

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: December 10, 2014

PROJECT ANALYST: Fatimah Wilson

INTERIM CHIEF: Martha Frisone

PROJECT I.D. NUMBER: F-10333-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte / Add four dialysis stations for a total of 36 certified stations upon completion of this project, Project I.D. #F-10249-14 (add two stations) and Project I.D. #F-10091-13 (add three stations) / Mecklenburg County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA North Charlotte, also referred to as BMA of North Charlotte, proposes to add four dialysis stations to the existing facility for a total of 36 certified dialysis stations upon completion of this project, Project I.D. #F-10249-14 (add two stations) and Project I.D. #F-10091-13 (add three stations). BMA of North Charlotte is an existing 28-station dialysis facility in Mecklenburg County, located at 5220 North Tryon Road, Charlotte. The facility is currently approved to provide in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support.

The applicant was previously approved to establish a home training program pursuant to Project I.D. #F-10091-13, however, in this application, the applicant proposes not to develop the home hemodialysis training program at the BMA of North Charlotte facility. In Section I.8, page 2, the applicant states,

*“In CON Project I.D. #F-10091-13 BMA proposed to included [sic] home dialysis therapies at the facility. In CON Project I.D. #F-10249-14, BMA continued to project the addition of home dialysis therapies to the facility. BMA has now determined that the patient population of the area is more in need of in-center dialysis stations, as opposed to taking limited space to develop the home dialysis program. BMA has not abandoned the concept of providing home dialysis therapies, but rather has determined that space at the BMA North Charlotte facility could be better utilized, to serve a larger number of patients, if dedicated to in-center dialysis. Patients who would normally be referred for home dialysis, will continue to be referred for home dialysis but to another of the BMA facilities in the Charlotte area which has sufficient space to dedicate to home dialysis therapies.”*

The July 2014 Semiannual Dialysis Report (SDR) states as of December 31, 2013 there were 27 certified dialysis stations at BMA of North Charlotte and five stations pending certification (two stations approved in Project I.D. #F-10249-14 and three stations approved in Project I.D. #F-10091-13). The July 2014 SDR also shows BMA of North Charlotte was dialyzing 119 in-center patients, which is an 110% utilization rate [ $119 \text{ patients} / 27 \text{ certified stations} = 4.41$ ;  $4.41 / 4 = 1.10$ , or 110%]. According to correspondence received by the Certificate of Need (CON) Section from the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation (DHSR), one of the three pending stations pursuant to Project I.D. #F-10091-13 was certified effective March 10, 2013, thus the facility is currently certified for a total of 28 stations.

### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 SDR, the county need methodology shows there is a surplus of 13 dialysis stations in Mecklenburg County; therefore, based on the county need methodology, there is no need for additional stations in Mecklenburg County. In fact, the July 2014 SDR shows there is a surplus of 13 stations in Mecklenburg County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA of North Charlotte, in the July 2014 SDR is 110.2% and 4.41 patients per station. This utilization rate was calculated based on 119 in-center dialysis patients and 27 certified dialysis stations ( $119 \text{ patients} / 27 \text{ stations} = 4.41 \text{ patients per station} / 4 = 1.102$ ).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**OCTOBER 1 REVIEW - JULY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		110.2%
Certified Stations		27
Pending Stations		5
<b>Total Existing and Pending Stations</b>		<b>32</b>
In-Center Patients as of 12/31/13 (SDR2)		119
In-Center Patients as of 06/30/13 (SDR1)		119
Step	Description	
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center Change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.0000
(ii)	Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.0000
(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	119.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	37.1875
	and subtract the number of certified and pending stations as recorded in SDR2 [32] to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

Policy GEN-3: Basic Principles, page 38, of the 2014 SMFP is applicable to this review. Policy GEN-3 states:

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

The applicant addresses Policy GEN-3 beginning on page 19 of the application.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 5-8, Section II, pages 19-20, Section V, pages 38-43 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section II, pages 20-21, Section III, pages 30-35, Section V, pages 38-43, Section VI, page 44, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section II, pages 21-22, Section III, pages 30-35, Section V, page 43, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

**Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add four dialysis stations to the existing BMA of North Charlotte dialysis facility for a total of 36 dialysis stations upon completion of this project, Project I.D. #F-10249-14 (add two stations) and Project I.D. #F-10091-13 (add three stations).

**Population to be Served**

In Section IV.1, page 36, the applicant states the number of patients served at BMA of North Charlotte, as of June 30, 2014 as follows:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Mecklenburg	0	122
Cabarrus	0	1
York, SC	0	1
Total	0	124

The applicant proposes to add four dialysis stations to the existing BMA of North Charlotte dialysis facility for a total of 36 certified dialysis stations upon the completion of this project, Project I.D. #F-10249-14 (add two stations) and Project I.D. #F-10091-13 (add three stations). In Section II, page 15 and Section III.7, page 32, the applicant identifies the patient population it proposes to serve for the first two years of operation following completion of the project on December 31, 2015, as summarized in the table below:

**Projected Dialysis Patient Origin  
 January 2016 – December 2017**

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Mecklenburg	139.0	144.9	98.6%	98.6%
Cabarrus	1.0	1.0	0.7%	0.7%
York, SC	1.0	1.0	0.7%	0.7%
Total	141.0	146.9	100.0%	100.0%

However, the project analyst determined that the numerical data provided by the applicant was inconsistent. Specifically, the applicant erroneously began its census with 124 Mecklenburg County patients instead of 122 Mecklenburg County patients, as stated in Section IV.1, page 36. In response to a request for clarification, the applicant confirmed that the data in the following table correctly reflects the population it proposes to serve for the first two years of operation following completion of the project.

**Projected Dialysis Patient Origin  
 January 2016 – December 2017**

COUNTY	IN-CENTER PATIENTS		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	Year 1	Year 2	Year 1	Year 2
Mecklenburg	136.6	142.3	98.6%	98.6%
Cabarrus	1.0	1.0	0.7%	0.7%
York, SC	1.0	1.0	0.7%	0.7%
Total	138.6	144.3	100.0%	100.0%

The applicant adequately identified the population BMA of North Charlotte proposes to serve.

**Analysis of Need**

As discussed in Criterion (1), based on the facility need methodology for adding dialysis stations, the potential number of stations needed is five stations. The applicant proposes to add four stations.

In Section II, pages 13-15 and Section III.7, pages 31-33, the applicant provides the assumptions and methodology it used to determine the need for additional stations and to project BMA of North Charlotte’s proposed patient utilization, which are summarized below:

1. The project is scheduled for completion and certification of stations on December 31, 2015, projecting January 1, 2016 through December 31, 2016 as Operating Year 1, and January 1, 2017 through December 31, 2017 as Operating Year 2.

2. On June 30, 2014, BMA of North Charlotte was providing dialysis treatment for 124 in-center patients, 122 of whom were residents of Mecklenburg County.
3. BMA of North Charlotte assumes the Mecklenburg County ESRD in-center patient population utilizing the facility will increase at 7.1% per year. On page 31, the applicant states,

*“BMA assumes that the dialysis patient population utilizing BMA North Charlotte are a part of the Mecklenburg County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Mecklenburg County Five Year Average Annual Change Rate as published in the July 2014 SDR. That rate is 7.1% annual. Within CON Project I.D. #F-10091-13 and again in CON Project I.D. #F-10249-14 BMA projected that four patients dialyzing at BMA North Charlotte would change to home dialysis each year. BMA maintains that projection within this application. However, those four patients will now be referred to the BMA Charlotte facility on Baxter Street in Charlotte. BMA North Charlotte is also providing dialysis treatment for two patients who are not residents of Mecklenburg County. BMA assumes those patients are dialyzing at BMA North Charlotte by way of patient choice. BMA assumes these two patients will continue to dialyze at the BMA North Charlotte facility, but will not demonstrate any growth in this segment of the facility census. Rather, these two patients are added to the census at appropriate points in time.”*

Even without any growth, the current number of in-center patients demonstrates a need for at least 38 stations [ $124 / 3.2 = 38.75$ ]. Upon completion of this proposal and the previously approved projects, the facility will have only 36 stations.

#### Projected Utilization

In Section II, page 14 and Section III, page 32, the applicant provides the calculations used to arrive at the projected patient census for Operating Year One (2016) and Operating Year Two (2017). However, the project analyst determined that the numerical data provided by the applicant in those sections was inconsistent. Specifically, the applicant erroneously began its census with 124 Mecklenburg County patients instead of 122 Mecklenburg County patients, as stated in Section IV.1, page 36. In response to a request for clarification, the applicant confirmed that the following table correctly reflects the assumptions and methodology used to project the future patient population at BMA of North Charlotte.

	In-Center
BMA begins with facility census of Mecklenburg County patients as of June 30, 2014.	122
BMA projects growth of the census by the Mecklenburg County Five Year Average Annual Change Rate (AACR) for six months to December 31, 2014.	$[(122 \times (.071 / 12 \times 6))] + 122 = 126.3$
BMA projects growth of the census by the Mecklenburg County Five Year AACR for one year to December 31, 2015	$(126.3 \times 0.071) + 126.3 = 135.3$
In Project I.D. #F-10091-13 BMA projected four patients to change to home dialysis. These are subtracted from the projected census at this point. The patients are referred to BMA Charlotte.	$135.3 - 4 = 131.3$
BMA adds the two patients from other counties. This is the projected beginning census for this project, <b>December 31, 2015.</b>	$131.3 + 2 = 133.3$
BMA again projects growth of the Mecklenburg County patients by the Mecklenburg County Five Year AACR for one year.	$(131.3 \times 0.071) + 131.3 = 140.6$
In Project I.D. #F-10091-13 BMA projected four patients to change to home dialysis. These are subtracted from the projected census at this point.	$140.6 - 4 = 136.6$
BMA adds the two patients from other counties. This is the projected ending census for Operating Year 1, <b>December 31, 2016.</b>	$136.6 + 2 = 138.6$
BMA again projects growth of the Mecklenburg County patients by the Mecklenburg County Five Year AACR for one year.	$(136.6 \times 0.071) + 136.6 = 146.3$
In Project I.D. #F-10091-13 BMA projected four patients to change to home dialysis. These are subtracted from the projected census at this point.	$146.3 - 4 = 142.3$
BMA adds the two patients from other counties. This is the projected ending census for Operating Year 2, <b>December 31, 2017.</b>	$142.3 + 2 = 144.3$

At the end of Operating Year One, BMA of North Charlotte is projecting a patient census of 138 in-center patients, for a utilization rate of 95.8% or 3.8 patients per station ( $138 / 36 = 3.8$ ). At the end of Operating Year Two, BMA of North Charlotte is projecting a patient census of 144 in-center patients, for a utilization rate of 100% or 4.0 patients per station ( $144 / 36 = 4.0$ ).

Projected patient in-center utilization at the end of Operating Year One is 3.8 in-center patients per station per week which exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

In Section VI.1(a), page 44, the applicant states,

*“It is clear that BMA provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”*

On page 44, the applicant states that the patient population of BMA of North Charlotte is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
BMA of North Charlotte	11.4%	53.8%	84.8%	30.3%	88.6%

Note: The Medicare percentage represents the percentage of patients receiving some type of Medicare benefit, not the percentage of facility treatment reimbursement. The above percentages are not meant to total to 100% of facility utilization.

On pages 45 and 64, the applicant projects that 83.7% of its patients will be covered by some form of Medicare or Medicaid. The applicant adequately demonstrates 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.

**Conclusion**

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional stations at BMA of North Charlotte, 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.

CA

In Section III.9, pages 34-35, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states utilization at BMA facilities in the area is up from 87.56% to 91.92% in a six month period. All BMA facilities utilization has increased as of June 30, 2014, with the exception of BMA of East Charlotte. According to the July 2014, BMA of North Charlotte is at a 110% utilization (119 patients / 27 certified stations = 4.41;  $4.41 / 4 = 1.10$ , or 110%). The applicant states that failure to expand the facility potentially denies patients a choice of dialysis at BMA of North Charlotte. The facility is also projected to exceed 80% utilization by the end of the first operating year for the proposed project, thus the applicant rejected this alternative.
- 2) The applicant could have applied for fewer stations, but rejected this alternative because it would not meet the growing demand for dialysis services at BMA of North Charlotte.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the BMA of North Charlotte proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall materially comply with all representations made in the certificate of need application.**
2. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall develop and operate no more than four additional dialysis stations for a total of no more than 36 certified stations upon completion of this project, which shall include any isolation stations.**
3. **Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 36 dialysis stations, which shall include any isolation stations.**

- 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of North Charlotte shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 53, the applicant projects a capital cost of \$235,400 for the proposed project, funded through accumulated reserves. In Section IX, page 59, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 24 includes a letter dated September 15, 2014 from the Vice President of Fresenius Medical Care Holdings, Inc., which states:

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

*BMA is submitting a Certificate of Need Application to add four dialysis stations to the BMA North Charlotte facility in Mecklenburg County. ... As Vice President, I am authorized and do hereby authorize the addition of four dialysis stations for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$235,400 as may be needed for this project."*

In Exhibit 4, the applicant provides the audited financial statements for FMC and Subsidiaries for the years ended December 31, 2012 and 2013. As of December 31, 2013, FMC and Subsidiaries had cash and cash equivalents totaling \$275.7 million with \$16.6 billion in total assets and \$8.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 60, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
Private Pay	\$1,425.00
Commercial	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
VA	\$231.12
Medicare / Medicaid	\$239.00
Medicare / Commercial	\$239.00
State Kidney Program	\$100.00
Self/Indigent	\$1,425.00

The applicant states the commercial charge listed does not reflect actual reimbursement.

In Section X.2, page 62 and X.4, page 67, the applicant reported projected revenues and expenses as follows:

BMA North Charlotte		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$7,946,760	\$8,124,031
Total Operating Costs	\$6,142,373	\$6,298,042
Net Profit	\$1,804,387	\$1,825,990

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X of the application for the applicant’s assumptions.

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

C

BMA North Charlotte proposes to add four in-center dialysis stations for a total of 36 dialysis stations upon completion of this project, Project I.D. #F-10249-14 and Project I.D. #F-10091-13. The applicant operates eight of the 17 dialysis facilities in Mecklenburg County. DaVita, Total Renal Care (TRC) and Carolinas Medical Center (CMC) are the other providers of dialysis services in Mecklenburg County, as shown in the table below.

**Mecklenburg County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/13</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA Beatties Ford (BMA)	32	84.38%	3.4
BMA Nations Ford (BMA)	24	108.33%	4.3
BMA East Charlotte (BMA)	24	78.13%	3.1
BMA North Charlotte (BMA)	27	110.19%	4.4
BMA West Charlotte (BMA)	29	68.97%	2.8
Carolinas Medical Center (CMC)	9	55.56%	2.2
Charlotte Dialysis (DaVita)	34	84.56%	3.4
Charlotte East Dialysis (DaVita)	24	73.96%	3.0
DSI Charlotte Latrobe (TRC)	24	65.63%	2.6
DSI Glenwater (TRC)	42	67.86%	2.7
FMC Charlotte (BMA)	40	80.63%	3.2
FMC Matthews (BMA)	21	89.29%	3.6
FMC Southwest Charlotte (BMA)*	0	0.00%	0.0
Huntersville Dialysis (DaVita)*	0	0.00%	0.0
Mint Hill Dialysis (DaVita)	10	82.50%	3.3
North Charlotte Dialysis (DaVita)	35	82.14%	3.3
South Charlotte Dialysis (DaVita)	20	82.50%	3.3

Source: July 2014 SDR, Table A.

\*New Site, no data reported

As shown in the table above, nine of the seventeen Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), two of the seventeen facilities are operating at or above 70% utilization (3.0 patients per station), three of the seventeen facilities are operating below 70% utilization and two of the seventeen facilities were not operational at the time of this report.

BMA of North Charlotte was serving 119 patients weekly on 27 certified stations, which is 4.41 patients per station or 110% of capacity, as of December 31, 2013. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve. The growth projections are based on a projected 7.1% average annual change rate in the number of dialysis patients at the BMA of North Charlotte facility. At the end of Operating Year Two, BMA North Charlotte projects the utilization will be 4.0 in-center patients per station (144 patients / 36 dialysis stations = 4.0), which is 100% of capacity.

The applicant adequately demonstrates the need to develop four additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of

existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

The following table shows current and projected staffing for BMA of North Charlotte, as provided by the applicant in Section VII.1, page 49:

<b>BMA North Charlotte</b>			
<b>Position</b>	<b>Current FTEs</b>	<b># of FTE Positions to be Added</b>	<b>Total FTE Positions</b>
RN	7.00	1.00	8.00
Tech.	14.00	2.00	16.00
Clinical Manager	1.00	0.00	1.00
Medical Director	Contracted Position		
Admin. (FMC Dir. Ops.)	0.15	0.00	0.15
Dietician	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Chief Tech.	0.25	0.00	0.25
Equipment Tech.	1.00	0.00	1.00
In-Service	0.25	0.00	0.25
Clerical	1.00	0.50	1.50
<b>Total</b>	<b>26.65</b>	<b>3.50</b>	<b>30.15</b>

As shown in the above table, the applicant proposes to employ a total of 30.15 full-time equivalent (FTE) positions to staff BMA of North Charlotte upon completion of the proposed project. In Section V.4, page 40, the applicant states that Daniel Tierney, M.D., a nephrologist with Metrolina Nephrology Associates, will serve as medical director of the facility. Exhibit 21 contains a letter from Dr. Tierney stating his intention to continue as the medical director for BMA of North Charlotte.

The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including the medical director, for the provision of the proposed dialysis services. 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 38, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 21 contains a letter from the medical director of the facility expressing his support for the proposed project, and Exhibit 22 contains a letter of support for the project signed by existing patients of the facility. 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(b), page 45, the applicant reports that 83.7% of the in-center patients who received treatments at BMA of North Charlotte had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment source of the facility:

<b>BMA of North Charlotte In-Center Patients</b>	
Source of Payment	Percentage
Private Pay	0.00%
Commercial Insurance	12.32%
Medicare	70.38%
Medicaid	6.31%
VA	3.36%
Medicare/Medicaid	0.00%
Medicare/Commercial	7.04%
State Kidney Program	0.00%
Self/Indigent	0.60%
<b>Total</b>	<b>100.00%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Mecklenburg County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>CY2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Mecklenburg County	15%	5.1%	20.1%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the 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, women or handicapped persons utilizing health services.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*<sup>2</sup> (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

<sup>1</sup><http://www.esrdnetwork6.org/utlils/pdf/annualreport/2013%20Network%206%20Annual%20Report.pdf>

<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

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

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

<b>ESRD SPENDING BY PAYOR*</b>		
<b>PAYOR</b>	<b>SPENDING IN BILLIONS</b>	<b>% OF TOTAL SPENDING</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>TOTAL</b>	<b>\$49.2</b>	<b>100.0%</b>

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

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;

<sup>3</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

C

In Section VI.1(f), page 46, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”*

In Section VI.6 (a), page 47, the applicant states there have been no patient civil rights access complaints filed within the last five years. Therefore, 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 45, the applicant provides the projected payor mix for the proposed services at BMA of North Charlotte, which is shown below:

<b>BMA of North Charlotte In-Center Patients</b>	
<b>Source of Payment</b>	<b>Percentage</b>
Private Pay	0.00%
Commercial Insurance	12.32%
Medicare	70.38%
Medicaid	6.31%
VA	3.36%
Medicare/Medicaid	0.00%
Medicare/Commercial	7.04%
State Kidney Program	0.00%
Self/Indigent	0.60%
<b>Total</b>	<b>100.00%</b>

The applicant projects no change from the current payor mix for in-center dialysis services, which is 83.7% Medicare and Medicaid. 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, page 47, the applicant states,

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

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

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

C

In Section V.3, page 39 the applicant states,

*“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.”*

Exhibit 19 contains a letter from the applicant to Carolinas College of Health Services inviting the school to include the facility in its clinical rotations for nursing students. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact

upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA of North Charlotte proposes to add four dialysis stations to the existing facility for a total of 36 stations upon completion of this project, Project I.D. #F-10249-14 and Project I.D. #F-10091-13. The applicant operates eight of the 17 dialysis facilities in Mecklenburg County. DaVita, Total Renal Care (TRC) and Carolinas Medical Center (CMC) are the other providers of dialysis services in Mecklenburg County, as shown in the table below.

**Mecklenburg County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/13</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
BMA Beatties Ford (BMA)	32	84.38%	3.4
BMA Nations Ford (BMA)	24	108.33%	4.3
BMA of East Charlotte (BMA)	24	78.13%	3.1
BMA of North Charlotte (BMA)	27	110.19%	4.4
BMA of West Charlotte (BMA)	29	68.97%	2.8
Carolinas Medical Center (CMC)	9	55.56%	2.2
Charlotte Dialysis (DaVita)	34	84.56%	3.4
Charlotte East Dialysis (DaVita)	24	73.96%	3.0
DSI Charlotte Latrobe (TRC)	24	65.63%	2.6
DSI Glenwater (TRC)	42	67.86%	2.7
FMC Charlotte (BMA)	40	80.63%	3.2
FMC Matthews (BMA)	21	89.29%	3.6
FMC Southwest Charlotte (BMA)*	0	0.00%	0.0
Huntersville Dialysis (DaVita)*	0	0.00%	0.0
Mint Hill Dialysis (DaVita)	10	82.50%	3.3
North Charlotte Dialysis (DaVita)	35	82.14%	3.3
South Charlotte Dialysis (DaVita)	20	82.50%	3.3

Source: July 2014 SDR, Table A.

\*New Site, no data reported

As shown in the table above, nine of the seventeen Mecklenburg County dialysis facilities are operating above 80% utilization (3.2 patients per station), two of the seventeen facilities are operating at or above 70% utilization (3.0 patients per station), three of the seventeen facilities are operating below 70% utilization and two of the seventeen facilities were not operational at the time of this report.

In Section V.7, page 43, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states,

*“BMA does not expect this proposal to have effect on the competitive climate in Mecklenburg County. According to the July 2014 SDR there were 17 dialysis facilities operating (or planned) within Mecklenburg County. These facilities offer 446 dialysis stations to the more than 1,400 ESRD patients of Mecklenburg County. BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who choose dialysis at a BMA facility.*

*This facility also has added value stemming from the strength of our relationship with Metrolina Nephrology Associates. Metrolina Nephrology Associates is a premier group of nephrologists practicing across south central North Carolina. As evidence by the physician letters of support, the practice brings together the collaborative efforts of 29 very qualified nephrologists to provide care for the patients choosing to dialyze at BMA North Charlotte.*

*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 79% of the In-center patients will be relying upon government payors. The facility must capitalize upon every opportunity for efficiency.*

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility is no different.*

*This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives.”*

See also 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 any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to add three dialysis stations at the BMA of North Charlotte facility and that it is a cost-effective alternative. The discussion regarding analysis of need and alternatives found in Criteria (3) and (4) respectively is incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA of North Charlotte operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
  - (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable regulatory review criteria. The specific criteria are discussed below:

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

*.2202(a)(1) Utilization rates;*

)

-C- See Section III.1, page 29, which indicates the facility had a 110% utilization rate as of December 31, 2013.

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

)

-C- In Section IV.2, page 36, the applicant reports 2011, 2012 and 2013 facility mortality rates of 4.8%, 13.4% and 9.5%, respectively.

*.2202(a)(3) The number of patients that are home trained and the number of patients on Home dialysis;*

)

-NA- In Section IV.3, page 36, the applicant states that BMA of North Charlotte does not operate a home dialysis program. Patients who are candidates for home dialysis are referred to BMA Charlotte.

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

)

-C- In Section IV.4, page 36, the applicant states BMA of North Charlotte referred five patients for transplant evaluation in 2013, and had one patient receive a transplant in 2013.

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

)

-C- In Section IV.5, page 36, the applicant states that BMA of North Charlotte has two patients on the transplant 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 37, the applicant reports a total of 146 hospital admissions in 2013; 136 were non-dialysis related and 10 were dialysis-related.

.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 37, the applicant reports that in 2013 there were no patients with an infectious disease, and no patients converted to infectious status in 2013.

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

.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 of North Charlotte 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 of North Charlotte 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 of North Charlotte 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- Exhibit 12 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

.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 of North Charlotte 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, water supply, and other relevant health and safety requirements.*

-C- See Sections II.1, page 13; VII.2, page 50 and XI.6(g), page 73. The applicant states, “BMA of North Carolina provides and will continue to provide to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements.”

.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- The applicant projected patient origin based on historical experience for the first two years of operation following completion of the project, as shown below.

**Projected Patient Origin**

County	Year 1 CY2016	Year 2 CY2017	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Mecklenburg	136.6	142.3	98.6%	98.6%
Cabarrus	1.0	1.0	0.7%	0.7%
York, SC	1.0	1.0	0.7%	0.7%
<b>Total</b>	138.6	144.3	100.0%	100.0%

.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 of North Charlotte 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 for such services.*
- C- *In Section II.1, page 16, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- BMA North Charlotte is an existing facility.
- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- The applicant projects to serve 138 in-center patients by the end of Operating Year 1, which is 3.8 patients per station ( $138 / 36 = 3.8$ ). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

## 10 NCAC 14C .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- These services are provided by Carolinas Medical Center. See Section V.1, page 38 and Exhibit 25.

.2204(2) *Maintenance dialysis;*

-C- Provided at BMA of North Charlotte. See Section V.1, page 38.

.2204(3) *Accessible self-care training;*

-C- Provided by referral to BMA Charlotte. See Section V.2(d), page 39 and Exhibit 20.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- Provided by referral to BMA Charlotte. See Section V.2(d), page 39 and Exhibit 20.

.2204(5) *X-ray services;*

-C- Provided by Carolinas Medical Center. See Section V.1, page 38 and Exhibit 25.

.2204(6) *Laboratory services;*

-C- Provided by SPECTRA Laboratories, Inc. See Section V.1, page 38, and Exhibit 15.

.2204(7) *Blood bank services;*

-C- Provided by Carolinas Medical Center. See Section V.1, page 38 and Exhibit 25.

.2204(8) *Emergency care;*

-C- Provided by BMA of North Charlotte facility staff and the hospitals. See Section V.1, page 38 and Exhibit 25.

.2204(9) *Acute dialysis in an acute care setting;*

- C- Provided by Carolinas Medical Center. See Section V.1, page 38 and Exhibit 25.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- Provided by Carolinas Medical Center, Sanger Heart and Vascular and MNA Vascular Access Center. See Section V.1, page 38.
- .2204(11) *Transplantation services;*
- C- Provided by Carolinas Medical Center. See Section V.1, page 38 and Exhibit 26.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- Provided by referral to NC Division of Vocational Rehabilitation Services. See Section V.1, page 38.
- .2204(13) *Transportation*
- C- Provided by Charlotte Area Transportation (CATS), A-1 Wheelchair Transport or area taxi services. See Section V.1, page 38.

#### **10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section VII.1, page 49, the applicant provides the proposed staffing. In Section VII.2, page 50, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.
- .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 50, and Exhibits 9 and 10 for a outline of training and continuing education programs.