patients, 20 Vance County patients, and 2 patients each from Franklin, Warren and Mecklenburg (VA) county for a total of 85 in-center patients. The applicant notes that two patients are expected to transfer to FMC Tar River upon completion of CON Project I.D. # K-10099-13 (currently under appeal). On page 43, the applicant identifies the in-center population it proposes to serve during the first two operating years following project completion as illustrated in the following table:

Neuse River Dialysis Center, In-Center Patient Projections

County	Operating YR 1 FY16	Operating YR 2 FY17	County Patients as a Percentage of Total	
	In-Center Pts.	In-Center Pts.	Year 1	Year 2
Granville	58.1	58.5	71.1%	71.1%
Vance	19.7	19.8	24.1%	24.1%
Warren	2.0	2.0	2.4%	2.4%
Mecklenburg, VA	2.0	2.0	2.4%	2.4%
Total	81.7	82.3	100.0%	100.0%

The applicant adequately identified the population Neuse River Dialysis Center proposes to serve.

Need Analysis

In Section II.7, pages 12-22, the applicant provides the assumptions and methodology it used to project need for three additional dialysis stations at Neuse River Dialysis Center.

Assumptions

- Project completion date is projected for December 31, 2015
 Operating Year 1 – January 1, 2015 to December 31, 2016
 Operating Year 2 – January 1, 2016 to December 31, 2017
- The January 2014 SDR reports that Neuse River Dialysis Center was operating at 87.5% utilization with a census of 77 in-center patients dialyzing on 22 certified dialysis stations as of June 30, 2013.
- BMA assumes that the entire patient population of Neuse River Dialysis Center will increase at a rate commensurate with the Granville County Five Year Average Change Rate of 3.2% (as published in the January 2014 SDR).
- The facility Need Methodology calculations indicate that the facility is increasing at a rate of 8.1% (see Section III.2, page 37, Facility Need Methodology). According to the July 2013 SDR by December 31, 2012, Neuse River Dialysis Center was serving 74 patients with 18 stations for a utilization rate of 102.78% and 4.11 patients per station. By June 30, 2013, the facility was serving 77 patients with 22 stations for a utilization rate of 87.50% and 3.50 patients per station.
- Two current Franklin County patients are expected to transfer to FMC Tar River, pending the completion of Project I.D. # K-10099-14 (currently under appeal). BMA adjusted patient origin to reflect that change.
- Neuse River Dialysis Center, assumes one patient in 2015 and 2016 and 2 patients in 2017 will change dialysis modality to home dialysis.

The applicant's projections are shown in the following table from page 42 of the application.

<i>FMC Neuse River</i>	<i>In-Center Patient Growth</i>
<i>BMA begins with facility census of June 30, 2013, less two patients from Franklin County.</i>	<i>75 patients</i>
<i>The census is increased by 3.2% for one year to June 30, 2014.</i>	<i>$(75 \times .032) + 75 = 77.4$</i>
<i>The census is increased by 3.2% for one year to June 30, 2015.</i>	<i>$(77.4 \times .032) + 77.4 = 79.9$</i>
<i>The census is increased by 1.6% (half of 3.2%) for six months to December 31, 2015.</i>	<i>$(79.9 \times .016) + 79.9 = 81.2$</i>
<i>BMA has assumed one patient would change to home dialysis. That patient is subtracted at this point.</i>	<i>$81.2 - 1 = 80.2$</i>
<i>The In-Center census is again increased by 3.2% for one year to December 31, 2016. .</i>	<i>$(80.2 \times .032) + 80.2 = 82.7$</i>
<i>BMA has assumed one patient would change to home dialysis. The patient is subtracted at this point. This is the projected In-Center census for the end of Operating Year 1.</i>	<i>$82.7 - 1 = 81.7$</i>
<i>The In-Center census is again increased by 3.2% for one year to December 31, 2016.</i>	<i>$(81.7 \times .032) + 81.7 = 84.3$</i>
<i>BMA has assumed that two patients would change to home dialysis. Those patients are subtracted at this point. This is the project In-Center census for the end of Operating Year 2.</i>	<i>$84.3 - 2 = 82.3$</i>

BMA's projected utilization calculation is a function of the projected year end census rounded down to the whole number. Utilization at Neuse River Dialysis Center is projected to be the following from page 44:

Operating Year 1 (2016): 81 patients dialyzing on 25 stations = 3.24 patients per station
 $81 / (4 \times 25) = 0.810$, or 81.0%

Operating Year 2 (2017): 82 patients dialyzing on 25 stations = 3.28 patients per station
 $82 / (4 \times 25) = 0.820$, or 82%

Access

In Section VI. 1(a), page 55, the applicant states that as of this application, BMA operates 100 facilities in 42 North Carolina counties with another 8 facilities under development or pending CON approval. The patient population includes low income, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons. The applicant patient projects that 91.1% of the patients at Neuse River Dialysis Center will be covered by Medicare or Medicaid. The applicant demonstrates adequate access for medically underserved groups at Neuse River Dialysis.

In summary, the applicant adequately identifies the population to be served and demonstrates all residents of the area, and in particular, underserved groups are likely to have access to the services proposed. The applicant adequately demonstrates the need the proposed population has for three additional dialysis stations at Neuse River Dialysis Center. Therefore, the application is conforming to this criterion.

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

NA

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

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In Section III.9, page 46-47 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services, stating:

- a) *"BMA could apply for fewer expansion stations. This option seems to ignore the growing patient census at FMC Neuse River.*
- b) *Failure to apply for these stations will also eventually remove choice from patient options.*

Considering the alternatives, BMA has only one viable option: apply to expand.

The applicant adequately demonstrated the need for three additional stations based on the number of in-center patients it now serves and proposes to serve. See Criterion (3) for discussion of need which is hereby incorporated by reference as if fully set forth herein. Furthermore, the application is conforming to all other statutory and regulatory review criteria and thus is approvable. A project that cannot be approved cannot be an effective alternative. In summary, the applicant adequately demonstrates that this project is its least costly or most effective alternative to meet the need for additional dialysis stations at this facility. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Neuse River 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 Neuse River shall develop and operate no more than 3 additional dialysis stations for a total of no more than 25 certified stations which shall include any home hemodialysis training or isolation stations.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Neuse River shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 25 dialysis stations which shall include any isolation stations.**
 4. **Bio-Medical Applications of North Carolina, Inc. 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(b), page 63, the applicant shows that the total capital cost of this project is \$10,573. The applicant further indicates on page 67 that the Neuse River Dialysis Center is an operational facility. Consequently, there is no associated "start-up" expense involved. The applicant states on page 65:

"Exhibit 4 is a copy of the most recent FMC audited financial reports. The 2012 Consolidated Balance Sheet reflects more than \$341 million in cash, and total assets exceeding \$17 billion. It is obvious that FMC has the resources necessary for all projects."

In Exhibit 24 of the application, the applicant references the following in a letter dated March 17, 2014, which states:

"BMA is submitting a Certificate of Need application to add three dialysis stations to its FMC Neuse River facility in Granville County. The project calls for the following expenditure:

<i>Capital Expense</i>	<i>\$10,573</i>
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As Vice President, I am authorized and do hereby authorize the addition of three dialysis stations for capital costs identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$10,573, as may be needed for this project."

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

The rates in the following table were provided by the applicant in Section X.1, page 68 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

In-Center Medicare/Medicaid Allowable Charges

Payor	In-Center
Commercial Insurance	\$ 1,425.00
Self-Pay/Indigent	\$ 1,425.00
Medicare/Commercial	\$ 239.00
State Kidney Program	\$ 100.00
Medicare/Medicaid	\$ 239.00
Medicare	\$ 239.00
Medicaid	\$ 137.29
VA	\$ 146.79
Private Pay	\$ 1,425.00

In the revenue and expense statements in Section X. 2, page 70 and Section X.4, page 77, the applicant projects that revenues will exceed operating costs in each of the first two years of operation as shown in the following table:

**Neuse River Dialysis Center
 Revenue, Costs and Profit**

	Operating Year 1 FY16	Operating Year 2 FY17
Total Net Revenue	\$3,535,145	\$3,617,464
Total Operating Costs	\$3,304,546	\$3,405,442
Net Profit	\$ 230,599	\$ 212,022

The assumptions used in preparation of the pro formas, including the number of projected treatments, are based on reasonable, credible and supported assumptions. See Criteria 3 for a discussion of the applicant's projections which is hereby incorporated by reference as if fully set forth herein. See Section X, pages 68-71, for the applicant's assumptions.

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

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

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Neuse River Dialysis Center currently operates 22 certified dialysis stations and proposes to add three dialysis stations for a total of 25 dialysis stations upon completion of this project.

The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it served as of June 30, 2013. As of June 30, 2013, the 22 station Neuse River Dialysis Center was operating at 87.50% capacity ($77 / 22 = 3.5$, $3.5 / 4 = .875$). The target utilization is 80%.

The applicant is therefore eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 25 stations serving 81 patients in Year 1, which is a utilization rate of 81% ($81/25 = 3.24$; $3.24/4 = .81$).

Therefore, the application is conforming to the requirements in 10A NCAC 14C. 2203.

There are two dialysis facilities in Granville County. The following table shows the number of stations, patients per station and utilization based upon data in the January 2014 North Carolina Semiannual Dialysis Report:

Granville County Dialysis Facilities

Facility	Community	# of Station Certified as of 6/30/13	Pts. Per Station	% Utilized
FMC Neuse River	Oxford	22	3.50	87.50%
FMS Oxford	Oxford	19	3.42	85.53%

The applicant adequately demonstrates that the proposed project will not result in unnecessary duplication of existing or approved health capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 60, the applicant provides the current and projected staffing for Neuse River Dialysis Center as shown in the following table:

Neuse River Dialysis Center Current and Projected Staffing

Position	# of Current FTE Positions	# of FTE Positions to be added	# of Projected FTE Positions
RN	3.00	1.0	4.00
PCT.	7.00	2.0	9.00
Clinical Manager	1.00	0	1.00
Medical Director	Contract Position not a facility FTE.		
Administrator	0.15	0	0.15
Dietitian	0.40	0	0.40
Social Worker	0.40	0	0.40
Home Training	0.66	1.34	2.00
Chief Tech	0.15	0	0.15
Equipment Tech	0.75	0	0.75
In-Service	0.15	0	0.15
Clerical	1.00	0	1.00
Total	14.66	4.34	19.00

The applicant indicates 14.66 current FTEs and is projecting the addition of 4.34 FTEs upon project completion. The applicant indicates in Section VII.4, page 61; that it does not expect any difficulty in recruiting staff.

In Section VII.10, page 62, the applicant provides the projected direct care staff upon project completion for each shift offered in the facility as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7A – 12N	7	7	7	7	7	7
Afternoon	12N-5P	7	7	7	7	7	7
Evening							

Exhibit 21 contains a letter dated February 4, 2014 from the current medical director Tomasz R. Gawecki, MD, (a certified Nephrologist) indicating he will continue in the role of medical director for Neuse River Dialysis Center.

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 to this criterion.

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

C

In Section V.1, page 50, the applicant lists the providers of necessary ancillary and support services. On pages 50-54, the applicant describes how the facility will coordinate services with the existing healthcare system. The following exhibits contain agreements for the indicated support relationships:

- Exhibit 25 - Hospital Affiliation Agreement with Durham Regional Hospital
- Exhibit 26 - Transplant Agreement with Duke University Medical Center
- Exhibit 15 - Spectra Laboratory Services Agreement
- Exhibit 19 - Invitation to Durham Technical Community College to utilize Neuse River Dialysis Center as a training site

The applicant adequately demonstrates that the necessary ancillary and support services will continue to be available and that the proposed services will continue to be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

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In Section VI.1 (a), page 55, the applicant states the following;

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA currently operates 100 facilities in 42 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. The patient population of the FMC Neuse River facility is comprised of the following:

Facility	Medicaid / Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>FMC Neuse River Dialysis Center</i>	47.3%	45.9%	78.4%	41.9%	77.0%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.4% of the facility treatment reimbursement is from Medicare.

It is clear that FMC Neuse River 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. ...For example, Medicare represented 83.97% of North Carolina dialysis treatments in BMA facilities in FY 2013. Medicaid treatments represented an additional 4.82% of treatments in BMA facilities for FY 2013, Low income and medically 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, and ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies.”

As shown in the following table from page 56, 96.57% of Neuse River Dialysis Center current in-center patients have some or all of their services paid for by some form of government reimbursement. In Section VI.1 (b) (c), page 56, the applicant provides the current and projected payor mix for Neuse River Dialysis Center in-center patients. The applicant projects no change in reimbursement, between current and projected reimbursement, as shown in the following table:

**Neuse River Dialysis Center
 Current and Projected Payor Mix**

Payor Source	Current / Projected Percent of Total
Commercial Insurance	3.43%
Medicare	79.74%
Medicaid	5.10%
Medicare/Commercial	6.24%
VA	5.49%
Medicare/Commercial	6.24%
Total	100.00%

The applicant demonstrated that medically underserved populations currently have adequate access to dialysis services provided at Neuse River Dialysis Center. Therefore, the application is conforming to this criterion.

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 Granville County and statewide.

**Percent of Medicaid Eligible
 By County and State**

County	2010 Total # of Medicaid Eligible as % of Total Population	2010 Total # of Medicaid Eligible Age 21 and older as % of Total Population	CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)
Granville	14.7%	6.3%	18.4%
Statèwide	16.5%	6.7%	19.7%

More current data, particularly with regard to the estimated uninsured percentages, was not available.
 Source: [www.ncdhhs.gov/dema-Medicaid Eligible-Granville County](http://www.ncdhhs.gov/dema-Medicaid%20Eligible-Granville%20County) 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 Neuse River Dialysis Center. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35 (ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence-one year statistics as of 1/1/2012-12/21/2012, page 74).

The Office of State Budget and Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition data is available by race, age or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender 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.

Additionally, The United States Renal Data System, in its 2013 USRDS Annual Data Report (page 216-223) provides the following national statistics for FY 2011:

"The December 31, 2011, prevalent population included 430,273 patients on dialysis..." (page 216, [www.usrds.org / adr. asp](http://www.usrds.org/adr.aspx))

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p.216). The report further states:

"In the 2011 prevalent population, 84 percent of hemodialysis patients and 81% of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant." (p. 216)

The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD Spending Nationally by Payor

Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 327.

The Southeastern Kidney Council (SKC) Network 6, 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

**2012 Number and Percent of Dialysis Patients
 By Age, Race, and Gender**

	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65 +	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African-American	9,346	62.7%
White	5,191	34.8%
Other	380	2.6%
Total	14,917	100.0%

Source: SKC Network 6, Table includes North Carolina, statistics only

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 application Section VI.1 (f), page 58, the applicant states, "*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.*" In Section VI.6 (a), page 59, 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 56, the applicant provides the projected payor mix for the proposed services at Neuse River Dialysis Center. The applicant projects no change from the current payor mix for dialysis visits as shown in the table below.

**Neuse River Dialysis Center
Current and Projected Payor Mix**

Payor Source	Current & Projected Percent of Total
Commercial Insurance	3.43%
Medicare	79.74%
Medicaid	5.10%
VA	5.49%
Medicare/Commercial	6.24%
Total	100.00%

The applicant projects that 96.57% of the patients will have some or all of their dialysis costs paid through a government source. The applicant demonstrates that medically underserved populations will continue to have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5 (a), page 58, 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 Neuse River will have an open policy, which means that any Nephrologist may apply to admit patients at the facility.”* Further, in Section VI.5 (b), page 59, the applicant states, *“... all patients will be admitted to the facility through one of the Nephrologists on the staff of FMC Neuse River. The Nephrologists expect to continue receiving referrals from the local physician community, home health agencies and acute care facilities.”*

The applicant adequately demonstrates that Neuse River Dialysis Center offers 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 application Section V.3 (a), page 51, the applicant references a letter in Exhibit 19 to Vance-Granville Community College Nursing Program inviting them to consider the Neuse

River Dialysis facility for inclusion in their clinic rotations for nursing students. 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 applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, 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

The applicant proposes to add three dialysis stations to its existing 22 station facility for a total of 25 certified stations upon completion of the project.

According to the January 2014 SDR, Neuse River Dialysis Center is one of two existing dialysis facilities in Granville County. The following table provides an operating profile of these two dialysis facilities.

Granville County Dialysis Facilities

Facility	Community	# of Station Certified as of 6/30/13	Pts. Per Station	% Utilized
Neuse River Dialysis Center	Oxford	22	3.50	87.5%
FMS Oxford	Oxford	19	3.42	85.5%

In Section V.7, page 54, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

“BMA does not expect this proposal to have [an] effect on the competitive climate in Granville County. According to the January 2014 SDR there were two dialysis facilities operating within Granville County. FMC Neuse River [and] FMS Oxford. Both are

operated by Fresenius. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.

This facility also has added value stemming from the strength of our relationship with Durham Nephrology Associates. ...

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

See Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The applicant adequately demonstrates that any enhanced competition will have a positive impact on cost-effectiveness, quality and access to dialysis services in Granville County. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need to add three dialysis stations, to the existing facility based on the facility need methodology. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to FMC Neuse River patients.
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable, credible and demonstrates adequate staffing for the provision of quality care in accordance with 42 C.F.R. Section 494. 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.
- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 55, the applicant states:

“It is clear that FMC Neuse River 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 in Section VI. 1(a), page 55, to demonstrate that medically underserved populations will continue to have adequate access to BMA 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 Neuse River</i>	47.3%	45.9%	78.4%	41.9%	77.0%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 78.4% of the facility treatment reimbursement is from Medicare.

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

According to files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Neuse River Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The specific findings are discussed below.

.2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- See Exhibit 5 (copy of the January 2014 SDR), which indicates the facility has an 87.5% utilization rate as of June 30, 2013.

- .2202(a)(2) *Mortality rates;*
-C- In Section IV.2, page 45 the applicant provides the following mortality rates: 2011-12.8%, 2012-7.1% and 2013-9.5%.
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section IV.3, page 48, the applicant indicates that it is providing home dialysis follow-up, care and supplemental training for 7 home dialysis patients. The facility provided home training to 5 home patients in 2013.
- .2202(a)(4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 48, the applicant states that in 2013 Neuse River Dialysis Center had 5 transplants referred and 2 transplants performed.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 45, the applicant states that 5 patients are on the waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related.*
-C- In Section IV.6, page 49, the applicant states that there were 28 dialysis related hospital admissions and 278 non-dialysis hospital related admissions during 2013.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-C- In Section IV.7, page 49 the applicant indicates there were 0 Hepatitis B patients and 0 Hepatitis B conversions.

(b) *An applicant that proposed develop a new facility, to 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- Neuse River Dialysis Center is an existing facility.

- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
 - (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Neuse River Dialysis Center is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Neuse River Dialysis Center is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Section XI.6 (f), page 83 and Exhibits 12 & 13 regarding back-up capabilities.
- .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- Neuse River Dialysis Centers an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
- C- See Section II.1, page 10, Section VII.2, page 61 and Section XI.6 (g) page 83.
- .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 III.7, pages 38-41.

.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- Neuse River Dialysis Center is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- See Section II, 10A NCAC 14C .2202 (9) page 17.

.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 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- Neuse River Dialysis Center is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section III.7, pages 39-41 the applicant projects to serve 81 in-center patients by the end of Year 1, which equates to 3.24 patients per station per week [$81 / 25 = 3.24$]. Further, the applicant projects to serve 82 in-center patients by the end of Year 2, which equates to 3.28 patients per station per week [$82 / 25 = 3.28$] at 82.0% utilization. See Criterion (3) for discussion of the reasonableness of the applicant's methodology which is hereby incorporated by reference as if fully set forth herein.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section III.7, pages 39-44, the applicant provides the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

.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 (e), page 50. Granville Health Systems and Duke Regional Hospital
- .2204(2) Maintenance dialysis;*
 - C- See Section V.1 (c), page 50. On Site
- .2204(3) Accessible self-care training;*
 - C- See Section V.1 (d), page 50. On Site
- .2204(4) Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1 (d), page 50. On Site
- .2204(5) X-ray services;*
 - C- See Section V.1 (g), page 50. Granville Health Systems
- .2204(6) Laboratory services;*
 - C- See Section V.1 (h), page 50. Spectra (Exhibit 15).
- .2204(7) Blood bank services;*
 - C- See Section V.1, (i), page 50. Granville Health Systems
- .2204(8) Emergency care;*
 - C- See Section V.1 (b), page 50. All staff is trained to respond, a fully stocked crash cart is maintained, and ambulance transport to hospital is accessible.
- .2204(9) Acute dialysis in an acute care setting;*
 - C- See Section V.1 (a), page 50. Duke Regional Hospital.
- .2204(10) Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1 (p), page 50. Referral to Carolina Vascular Access, Triangle Interventional, Regional Vascular Associates, Duke Vascular, Duke Regional Hospital or Duke Clinic.
- .2204(11) Transplantation services;*
 - C- See Section V.1 (f), page 50. Duke University Medical Center and UNC Hospitals.

- .2204(12) *Vocational rehabilitation counseling and services; and*
-C- In Section V. 1 (o), page 50, the applicant states that referrals will be made to Vocational Rehabilitation Services for Grandville and Vance Counties.

- .2204(13) *Transportation*
-C- See Section V.1 (q), page 50. KARTS.

.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 494 (formerly 405.2100)*
-C- In Section VII.1 and VII.2, pages 60-61, the applicant provides the proposed staffing. In Section VII, 2, page 61 the applicant states, the facility does and will comply with all staffing requirements set forth in the 42 C.F.R. Section 494. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis service to be provided.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
-C- See Section VII.5, page 61 and Exhibits 9 and 10 for an outline of continuing education programs.