

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

FINDINGS: February 12, 2014

PROJECT ANALYST: Gene DePorter

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10188-13/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Freedom Lake Dialysis/ Add 4 dialysis stations for a total of 26 upon project completion /Durham

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 Freedom Lake Dialysis [BMA- Freedom Lake] proposes to add four dialysis stations to its existing dialysis facility for a total of 26 dialysis stations upon completion of this project. BMA Freedom Lake Dialysis is located at 4016 Freedom Lake Drive, Durham.

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 15 stations and thus no need for an additional facility in Durham County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because, the utilization rate reported for BMA Freedom Lake in the July 2013 SDR is 3.27 patients per station [72 patients / 22 stations = 3.27 patients per station]. Application of the facility need methodology indicates a need for 7 additional stations, as illustrated in the following table. The Average Annual Change Rate for Durham County for the past five years is 0.7%. The applicant has chosen to use a growth rate of 5.72%.

J-10188-13-BMA Freedom Lake
 ESRD Facility Need Methodology-October Review

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		81.82%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		22
In-Center Patients as of 12/31/12 (SDR2)		72
In-Center Patients as of 6/30/12 (SDR1)		63
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	28.6%
(ii)	Divide the result of step (i) by 12	0.0238
(iii)	The quotient from (ii) is multiplied by 12 (the number of months from December 31, 2012 until December 31, 2013.	0.2857
(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	92.5714
(v)	Divide the result of step (iv) by 3.2 patients per station	28.9286
	and subtract the number of certified and pending stations as recorded in SDR2 [22] to determine the number of stations needed	7

Based upon the calculations in the above table there is a need for 7 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.*” As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations allowed is 7. The applicant is proposing to add 4 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 22, and 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.”

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 13 includes BMA Freedom Lake’s Quality Improvement Program.

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

Promote Equitable Access

In Section II. (9), page 24, 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. ...BMA assumes that the patient population of

BMA Freedom Lake will continue to increase at a rate equal to the Durham County Five Year Average Annual Change Rate as published in the July 2013 SDR. Consequently, additional stations are needed in BMA Freedom Lake.”

In Section VI 1(a), page 47 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, or other traditionally underserved persons.”

In Section VI, 1(a), page 47, BMA states that the facility has the following demographic profile:

BMA Freedom Lake Facility Demographics

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Freedom Lake	25.0%	39.5%	98.7%	42.1%	77.6%

In Section VI.2, page 50, the applicant states:

“The design of the facility 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 Section XIIX of the North Carolina applicable 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 51, 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.’ Exhibit 9, Appendix IV contains the applicant’s HIV/HBV Policy and Procedure.

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

Maximize Healthcare Value

In Section II., page 24, the applicant states:

“BMA is projecting a capital expenditure of only \$11,850 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 96.3% 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 of dialysis. BMA does.”

However, the applicant does not adequately demonstrate the proposed project is the least costly or most effective alternative and that the project will not result in unnecessary duplication of existing health service capabilities or facilities. See discussion in Criterion (4) and (6), which is incorporated hereby as if fully set forth herein. Based on those facts the applicant does not adequately demonstrate that the proposal will maximize healthcare value. The applicant does not adequately demonstrate the proposal will incorporate the basic values of Policy GEN-3. Therefore, the application is nonconforming to this criterion.

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

C

The applicant, BMA-Freedom Lake, proposes to add 4 dialysis stations to its existing facility in Durham for a total of 26 stations upon completion of this project. BMA Freedom Lake does not currently provide home training and does not propose to add home training in this application.

Population to Be Served

In Section III. 7, page 40, the applicant identified the in-center dialysis patient population it served as of December 31, 2012 as 71 Durham County patients, 2 Granville County patients, 2 Person County patients and 1 Alamance County patient for a total of 76 patients. On page 38, 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 Freedom Lake, In-Center Patient Projections
 Operating Years 1 and 2**

County	Operating YR 1 1/1/15-12/31/15	Operating YR 2 1/1/2016-12/31/16	County Patients as a Percentage of Total	
			Year 1	Year 2
	In-Center Patients	In-Center Patients		
Durham	81.6	86.3	94.23%	94.52%
Alamance	1.0	1.0	1.15%	1.10%
Granville	2.0	2.0	2.31%	2.19%
Person	2.0	2.0	2.31%	2.19%
Total	86.6	91.3	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Need Analysis

In Section III.7, pages 36-37, the applicant provides the assumptions and methodology it used to project need for four additional dialysis stations at BMA-FREEDOM LAKE. The applicant states,

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

Assumptions

- Project completion date is projected for December 31, 2014
 Operating Year 1 –January 1, 2015 to December 31, 2015
 Operating Year 2 –January 1, 2016 to December 31, 2016
- July 2013 SDR reports BMA Freedom Lake utilization at 81.82% with 72 patients dialyzing on 22 stations. As of June 30, 2013. The inpatient census was 76.
- As of June 30, 2013 BMA Freedom Lake was providing dialysis services for 71 Durham County patients five patients from other counties. BMA assumes that these out-of-county patients will continue dialysis at BMA Freedom Lake.
- The BMA Freedom Lake in-center patient census has grown at a rate exceeding the Durham County Five Year Average Change Rate of 0.7% for dialysis services (as published in Table B. of the July 2013 SDR. According to the applicant the annualized growth rate for the last five years was 28.6%.
- BMA assumes that the patient population of BMA Freedom Lake will increase at an annual rate of 5.72% (which is 1/5 of 28.6%).

- The facility need methodology identified a need for seven additional dialysis stations. The applicant has proposed to add four stations.
- The January 2013 SDR reports that BMA Freedom Lake was operating at 71.59% of capacity with a census of 63 patients dialyzing on 22 certified dialysis stations as of June 30, 2012. The July 2013 SDR reports BMA Freedom Lake operating at 81.82% with 72 patients dialyzing on 22 certified dialysis stations.
- BMA Freedom Lake does not project to operate a third dialysis shift at BMA Freedom Lake due to lack of patient interest.

Methodology

<i>BMA Freedom Lake</i>	<i>In-Center Patient Growth</i>
<i>BMA begins with Durham County patients utilizing the BMA Freedom Lake dialysis facility as of June 30, 2013</i>	<i>71 Durham County patients</i>
<i>BMA projects growth of this patient population using a rate of 5.72% for six months to December 31, 2013</i>	<i>$[71 \times (.0572 / 12 \times 6)] + 71 = 73.0$</i>
<i>BMA projects growth of this patient population using a rate of 5.72% for one year to December 31, 2014</i>	<i>$(73 \times .0572) + 73 = 77.2$</i>
<i>BMA adds the five patients from other counties. This is the projected beginning census for this project.</i>	<i>$77.2 + 5 = 82.2$</i>
<i>BMA projects growth of Durham County patient population using a rate of 5.72% for one year to December 31, 2015.</i>	<i>$(77.2 \times .0572) + 77.2 = 81.6$</i>
<i>BMA adds five patients from other counties. This is the end of Operating Year One.</i>	<i>$81.6 + 5 = 86.6$</i>
<i>BMA projects growth of Durham County patient population using a rate of 5.72% for one year to December 31, 2016.</i>	<i>$(81.6 \times .0572) + 81.6 = 86.3$</i>
<i>BMA adds the five patients from other counties. This is the projected beginning census of this project. This is the end of Operating Year 2.</i>	<i>$86.3 + 5 = 91.3$</i>

Utilization of BMA Freedom Lake is projected to be the following;

Operating Year 1-

86 patients dialyzing on 26 stations = 3.31 patients per station
 $86 / (4 \times 26) = 0.827$, or 82.7%

Operating Year 2-

91 patients dialyzing on 26 stations = 3.50 patients per station
 $91 / (4 \times 26) = 0.875$, or 87.5%

Operating Years 1 and 2 exceed the 3.2 patients per station per week required by 10A NCAC 14C .2203(b). Project utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI. 1(a), page 47, the applicant states that each of BMA's 100 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects that 96.2% of the patients at BMA Freedom Lake will be covered by Medicare or Medicaid. The applicant demonstrates adequate access for medically underserved groups at BMA Freedom Lake.

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

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

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 39 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services which were to either maintain the status quo or increase the number of dialysis stations at the facility. The applicant failed to consider transferring stations from FMC Briggs Avenue and/or FMC West Pettigrew to BMA Freedom Lake. As discussed in criterion (6), which is incorporated hereby as if fully set forth herein, the applicant did not adequately demonstrate that the alternatives it considered were less costly or

more effective than the option of transferring four dialysis stations from FMC Briggs Ave and/or FMC West Pettigrew to BMA Freedom Lake.

The application is not conforming or conditionally conforming to all other applicable statutory and regulatory review criteria, See criterion (1), (6) and (18a). An application that cannot be approved is not an effective alternative. Therefore, the applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII. 1(b), page 55, Table VIII. 1; the applicant shows that the total capital cost of this project is \$10,750. The applicant further indicates that the BMA Freedom Lake facility is an operational facility. Consequently, there is no associated start-up expense involved. The applicant states the following:

“Exhibit 10 is a copy of the most recent FMC audited financial report. 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, the applicant states the following in a letter dated September 16, 2013:

“BMA is submitting a Certificate of Need Application to add four dialysis stations to its BMA Freedom Lake facility in Durham County. The project calls for the following capital expenditure on behalf of BMA:

Capital Expenditure \$10,750

As Vice President, I am authorized and do hereby authorize the development of these four dialysis stations for capital costs of \$30,000 [sic]. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$10,750.”

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 application Section X.1, page 61 and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

In-Center Medicare/Medicaid Rates ①

	In-Center
--	-----------

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 62 and Section X.4, page 66, 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 Freedom Lake
 Revenue, Costs and Profit-Operating Years 1 and 2**

	Operating Year 1 7/1/14-6/30/15	Operating Year 2 7/1/15-6/30/16
Total Net Revenue	\$3,292,276	\$3,492,584
Total Operating Costs	\$2,727,132	\$2,842,717
Net Profit	\$ 565,144	\$ 649,867

The assumptions used in preparation of the pro forma, including the number of projected treatments, are reasonable. See Section X, pages 61-67, for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of 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.

NC

The applicant proposes to add four dialysis stations to the existing BMA Freedom Lake facility for a total 26 dialysis stations upon completion of this project. As of December 31, 2012, the 22 station BMA Freedom Lake facility was operating at 81.82% capacity ($72 / 22 = 3.27$; $3.27 / 4 = .8182$). The target utilization is 80%. The applicant therefore is eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 26 stations serving 86 patients at the end of Year 1 which is a utilization rate of 82.25% ($86 / 26 = 3.30$; $3.30 / 4 = .8225$). Therefore, the applicant is conforming with the requirement in 10A NCAC 14C .2203.

① http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End_Stage_Renal_Disease_Pro prospective_Payment_System_INC905143.pdf

There are 8 dialysis facilities in Durham County. Of the 8 Durham County facilities, BMA owns 4, DaVita owns 3 and Duke University Hospital owns one. The following table

shows the ESRD facilities in Durham County by community, number of stations and utilization of dialysis stations based upon data in the July 2013 North Carolina Semiannual Dialysis Report.

Durham County Dialysis Facilities

Facility	Community	# of Station	# of In-Center Pts.	Pts. Per Station	% Utilized
Duke Univ. Hospital	Durham	16	52	3.25	81.25%
Durham Dialysis	Durham	24	90	3.75	93.75%
Durham West Dialysis	Durham	29	97	3.34	83.62%
FMC-Briggs Avenue	Durham	29	74	2.55	63.79%
FMC-West Pettigrew	Durham	20	44	2.20	55.00%
FMC South Durham	Durham	12	37	3.08	77.08%
Freedom Lake Dialysis	Durham	22	72	3.27	81.82%
Southpoint (DaVita)	Durham	12	46	3.83	95.83%

Source: July 2013 North Carolina Semiannual Dialysis Report Table A, Durham County.

As shown in the table above, the other three FMC facilities are operating below the target with a collective utilization of 2.5 patients per station. ($155 / 61 = 2.54$). However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for BMA Freedom Lake in the July 2013 SDR is 81.82% or 3.27 patients per station. The utilization rate was calculated based on 72 in-center patients on 22 certified dialysis stations ($72 / 22 = 3.272$; $3.272 / 4 = .8180$). The target is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. The facility is eligible to expand its facility and may apply for additional stations based on the calculations above. Upon completion of the proposed project the facility will have 26 stations serving 86 patients at the end of Year 1 (December 2015), which is a utilization rate of 82.7% or 3.3 patients per station ($86 / 26 = 3.31$; $3.31 / 4 = .8275$) exceeding 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203 (b).

The table below shows the number of in-center patients as of 12/31/2012 and 6/30/13 for the three FMC facilities in Durham County. The project analyst notes that in the referenced six month period there was a total increase of 26 in-center patients with over 88% going to FMC West Pettigrew.

Facility	# of Certified Dialysis Stations 12/31/2012	# of In-Center Patients 12/31/2012	# of In-Center Patients 6/30/12	Difference	Utilization By Percentage 12/31/2012
FMC-Briggs Avenue	29	74	65	9	63.79%
FMC-West Pettigrew	20	44	56	-12	55.00%
FMC South Durham	12	37	36	1	77.08%
Freedom Lake	22	72	63	9	81.88%
Total	83	227	220	7	

FMC-West Pettigrew has the lowest utilization rate at 55.00%. The utilization rate was calculated based on 44 in-center dialysis patients and 20 certified dialysis stations ($44/20 = 2.2$; $22/4 = 0.55$ or 55%).

According to Table B of the July 2013 SDR, Durham County has a 15 station surplus. An alternative approach that the applicant could have followed would be to transfer 4 stations from FMC West Pettigrew to BMA Freedom Lake; reducing the number of stations at FMC West Pettigrew to 16 while still increasing the number of stations at BMA Freedom Lake to 26 (this would not affect the number of surplus dialysis stations in Durham County). The project analyst projects utilization and patients per station for FMC West Pettigrew as of the beginning of the proposed project at BMA Fayetteville (July 1, 2014), assuming its approval.

FMC West Pettigrew – as of July 1, 2014

Assuming no change in stations

Step 1: December 31, 2012: 44 patients

Step 2: Grow the patients at the Durham County Five Year Average Annual Change Rate for the period January 1, 2013 to December 31, 2013: $44 \times 1.007 = 44.31$ patients.

Step 3: Grow the patients at the Durham County Five Year Average Annual Change Rate for the period January 1, 2014 to June 30, 2014 (the beginning of proposed Project Year 1) = $44.308 \times 1.007 = 44.62$ or 44 patients.

Step 4: $44 / 19 = 2.316$ patients per station or $2.316 / 4 = 0.5789$ or 57.89%

At the start of the proposed project Year 1, the FMC West Pettigrew facility would have a utilization rate of 57.9% or 2.32 patients per station. Next, the project analyst calculated the utilization rate and patients per station at FMC West Pettigrew as if FMC had transferred four existing dialysis stations from FMC West Pettigrew to the BMA Freedom Lake facility rather than developing four new dialysis stations at BMA Freedom Lake, as proposed. Thus, as of July 1, 2014 FMC West Pettigrew would only have 16 dialysis stations (20 minus 4 dialysis stations transferred to BMA Freedom Lake).

As of July 1, 2014 (the proposed start of Project Year 1 for the BMA Freedom Lake project):

FMC West Pettigrew: $44 / 16 = 2.75$ patients per station or $2.75 / 4 = 0.6875$ or 68.8% utilization.

BMA Freedom Lake and FMC West Pettigrew are approximately 4 miles and 10 minutes driving time from each other. Durham County, in the July 2013 SDR, shows a surplus of 15 dialysis stations. If BMA Freedom Lake developed four new dialysis stations, as proposed, FMC would be adding to the Durham County surplus. In contrast, as shown above, if FMC transferred 4 dialysis stations from FMC West Pettigrew to BMA Freedom Lake: 1) the demonstrated need at BMA Freedom Lake would be met; 2) FMC would not be adding four dialysis stations to the existing Durham County surplus of dialysis stations; and 3) FMC West Pettigrew's utilization would still remain well below the target utilization of 80%.

The applicant does not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is nonconforming 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 52, the applicant provides the current and projected staffing for BMA Freedom Lake as shown in the following table:

BMA Freedom Lake Current and Projected Staffing

	# of Current (FTE) Positions	# of (FTE) Positions to be added	# of Projected (FTE) Positions
RN	4.00	0.00	4.00
LPN	1.00	0.00	1.00
PCT	6.00	0.00	6.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contract Position not a facility FTE.		
Administrator	0.20	0.00	0.20
Dietitian	0.40	0.00	0.40
Social Worker	0.37	0.00	0.37
Chief Tech	0.20	0.00	0.20
Equipment Tech	0.75	0.00	0.75
In-Service	0.20	0.00	0.20
Medical Records	0.00	0.00	0.00
Clerical	1.00	0.00	1.00
Total	15.12	0.00	15.12

The applicant operates with current staff of 15.12 FTE and is not projecting any change in staff. The applicant indicates in Section VII.4, page 53; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in Section VII and the estimated annual salaries and revenues are reasonable and credible.

In a letter in Exhibit 21, the current medical director (a certified Nephrologist) indicates he will continue in the role of medical director for BMA Freedom Lake. 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

BMA-Freedom Lake is an existing kidney disease treatment center certified by the Centers for Medicare and Medicaid. In Section V. 1, page 42, the applicant provides a table that lists the providers of the necessary ancillary and support services. The following exhibits contain agreements for various support relationships; as indicated

- Exhibit 16-Hospital Transfer Agreement with Durham Regional Hospital.
- Exhibit 17-Transplant Agreement with Duke University Medical Center.
- Exhibit 18-Spectra Laboratory Services Agreement.
- Exhibit 19-Letter of Invitation to Durham Technical Community College to Utilize BMA Freedom Lake as a Training Site.
- Exhibit 20-Home Training Agreement with West Pettigrew Dialysis

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. The information provided in Section V is reasonable and credible and supports a finding of conformity with this criterion. Therefore, the applicant 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 47, and 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 or other traditionally underserved persons. The patient population of BMA Freedom Lake is comprised of the following:

Facility	Medicaid/Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
<i>BMA Freedom Lake</i>	25.0%	39.5%	98.7%	42.1%	77.6%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 98.7% of the facility treatment reimbursement is from Medicare.

It is clear that BMA Freedom Lake 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 underserved 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, 96.2% of BMA Freedom Lake current in-center patients have some or all of their care paid for by Medicare or Medicaid. In Section VI.1 (b), page 48, the applicant provides the current and projected payor mix for BMA Freedom Lake. The applicant projects no change in reimbursement, between current and projected reimbursement, as shown in the following table:

**BMA Freedom Lake
 Current and Projected Payor Mix**

Payor Source	Current & Projected Percent of Total
Commercial Insurance	3.7%
Medicare	92.0%
Medicaid	4.2%
Total	100.0%

The applicant demonstrates that medically underserved populations currently have adequate access to dialysis services provided at BMA-FREEDOM LAKE. 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 Durham County and statewide.

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

County	Total # of Medicaid Eligible as % of Total Population ❷	Total # of Medicaid Eligible Age 21 and older as % of Total Population ❸	% Uninsured CY 08-09 (Estimate by Cecil G. Sheps Center) ❹
Durham	15.6%	5.7%	20.1%
Statewide	16.5%	6.7%	19.7%

More current data, particularly with regard to the uninsured percentages, was not available.
 Source: www.ncdhhs.gov/dema-Medicaid Eligible-Durham 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 Freedom Lake. 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. ❺

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 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.

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:

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

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+	44.65%

“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.”

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

ESRD Spending Nationally by Payor ⑦

Payor	Spending in	% of Total
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	Billions	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%

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 ⑧**

Age	# of ESRD Patients	% of Dialysis Population
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.3%
Male	5,105	54.6%
Race		
African-American	5,096	54.5%
White	4,027	43.1%
Other	219	2.3%
Total	9,342	100.0%

- ② Medicaid Eligible by Age for Durham County and State, June 2010.
- ③ Medicaid Eligible Age 21+ for Durham County and State, June 2010.
- ④ Percent Uninsured, Cecil G. Sheps Center, CY 2008-2009.
- 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>
- ⑦ Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.
- ⑧ 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 49, 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 51, 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 Freedom Lake. The applicant projects no change from the current payor mix for dialysis visits as shown in the table below.

**BMA Freedom Lake
Current and Projected Payor Mix**

Payor Source	Current & Projected Percent of Total
Commercial Insurance	3.7%
Medicare	92.0%
Medicaid	4.2%
Total	100.0%

The applicant projects that 96.2% of the patients will be Medicare and Medicaid beneficiaries. The applicant demonstrates that medically underserved populations would 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 50, the applicant states, “*Those Nephrologists who apply for and receive medical privileges will admit patients with End Stage Renal Disease to the facility. BMA Freedom Lake has an open policy, which means that any Nephrologist may apply to admit patients at the facility.*” Further, in Section VI.5 (b), page 50, the applicant states, “*... all patients will be admitted to the facility through one of the*

Nephrologists on the staff of BMA Freedom Lake. Referrals for treatment will continue to come from Durham Regional Hospital and practicing physicians in the area as patients demonstrate a need for nephrology physician services.”

The applicant adequately demonstrates that BMA Freedom Lake 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), pages 43-44, the applicant references a letter (Exhibit 19) to the Dean of the Durham Technical Community College Nursing Program encouraging the school to include the facility in its clinical rotation 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 information provided in application Section V. 3 is reasonable and credible and supports a finding of conformity with this criterion.

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

NC

The applicant proposes to add four dialysis stations to its existing facility for a total of 26 stations upon completion of the project.

The following table provides a profile of the eight dialysis providers in Durham County. Of the 8 Durham County facilities, BMA owns four, DaVita owns 3, and Duke University Hospital owns one.

Durham County Dialysis Facilities as of 12/31/2012

Facility (Station)	Community	# of Station	Pts. Per Station	% Utilized
Duke Univ. Hospital	Durham	16	3.25	81.25%
Durham Dialysis	Durham	24	3.75	93.75%
Durham West Dialysis	Durham	29	3.34	83.62%

FMC-Briggs Avenue	Durham	29	2.55	63.79%
FMC-West Pettigrew	Durham	20	2.20	55.00%
FMC South Durham	Durham	12	3.08	77.08%
Freedom, Lake Dialysis	Durham	22	3.27	81.82%
Southpoint (DaVita)	Durham	12	3.83	95.83%

Source: July 2013 North Carolina Semiannual Dialysis Report Table A, Durham County.

In Section V.7, page 46, the applicant states;

“BMA does not expect that this proposal will have any effect on competition within Durham County; this is a proposal to expand the existing facility by adding four needed dialysis stations at BMA Freedom Lake Dialysis. The patients to be served by this facility are existing dialysis patients, and future patients residing in Durham County. This project will not change the competitive environment within Durham County.”

The applicant adequately demonstrates that the proposal would have a positive impact upon the cost effectiveness, quality and access to the proposed services. See Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Durham County. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need to add four dialysis stations to the existing facility;
- The applicant adequately demonstrates it will continue to provide quality services; and
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations.

However, the applicant did not adequately demonstrate that the proposed project will have a positive impact on cost-effectiveness. Thus, the application is non-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.

The applicant currently provides dialysis services at Freedom Lake Dialysis in Durham. According to the files at the Acute and Home Care Division of the Health Service Regulation, no incidents occurred, within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the state. 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 proposal is 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, a copy of the July 2013 SDR, Tables A and B, which indicates the facility has an 82% utilization rate as of December 31, 2012. The projected utilization for Year 1 and Year 2 of operations is 83% and 88% respectively.

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 40 the applicant provides the following mortality rates-Year 2010-21.2%, 2011-18.2%, and 2012-9.1%.

.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 42, the applicant states that it does not provide home dialysis training. Patients requiring this capability utilize FMC West Pettigrew in Durham.

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

-C- Section IV.4, page 40, 2012: Transplants referred (8) and Transplants performed (1),

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

-C- See Section IV.5, page 40, 4 patients are on the waiting list.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related-65.*

-C- See Section IV.6, page 40:

Dialysis related hospital admissions were 33 and non-dialysis hospital related were 47.

.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- Section IV.7, page 41 indicates 2 Hepatitis B patients.

(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 Freedom Lake 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 Freedom Lake 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 Freedom Lake 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 71 and Exhibits 12 and 29 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 Freedom Lake 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 71 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 35-38 and discussion in Criterion (3).
- .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 Freedom Lake 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 VI.1 (a)-(f), pages 47-50.

.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 Freedom Lake 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 four 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 35-38 the applicant projects to serve 86 in-center patients by the end of Year 1, which equates to 3.31

patients per station per week $[86 / 26 = 3.31]$. Further, the applicant projects to serve 91 in-center patients by the end of Year 2, which equates to 3.50 patients per station per week $[91 / 26 = 3.50]$.

- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II (7), pages 12-15 and Section III.7, pages 35-38, the applicant provides the assumptions and methodology used to project utilization of the additional stations.

.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 42. Duke Regional Hospital
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1 (c), page 42. On Site
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1 (d), page 42. Home Training is provided at FMC West Pettigrew facility.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1 (d), page 42. Provided by FMC West Pettigrew
- .2204(5) *X-ray services;*
 - C- See Section V.1 (g), page 42. Duke Regional Hospital or Durham Radiology.
- .2204(6) *Laboratory services;*
 - C- See Section V.1 (h), page 42. SPECTRA (Exhibit 18).
- .2204(7) *Blood bank services;*
 - C- See Section V.1, (i), page 42. Duke Regional Hospital
- .2204(8) *Emergency care;*
 - C- See Section V.1 (b), page 42. All staff are trained to respond, a fully stocked crash cart is maintained, and ambulance transport to Duke Regional Hospital is accessible
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1 (a), page 42. Duke Regional Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1 (p), page 42. Referral to Carolina Vascular Access, Duke Regional Hospital and Triangle Interventional

Services.

- .2204(11) *Transplantation services;*
 - C- See Section V.1 (f), page 42. Duke University Medical Center
- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- See Section V. 1 (o), page 42. Durham County Vocational Rehabilitation Services.
- .2204(13) *Transportation*
 - C- See Section V.1 (q), page 42. Durham Area Transportation Authority or Red Cross.

.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, page 52 the applicant provides the proposed staffing. In Section VII, 2, page 53 the applicant states the proposed facility will comply with all staffing requirements set forth in the Federal code. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis service to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- .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- In Section VII.5, page 53 and Exhibits 14 and 15, the applicant provides documents that support its ongoing continuing education programs.