

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

FINDINGS: December 20, 2013

PROJECT ANALYST: Gene DePorter

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: K-10187-13/ Bio-Medical Applications of North Carolina, Inc d/b/a BMA Neuse River/ 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.

NC

Bio-Medical Applications (BMA) of North Carolina, Inc. d/b/a BMA 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 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the July 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of three dialysis stations 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 patient per station ratio is 3.2 or greater. The July 2013 SDR shows BMA Neuse River (referred to in the SDR as FMC Services Neuse River) is operating with 4.11 patients per station [74 / 18 = 4.11] or 102.78% utilization [4.11 / 4 = 1.0278]. Application of the facility need methodology indicates a need for 4 additional stations, as illustrated in the following table. The patients per station exceed the minimum standard of 3.20 patients per station.

**K-10187-13-BMA Neuse River**

ESRD Facility Need Methodology-October Review

Required SDR Utilization		80%
Center Utilization Rate as of December 31, 2012		102.8%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		22
In-Center Patients as of 12/31/12 (SDR2)		74
In-Center Patients as of 6/30/12 (SDR1)		70
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12 (SDR1)	11.4%
(ii)	Divide the result of step (i) by 12	0.0095
(iii)	The quotient from (ii) is multiplied by 12 (the number of months from December 31, 2012 until December 31, 2013)	0.1143
(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	82.4400
(v)	Divide the result of step (iv) by 3.2 patients per station	25.7625
	and subtract the number of certified and pending stations as recorded in SDR2 [22] to determine the number of stations needed	4

Based upon the calculations in the above table there is a need for 4 additional dialysis stations. Step (c) of the facility need methodology, page 381 of the 2013 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 2013 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 25, the applicant describes how this proposal will promote safety and quality:

*“BMA is a high quality health care provider. 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**

<b>Corporate Programs</b>	<b>Facility Programs</b>
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 13 includes BMA Neuse River’s Quality Improvement Program. The applicant adequately demonstrates the proposal will promote safety and quality of care.

Promote Equitable Access

In Section II, page 27, the applicant describes how the proposal will promote equitable access for medically underserved groups, as follows:

*“10A NCAC 14C .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. ... BMA assumes that the patient population of BMA Neuse River will continue to increase. Consequently, additional stations are needed in BMA Neuse River.”*

In Section VI.1(a), page 52 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 seven 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 52, the applicant projects that the facility will have the following patient demographic profile:

**BMA Neuse River Facility Patient Demographics**

<b>Facility</b>	<b>Medicaid/ Low Income</b>	<b>Elderly (65+)</b>	<b>Medicare</b>	<b>Women</b>	<b>Racial Minorities</b>
<b>BMA Neuse River</b>	28.0%	48.0%	70.7%	48.0%	81.3%

In Section VI.2, pages 54-55, 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 the 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 56, 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 [an] acceptable reason to refuse referral of a patient. Established referral patterns should be followed without regard to AIDS status of patients.’” See Exhibit 9, for a copy of the applicant’s HIV/HBV Policy and Procedures.*

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

Maximize Healthcare Value

In Section II., page 27, the applicant states:

*“BMA is projecting a capital expenditure of \$10,573 for this project. This expenditure is necessary in the normal course of doing dialysis business. 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 90.6% of the treatments are covered by Medicare and Medicaid. 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 how the proposal will maximize healthcare value. However, the applicant does not demonstrate that its projected volumes for the proposed services incorporate the basic principles in meeting the needs of the patients to be served. Its projections are not based on reasonable, credible and supported assumptions. Therefore, the application is not 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.

NC

The applicant, BMA Neuse River, 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. In May of 2012, the applicant had 18 certified dialysis stations before the approval of two separate projects:

Project K-8775-12 relocated 3 stations from BMA Neuse River to FMS Oxford, for a total of 15 stations at BMA Neuse River upon project completion. Then, Project K-8802-12 added 7 new dialysis stations to BMA Neuse River for a total of 22 stations upon project completion. BMA Neuse River currently operates 22 certified dialysis stations.

In addition to in-center hemodialysis, the applicant will continue to offer home training for home peritoneal dialysis and home hemodialysis.

Population to Be Served

In Section III. 7, page 39, the applicant identifies the in-center dialysis patient population it served as of June 30, 2013 as 48 Granville County patients, 14 Vance County patients, and one patient each from Warren, Franklin, and Mecklenburg County, Virginia for a total of 65 in-center patients. On page 42, 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:

**BMA Neuse River, In-Center Patient Projections**

County	Operating YR 1	Operating YR 2	County Patients as a	
	FY16	FY17	Percentage of Total	
	In-Center Pts.	In-Center Pts.	Year 1	Year 2
Granville	65.4	71.8	76.9%	78.8%
Vance	14.0	14.0	17.8%	16.4%
Warren	1.0	1.0	2.1%	1.9%
Franklin	1.0	1.0	1.0%	1.0%
Mecklenburg, VA	1.0	1.0	2.1%	1.9%
<b>Total</b>	<b>82.4</b>	<b>88.8</b>	<b>100.0%</b>	<b>100.0%</b>

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

Need Analysis

In Section III.7, pages 39-40, the applicant provides the assumptions and methodology it used to project need for three additional dialysis stations at BMA Neuse River. The applicant states:

*“Projections of future patient populations of BMA Neuse River are derivative of the facility patient population census as of June 30, 2013 (See table IV.1). The following demonstrates the calculations used to arrive at the projected census for Operating Years One and Two:”*

Assumptions

- Project completion date is projected for June 30, 2015  
 Operating Year 1 – July 1, 2015 to June 30, 2016  
 Operating Year 2 – July 1, 2016 to June 30, 2017
- As of June 30, 2013 BMA Neuse River was providing dialysis services for 48 patients from Granville County and 17 patients from other counties. BMA assumes that these out of county patients will continue dialysis at BMA Neuse River.
- The applicant states it will project growth of the Granville County patient population only.
- From June 30, 2012 - December 31, 2012, BMA Neuse River in-center patient census grew at a rate exceeding the Granville County Five Year Average

Change Rate of 3.2% (as published in the July 2013 SDR). According to the applicant the annual growth rate was 11.4% for the period ended December 31, 2012. (11.4% is actually the annualized growth rate for the period from 6/30/12-12/31/12  $[(74-70) / 70] \times 2 = 11.43\%$ ).

- The January 2013 SDR reports that BMA Neuse River was operating at 97.22% of capacity with a census of 70 patients dialyzing on 18 dialysis stations for a per station rate of 3.89, as of June 30, 2012.
- The July 2013 SDR reports BMA Neuse River operating at 102.78% with 74 patients dialyzing on 18 dialysis stations or 4.11 patients per station.
- BMA Neuse River States a growth rate of 11.4% is appropriate given its location and service to patients outside of Granville County.
- In Operating Years 1 and 2, BMA Neuse River assumes 1 patient per year will change dialysis modality to home hemodialysis.

The applicant's projections are shown below from page 42.

<i><b>BMA Neuse River</b></i>	<i><b>In-Center Patient Growth</b></i>
<i>BMA begins with Granville County patients utilizing the BMA Neuse River dialysis facility as of June 30, 2013</i>	<i>48 Granville County patients</i>
<i>BMA projects growth of this patient population using a rate of 11.4% for one year to June 30, 2014.</i>	<i><math>(48 \times .114) + 48 = 53.5</math></i>
<i>BMA projects growth of this patient population using a rate of 11.4% for one year to June 30, 2015.</i>	<i><math>(53.5 \times .114) + 53.5 = 59.6</math></i>
<i>BMA adds the 17 patients from other counties. This is the projected beginning census for this project.</i>	<i><math>59.6 + 17 = 76.6</math></i>
<i>BMA projects growth of Granville County patient population using a rate of 11.4% for one year to June 30, 2016.</i>	<i><math>(59.6 \times .114) + 59.6 = 66.4</math></i>
<i>BMA subtracts one patient projected to change modality to home hemodialysis.</i>	<i><math>66.4 - 1 = 65.4</math></i>
<i>BMA adds the 17 patients from other counties. This is the end of Operating Year 1.</i>	<i><math>65.4 + 17 = 82.4</math></i>
<i>BMA projects growth of Granville County patient population using a rate of 11.4% for one year to June 30, 2017.</i>	<i><math>(65.4 \times .114) + 65.4 = 72.9</math></i>
<i>BMA subtracts one patient projected to change modality to home hemodialysis.</i>	<i><math>72.9 - 1 = 71.9</math></i>
<i>BMA adds the 17 patients from other counties. This is the end of Operating Year 2.</i>	<i><math>71.9 + 17 = 88.9</math></i>

The applicant projects utilization of BMA Neuse River to be the following;

Operating Year 1: 82 patients dialyzing on 25 stations = 3.28 patients per station  
 $82 / (4 \times 25) = 0.820$ , or 82.0%

Operating Year 2: 88 patients dialyzing on 25 stations = 3.52 patients per station  
 $88 / (4 \times 25) = 0.8800$ , or 88%

However, the applicant's use of an 11.4% growth rate is not reasonable, credible and supported based on the June 30, 2013 in-center census and number of certified stations provided in Section III.7, page 39. As of June 30, 2013 the applicant's utilization was 73.75% or 2.95 patients per station. Because of the decrease in patient census (74 to 65) and the addition of 4 stations (18 to 22) from December 31, 2012 to June 30, 2013, the applicant's growth rate for the most recent six month period is -12.2%, it is not reasonable to use a 11.4% growth rate based on a prior six month period of growth. However, even if the applicant used the more conservative Granville County Five Year Average Change Rate of 3.2%, instead of an 11.4% growth rate; the applicant would not project enough patients to meet the 3.2 patients per station threshold required by 10A NCAC 14C .2203(b).

The following table demonstrates using a growth rate of 3.2% instead of 11.4%.

<i><b>BMA Neuse River</b></i>	<i><b>In-Center Patient Growth</b></i>
<i>BMA begins with Granville County patients utilizing the BMA Neuse River dialysis facility as of June 30,2013</i>	<i>48 Granville County patients</i>
<i>BMA projects growth of this patient population using a rate of 3.2% for one year to June 30, 2014.</i>	<i>(48 X .032) + 48 = 49.5</i>
<i>BMA projects growth of this patient population using a rate of 3.2% for one year to June 30, 2015.</i>	<i>(49.5 X .032 )+ 49.5 = 51.1</i>
<i>BMA adds the 17 patients from other counties. This is the projected beginning census for this project.</i>	<i>51.1 + 17 = 68.1</i>
<i>BMA projects growth of Granville County patient population using a rate of 3.2% for one year to June 30, 2016.</i>	<i>(51.1 X .032) + 51.1 = 52.74</i>
<i>BMA subtracts one patient projected to change modality to home hemodialysis.</i>	<i>52.74 – 1 = 51.74</i>
<i>BMA adds the 17 patients from other counties. This is the end of Operating Year 1.</i>	<i>51.74 + 17 = 68.74</i>
<i>BMA projects growth of Granville County patient population using a rate of 3.2% for one year to June 30, 2017.</i>	<i>(51.74 X .032) + 51.74 =53.40</i>
<i>BMA subtracts one patient projected to change modality to home hemodialysis.</i>	<i>53.41 – 1 = 52.40</i>
<i>BMA adds the 17 patients from other counties. This is the end of Operating Year 2.</i>	<i>52.41 + 17 = 69.40</i>

Using a growth rate of 3.2% instead of 11.4%, the applicant’s projected utilization at BMA Neuse River would be as follows:

Operating Year 1: 68 patients dialyzing on 25 stations = 2.72 patients per station  
 $2.72 / 4 = 0.68$ , or 68% utilization

Operating Year 2: 69 patients dialyzing on 25 stations = 2.76 patients per station  
 $2.76 / 4 = 0.69$ , or 69% utilization

As stated above, using a growth rate of 3.2%, the applicant would not project enough patients to meet the 3.2 patients per station threshold required by 10A NCAC 14C .2203(b). Therefore, the applicant fails to adequately demonstrate the need the population has for the proposed project.

Access

In Section VI, page 52, the applicant states that as of this application BMA operates 100 facilities in 42 North Carolina counties with another 7 facilities under development or pending CON approval. The patient population includes low-income, racial and ethnic

minorities, women, handicapped, elderly, and other underserved persons. The applicant projects that 95.8% of the patients at BMA Neuse River will be covered by Medicare or Medicaid. The applicant demonstrates adequate access for medically underserved groups at BMA Neuse River.

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. However, the applicant does not adequately demonstrate the need the proposed population has for three additional dialysis stations at BMA Neuse River. Therefore, the application is not 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.

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.

NC

In Section III.9, page 44 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services, stating:

- a) *“BMA could have chosen to not pursue this transfer and expansion of this facility. However, this option is not consistent with the growth of the patient population in the facility. This is not a suitable alternative.*
- b) *BMA evaluated the possibility of applying for fewer stations. However, as demonstrated by the need discussion, the facility will need seven [sic] 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.”*

However, the applicant did not adequately demonstrate the need for three additional stations based on the number of in-center patients it now serves. See Criterion (3) for discussion of need which is hereby incorporated by reference as if fully set forth herein. Furthermore, the application is not conforming to all other statutory and regulatory review criteria and thus is not approvable (See Criteria (1), (3), (5), (6), (18a), and 10A NCAC 14C .2200). A project that cannot be approved can not be an effective alternative. In summary, the applicant does not adequately demonstrate that this project is its least costly or most effective alternative. Consequently the application is disapproved.

- (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.

NC

In Section VIII. 1(b), page 60, the applicant shows that the total capital cost of this project is \$10,573. The applicant further indicates that the BMA Neuse River facility is an operational facility. Consequently, there is no associated “start-up” expense involved. The applicant states:

*“Exhibit 10 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 states the following in a letter dated September 16, 2013:

*“BMA proposes to add three dialysis stations to the BMA Neuse River dialysis facility for a total of 25 dialysis stations upon completion of this project. The project requires the following capital expense on behalf of BMA:*

*Capital Expense                      \$10,573*

*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 66 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

**In-Center Medicare/Medicaid Allowable Charges**

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

VA	\$ 146.79
Private Pay	\$ 1,375.00

In the revenue and expense statements in Section X. 2, page 67 and Section X.4, page 73, the applicant projects that revenues will exceed operating costs in each of the first two years of operation as shown in the following table:

**BMA Neuse River  
Revenue, Costs and Profit**

	<b>Operating Year 1 FY15</b>	<b>Operating Year 2 FY16</b>
Total Net Revenue	\$4,074,495	\$4,400,219
Total Operating Costs	\$3,366,567	\$3,590,846
Net Profit	\$ 707,928	\$ 809,373

However, the assumptions used in preparation of the pro formas, including the number of projected treatments, are not 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.

In summary, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections regarding revenues and operating costs. Therefore, the application is not 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.

NC

BMA Neuse River 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. In 2012, the applicant operated 18 certified dialysis stations before the approval of two separate projects: Project K-8775-12 relocated 3 stations from BMA Neuse River to FMS Oxford, for a total of 15 stations at BMA Neuse River and 19 stations at FMS Oxford upon project completion. Then, Project K-8802-12 added 7 new dialysis stations to BMA Neuse River for a total of 22 stations upon project completion. Both projects were completed in early 2013.

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 July 2013 North Carolina Semiannual Dialysis Report:

**Granville County Dialysis Facilities**

<b>Facility</b>	<b>Community</b>	<b># of Station Certified as of 12/31/12</b>	<b>Pts. Per Station</b>	<b>% Utilized</b>
BMA Neuse River	Oxford	18	4.11	102.78%

FMS Oxford	Oxford	16	3.31	82.81%
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Source: July 2013 SDR

As stated above, by February 2013, BMA Neuse River was certified for 22 stations and FMS Oxford was certified for 19 stations.

The applicant does not adequately demonstrate the need for three additional stations based on the number of in-center patients it served as of June 30, 2013. As of December 31, 2012, the 18 station BMA Neuse River was operating at 102.78% capacity ( $74 / 18 = 4.111$ ;  $4.111 / 4 = 102.78$ ). The target utilization is 80%. However, by June 30, 2013, BMA Neuse River was certified for 22 stations and serving only 65 patients which is 2.95 patients per station or 73.86% utilization. Furthermore, the applicant's projections are not based on reasonable, credible and supported assumptions therefore; the applicant does not adequately demonstrate that the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is not 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 57, the applicant provides the current and projected staffing for BMA Neuse River as shown in the following table:

**BMA Neuse River Current and Projected Staffing**

Position	# of Current FTE Positions	# of FTE Positions to be added	# of Projected FTE Positions
RN	3.00	0	3.00
PCT.	7.00	0	7.00

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	1.00	0	1.00
Chief Tech	0.20	0	0.20
Equipment Tech	0.70	0	0.70
In-Service	0.20	0	0.20
Clerical	1.00	0	1.00
<b>Total</b>	<b>15.05</b>	<b>0</b>	<b>15.05</b>

The applicant indicates 15.05 current FTEs and is not projecting any change in that number upon project completion. The applicant indicates in Section VII.4, page 58; that it does not expect any difficulty in recruiting staff.

In Section VII.10, page 59, 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
<b>Morning</b>	7A – 12N	6	6	6	6	6	6
<b>Afternoon</b>	12N-5P	6	6	6	6	6	6
<b>Evening</b>							

Exhibit 21 contains a letter dated August 7, 2013 from the current medical director Tomasz R. Gawecki, MD, (a certified Nephrologist) indicating he will continue in the role of medical director for BMA Neuse River.

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 47, the applicant lists the providers of necessary ancillary and support services. On pages 48-50, 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 16 - Hospital Affiliation Agreement with Durham Regional Hospital
- Exhibit 17 - Transplant Agreement with Duke University Medical Center

Exhibit 18 - Spectra Laboratory Services Agreement

Exhibit 19 - Invitation to Durham Technical Community College to utilize BMA Neuse River as a training site

Exhibit 20 - West Pettigrew Dialysis Home Training Agreement

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will 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;

C

In Section VI.1(a), page 52, 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 seven 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 BMA Neuse River facility is comprised of the following:*

<b>Facility</b>	<b>Medicaid / Low Income</b>	<b>Elderly (65+)</b>	<b>Medicare</b>	<b>Women</b>	<b>Racial Minorities</b>
<b>BMA Neuse River</b>	28.0%	48.0%	70.7%	48.0%	81.3%

*Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 70.7% of the facility treatment reimbursement is from Medicare.*

*It is clear that BMA 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. ...For example, Medicare represented 84.8% of North Carolina dialysis treatments in BMA facilities in FY 2012. Medicaid treatments represented an additional 4.5% of treatments in BMA facilities for FY 2012, 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, ANSI Standards for Handicapped Access, and any other requirement of federal, state, and local bodies.”*

As shown in the following table from page 53, 95.8% of BMA Neuse River current in-center patients have some or all of their services paid for by some form of government reimbursement. In Section VI.1(b), page 53, the applicant provides the current and projected payor mix for BMA Neuse River in-center patients. The applicant projects no change in reimbursement, between current and projected reimbursement, as shown in the following table:

**BMA Neuse River**

**Current and Projected Payor Mix**

<b>Payor Source</b>	<b>Current &amp; Projected Percent of Total</b>
Commercial Insurance	4.3%
Medicare	85.6%
Medicaid	5.0%
VA	5.2%
Total	100.0%

The applicant demonstrated that medically underserved populations currently have adequate access to dialysis services provided at BMA Neuse River. 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**

<b>County</b>	<b>2010 Total # of Medicaid Eligible as % of Total Population</b>	<b>2010 Total # of Medicaid Eligible Age 21 and older as % of Total Population</b>	<b>CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)</b>
Granville	23.3%	11.7%	19.9%
Statewide	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](http://www.ncdhhs.gov/dema-Medicaid) Eligible-Granville County 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 BMA Neuse River. In fact, in 2011 only 5.8 of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35. ⑤

The Office of Budget and Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition data are 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 do 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

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

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

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

**The 2012 United States Renal Data System  
 Selected National Statistics as of December 31, 2010 ⑥**

Patients Receiving Hemodialysis Nationally- 376,000			
African American	38.23%	Male	55.65%
White	55.38%	65+	44.35%

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ...Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients respectively.”*

⑤ Southeastern Kidney Council ESRD Network 6 2011 Annual Report, Table 3, page 16.

⑥ Source: <http://www.cms.gov/Medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf>

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

**ESRD Spending Nationally by Payor**

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

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

The Southeastern Kidney Council (SKC) provides Network 6, 2011 Incident ESRD patient data by age, race and gender, as shown below:

**2011 Number and Percent of Dialysis Patients  
 By Age, Race, and Gender**

	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
<b>Total</b>	<b>9,342</b>	<b>100.0%</b>

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia

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

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

C

In application Section VI.1 (f), page 54, 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 56, 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 48, the applicant provides the projected payor mix for the proposed services at BMA Neuse River. The applicant projects no change from the current payor mix for dialysis visits as shown in the table below.

**BMA Neuse River  
Current and Projected Payor Mix**

<b>Payor Source</b>	<b>Current &amp; Projected Percent of Total</b>
Commercial Insurance	4.3%
Medicare	85.6%
Medicaid	5.0%
VA	5.2%
Total	100.0%

The applicant projects that 95.8% 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 55, the applicant states, "Those Nephrologist [sic] who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA 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 55, the applicant states, "... all patients will be admitted to the facility through one of the Nephrologists on the staff of BMA Neuse River. Referrals for treatment are expected to continue to come from Granville Med Hospital, and practicing physicians in the area as patients demonstrate a need for nephrology physician services."*

The applicant adequately demonstrates that BMA Neuse River 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 49, the applicant references a letter in Exhibit 19 to Vance-Granville Community College Nursing Program inviting them to consider the BMA Neuse River Dialysis facility for inclusion in their clinic rotations for nursing students and Health Occupation 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.

NC

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 July 2013 SDR, BMA Neuse River is one of two existing dialysis facilities in Granville County: BMA Neuse River with utilization of 102.78% and FMS Oxford with utilization of 82.81%. The following table reflects the status of the two facilities as of the July 2013 SDR which reflects data as of 12/31/12.

**Granville County Dialysis Facilities**

<b>Facility</b>	<b>Community</b>	<b># of Station Certified as of 12/31/12</b>	<b>Pts. Per Station</b>	<b>% Utilized</b>
BMA Neuse River	Oxford	18	4.11	102.78%
FMS Oxford	Oxford	16	3.31	82.81%

Source: July 2013 SDR

In 2012, the BMA received CON approval for two separate projects that were completed in early 2013:

- Project K-8775-12 relocated 3 stations from BMA Neuse River to FMS Oxford, for a total of 15 stations at BMA Neuse River and 19 stations at FMS Oxford upon project completion.

- Project K-8802-12 added 7 new dialysis stations to BMA Neuse River for a total of 22 stations upon project completion. Both projects were completed in early 2013.

As stated above, by February 2013, BMA Neuse River was certified for 22 stations and FMS Oxford was certified for 19 stations. As reported on page 39, as of June 30, 2013, BMA Neuse River was serving only 65 in-center patients on 22 stations which equals 2.95 patients per station or 73.9% utilization. The analyst assumes some patients followed the 3 stations that were transferred to FMS Oxford in early 2013.

In Section V.7, page 51, the applicant indicates;

*“This proposal will not have any effect on competition within Granville County: this is a proposal to add three stations to BMA Neuse River. The patients to be served by this facility are existing dialysis patients, and future patients residing in Granville and Vance Counties. At this time there are no other providers of dialysis services operating within Granville County. Consequently, the project will not change the competitive environment within either Granville or Granville County.”*

However, because BMA Neuse River is operating below 80% utilization, the expected effect of adding additional stations will not include a positive impact on cost-effectiveness, or access to dialysis services in Granville County.

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 does not demonstrate how the proposal will maximize healthcare value or that the expected effects of the proposal on competition would include a positive impact on cost-effectiveness and access to dialysis services in Granville County. This determination is based on the information in the application, and the following analysis:

- The applicant does not adequately demonstrates the need to add dialysis stations,
- The applicant does not adequately demonstrate that its proposal is a cost-effective alternative to meet projected patient volume at BMA Neuse River Dialysis Center,

Furthermore, the applicant does not demonstrate that its projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. The applicant’s projections are not based on reasonable, credible and supported assumptions. Therefore, the application is not 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.

According to files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA Neuse River 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.

NC

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. However, the proposal is not conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. 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 2 (copy of the July 2013 SDR), which indicates the facility has a 102.78% utilization rate as of December 31, 2012.

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

-C- In Section IV.2, page 45 the applicant provides the following mortality rates: Year 2010-4.8%, 2011-12.8%, and 2012-7.1%.

*.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 45, the applicant indicates that there were 10 home trained dialysis patients dialyzing with BMA Neuse River, as of June 30, 2013.

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

-C- In Section IV.4, page 45, the applicant states that in 2012

BMA Neuse River had 9 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 4 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 46, the applicant states that there were 14 dialysis related hospital admissions and 106 non-dialysis hospital related admissions during 2012.
- .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 46 the applicant indicates there were 2 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- BMA Neuse River 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- BMA Neuse River 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- BMA Neuse River 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 78 and Exhibit 12 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- BMA Neuse River is 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 XI.6 (g), page 78 and Exhibits 11 and 12.
- .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 39-41.
- .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- BMA Neuse River 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- BMA Neuse River 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.*

-NC- In Section III.7, pages 39-41 the applicant projects to serve 82 in-center patients by the end of Year 1, which equates to 3.40 patients per station per week [82 / 25 = 3.40]. Further, the applicant projects to serve 88 in-center patients by the end of Year 2, which equates to 3.52 patients per station per week [88 / 25 = 3.52]. However, the applicant did not adequately demonstrate the need for three additional stations based on the number of in-center patients it was serving and number of certified stations provided on page 39. As of June 30, 2013, the applicant's utilization was 73.75% or 2.95 patients per station. 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- See Section II (7), pages 13-15, In Section III.7, pages 39-41, 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 47. Granville Health System

- .2204(2) *Maintenance dialysis;*  
-C- See Section V.1 (c), page 47. On Site
- .2204(3) *Accessible self-care training;*  
-C- See Section V.1 (d), page 47. On Site
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*  
-C- See Section V.1 (d), page 47. On Site
- .2204(5) *X-ray services;*  
-C- See Section V.1 (g), page 47. Granville Medical Center
- .2204(6) *Laboratory services;*  
-C- See Section V.1 (h), page 47. Spectra (Exhibit 18).
- .2204(7) *Blood bank services;*  
-C- See Section V.1, (i), page 47. Granville Health System
- .2204(8) *Emergency care;*  
-C- See Section V.1 (b), page 47. 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 47. Duke Regional Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients;*  
-C- See Section V.1 (p), page 47. 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 47. Duke University Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and*  
-C- In Section V. 1 (o), page 47, the applicant states that referrals will be made to Vocational Rehabilitation Services for Vance and Granville Counties.
- .2204(13) *Transportation*  
-C- See Section V.1 (q), page 47. 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 57-58, the applicant provides the proposed staffing. In Section VII, 2, page 58 the applicant states, the proposed facility 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 58 and Exhibits 14 and 15 for an outline of continuing education programs.