

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 18, 2014

PROJECT ANALYST: Tanya S. Rupp

TEAM LEADER: Lisa J. Pittman

PROJECT I.D. NUMBER: H-10250-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County / Add three dialysis stations to existing facility for a facility total of 13 stations upon project completion / Anson 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. (BMA) d/b/a FMC Anson County, whose parent company is Fresenius Medical Care Holdings Inc., (FMC), proposes to add three dialysis stations to its existing facility for a total of 13 certified dialysis stations upon project completion. 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 *Table B: Dialysis Station Need Determination by County, in the January 2014 Semiannual Dialysis Report (SDR)*, there is a surplus of one dialysis station in Anson County. 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 FMC Anson County in the January 2014 SDR is 3.4 patients per station, or 85.0%. This utilization rate was calculated based on 34 in-center dialysis patients and 10 certified dialysis stations (34 patients / 10 stations = 3.4 patients per station.  $3.4 / 4 = 0.850$ ).

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

**APRIL 1 REVIEW-JANUARY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		85.0%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 6/30/13 (SDR2)		34
In-Center Patients as of 12/31/12 (SDR1)		28
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.4286
(ii)	Divide the result of step (i) by 12	0.0357
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.2143
(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	41.2857
(v)	Divide the result of step (iv) by 3.2 patients per station	12.9018
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed at FMC Anson County is three 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, on 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.”*

### Promote Safety and Quality

In Section I.13, pages 4 - 8, the applicant describes its corporate structure and how that structure contributes to the provision of quality dialysis services, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments as discussed below:

- Clinical Services Department
  - Serves as a clinical resource for the entire FMC network
  - Provides facilities with the best procedures and equipment available
  - Assists facility managers and medical personnel with questions and concerns on clinical operations
  - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program
  
- Technical Services Department
  - Oversees the technical and mechanical aspects of dialysis
  - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
  
- Regulatory Affairs and Law Departments
  - Deals with legal and regulatory issues
  - Provides interpretation of legislation and government policy to ensure compliance
  
- Other Management Resources, including but not limited to:
  - Health, Safety and Risk Management - provides safety and risk management services to each facility
  - Research – The Renal Research Institute involves dialysis facilities with strong ties to academic research institutions to ensure that all BMA dialysis facilities utilize the latest technology to deliver quality dialysis services to its patients.
  - Regional Vice Presidents – provide operational direction and monitoring of daily operations

In addition, in Section II.1, on pages 23 - 24, the applicant describes the programs currently in place for staff training and orientation, such as a 10-week training program for each new employee, followed by continuous updates. The applicant states staff members are trained in all clinical aspects of their job, facility and corporate policies and procedures, safety precautions, regulations, and CPR. The applicant further states that training is continually updated by the In-Service Instructor and Director of Nursing.

Additionally, in Exhibit 8, the applicant provides a copy of Fresenius Medical Care's (FMC) corporate *Quality Assessment and Performance Improvement for FMS Inpatient Services Programs*, which details FMC's procedures regarding safety and quality in its dialysis facilities. In Section II.3, on pages 30 – 33, the applicant describes additional measures

which are corporately mandated for all BMA facilities to ensure the provision of quality services in its dialysis facilities.

In Section V.7, page 49, the applicant states that all BMA facilities continue to find ways to contain operating costs while providing quality care to its patients. The applicant further states that the proposed project will not adversely affect quality, but will enhance the quality of life for ESRD patients in Anson County.

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

Promote Equitable Access

In Section II.1, page 25, the applicant states:

*“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that 80% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. Thus 80% of the In-Center revenue is derived from government payors.*

...

*BMA is also keenly sensitive to the second element of ‘equitable access’ – time and distance barriers. At this time, Anson County has one [sic] operational dialysis facility. As the dialysis patient population of Anson County continues to increase, the need for dialysis stations will continue to increase. BMA will apply to develop new dialysis facilities when needed. In this case, BMA is applying for two [sic] additional stations to meet a growing need in Anson County.”*

In addition, in Section VI.1, on page 50, the applicant states that BMA has a long history of providing dialysis services to the underserved populations in North Carolina. The applicant states that in North Carolina BMA facilities in FY 2013, Medicare represented 83.97% of dialysis treatments, and Medicaid represented an additional 4.82% of treatments.

The applicant provides a table to illustrate the payor mix of FMC Anson County, as shown below:

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Anson County	5.9%	23.5%	85.3%	64.7%	91.2%

The applicant adequately demonstrates that the proposal will promote equitable access to dialysis services in Anson County.

Maximize Healthcare Value

In Section II.1, on page 25, the applicant states:

*“BMA is projecting a capital expenditure of only \$8,250 for this project. BMA is not seeking State or Federal monies to develop the CON application or the additional dialysis stations at the facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to bring dialysis treatment close 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 80% of the treatments are covered by Medicare and Medicaid. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis. BMA does.*

The applicant adequately demonstrates that the proposal will maximize healthcare value.

Consequently, the applicant demonstrates that the proposed services incorporate *Policy GEN-3: Basic Principles* in meeting the needs of the patients to be served. The application is also consistent with the facility need determination in the 2014 SMFP. 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, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County, proposes to add three dialysis stations, pursuant to the Facility Need Methodology in the 2014 SMFP. Upon project completion, FMC Anson County will have 13 certified dialysis stations.

#### Population to be Served

In Section IV.2, on page 42, the applicant identifies the population currently served at FMC Anson County, as illustrated in the following table:

COUNTY OF RESIDENCE	# IN-CENTER PTS.	% OF TOTAL
Anson	33	97.06%

Chesterfield, SC	1	2.94%
<b>Total</b>	<b>34</b>	<b>100.0%</b>

In addition, in Section III.7, on page 39, the applicant provides a table to illustrate the population to be served following the addition of three dialysis stations, as shown below:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PTS. AS % OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Anson	41.2	1	43.2	2	97.69%	97.84%
Chesterfield, SC	1.0	0	1.0	0	2.31%	2.16%
<b>Total</b>	<b>42.2</b>	<b>1</b>	<b>44.2</b>	<b>2</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve following the addition of three dialysis stations.

Demonstration of Need

In Section III.2, on page 34, the applicant states the application is filed pursuant to the Facility Need Methodology in the 2014 SMFP.

In Section III.7, pages 36 - 38, the applicant provides the following assumptions for the proposed project:

“1. The January 2014 SDR reports that FMC Anson County was operating at 85.0% utilization with a census of 34 in-center patients dialyzing on 10 certified dialysis stations as of June 30, 2013.

2. This project is scheduled to be completed December 31, 2015.

*Operating Year 1 is the period from January 1, 2015 [sic] - December 31, 2016. Operating Year 2 is the period from January 1, 2016 [sic]- December 31, 2017.*

3. BMA does not assume that the patient population of FMC Anson County will increase at a rate commensurate with the Anson County Five Year Average Annual Change Rate as published in the January 2014 SDR. The Anson County growth rate is 2.9%.

4. As BMA has evaluated the growth of the FMC Anson County facility, BMA notes that the January 2013 SDR was not based upon actual numbers, but rather was based upon a calculated projection of probable census. Note the following from the cover letter to the January 2013 SDR:

*‘Following the release of the January 2013 North Carolina Semiannual Dialysis Report (SDR), it had come to our attention that data contained in Tables A and B of the report may not have been reflected accurately.*

*Tables A and B were reviewed and have been revised to correct any errors. The revised data now reflects the interim measure of using historical patterns to project a three year trend line to provide an average for in-center and in-home dialysis patients, as approved by the State Health Coordinating Council (SHCC).'*

*As BMA conducted its evaluation for this application, it appears that the census reported for FMC Anson County, in the January 2013 SDR was indeed erroneous. BMA notes that the July 2013 SDR (Exhibit 31), which was based upon information provided to the DHSR / Medical Facilities Planning Section, reports a census of only 28 patients at FMC Anson County as of December 31, 2012. BMA internal records do not reflect such a varied increase/decrease in the patient population of FMC Anson County.*

*5. The Facility Need Methodology calculations indicate that the facility is increasing at a rate of 42.9% (see III.2, Facility Need Methodology). This rate of growth is nearly 150% percent of the facility average since opening. Despite this demonstrated growth rate, BMA does not project the facility to continue such growth and will necessarily utilize a modest 7.27% growth factor.*

*6. BMA assumes the facility census will increase at a rate of 7.27%. This rate is based upon a [sic] average of the FMC Anson County facility census, since it has opened. The facility was certified in 2011 and first appeared with a census in the January 2011 SDR. The first reported census was for June 30, 2010 and was 17 patients.*

*BMA has calculated a growth rate for the facility in a manner similar to the methodology employed by the Medical Facilities Planning Section as in Table B of the SDR.*

<b>SDR DATA</b>	<b>JAN - 10</b>	<b>JAN - 11</b>	<b>JAN - 12</b>	<b>JAN - 13</b>	<b>JAN - 14</b>	<b>AVG. % CHANGE</b>
<i>FMC Anson Co.</i>	0	17	24	37	34	
<i>Raw Change</i>	--	17	7	13	-3	
<i>Annual % Change</i>	--	--	41.18%	54.17%	-8.11%	29.08%

*BMA does not suggest that the growth rate of 29.08% is sustainable. However, BMA does believe it is appropriate to utilize a growth rate greater than the Anson County Five Year Average Annual Change Rate as published in the January 2014 SDR. That growth rate is only 2.9%. Clearly, the Facility Need Methodology and the average of the facility growth since opening are far greater than 2.9%.*

*BMA will utilize a rate of one-fourth, or 25% of the calculated Average % of Change. BMA has calculated a growth rate of 7.26959, rounded to 7.27%.*

*7. FMC Anson County was serving 33 Anson County residents, and one patient from Chesterfield, S.C. as of June 30, 2013. BMA will project the one patient from*

*Chesterfield to continue dialysis at FMC Anson County as a function of patient choice. All other future patients are projected to be residents of Anson County.*

8. *BMA is also projecting to serve home training patients at the facility. BMA will project a modest change in the patient population of the facility and projects one patient in Operating Year 1 to change to home peritoneal dialysis. BMA further projects one patient in Operating Year 2 will change to home hemodialysis.”*

The applicant projects future patient population of FMC Anson County by applying a growth rate that differs from the Five Year Average Annual Change Rate (AACR) published in the January 2014 SDR. FMC Anson County was certified in December 2009. The patient census reported in the July 2010 SDR was 11, and the patient census in the January 2011 SDR, one year after certification, was 17 patients. The patient census in the January 2014 SDR was 34, which is double the patient census at the end of year one following certification of stations. The applicant calculated the average growth in patient population as 29.08% as shown above, and states it will utilize a 7.27% growth rate to project future patient population. It is reasonable and supported for the applicant to use a growth rate that equates to roughly one-quarter of the past rate of growth of that facility, even though it is higher than the Five Year AACR published in the January 2014 SDR.

In addition, the applicant only projects growth in the patient population residing in Anson County, and then adds to that growth the one patient from South Carolina in each of years one and two. The applicant could have projected growth of the entire facility census, including the one patient from South Carolina. Thus the growth projections are reasonable because they grow a population that is less than the actual facility census.

In Section III.2, on page 39, the applicant provides a table to illustrate projected patient growth at FMC Anson County following the addition of three dialysis stations, as shown below:

FMC Anson County Census as of 6/30/13	33
Apply BMA calculated AACR for one year to 6/30/14	$33 \times 1.0727 = 35.4$
Apply BMA calculated AACR for one year to 6/30/15	$35.4 \times 1.0727 = 38.0$
Apply one-half BMA calculated AACR for six months to 12/31/15	$38 \times 1.0363 = 39.4$
Add one patient from Chesterfield, SC*	$39.4 + 1 = 40.4$
Apply BMA calculated AACR for one year to 12/31/16	$39.4 \times 1.0727 = 42.2$



Subtract one Anson Count patient projected to switch to home dialysis	$42.2 - 1 = 41.2$
Add one patient from Chesterfield, SC <sup>^</sup>	$41.2 + 1 = 42.2$
Apply BMA calculated AACR for one year to 12/31/17	$41.2 \times 1.0727 = 44.2$
Subtract one Anson Count patient projected to switch to home dialysis	$44.2 - 1 = 43.2$
Add one patient from Chesterfield, SC <sup>**</sup>	$43.2 + 1 = 44.2$

\*The applicant states on page 39 that this is the beginning census for the facility

<sup>^</sup>The applicant states on page 39 that this is the ending census for Operating Year 1

<sup>\*\*</sup>The applicant states on page 39 that this is the ending census for Operating Year 2

Therefore, at the end of Operating Year 1, the applicant projects to serve 42.2 in-center dialysis patients on 13 certified dialysis stations, or 3.23 patients per station, which is a utilization rate of 80.77% [ $42 / 13 = 3.23$ .  $3.23 / 4 = 0.8077$ ]. At the end of Operating Year Two, the applicant projects to serve 44 in-center patients on 13 certified dialysis stations, or 3.4 patients per station, which is a utilization rate of 85% [ $44 / 13 = 3.38$ .  $3.38 \ / \ 4 = 0.846$ ]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth at FMC Anson County.

#### Access to Services

In Section VI.1, pages 50 - 51, the applicant states that Fresenius Medical Care Holdings, Inc., the parent company of BMS, currently operates 100 facilities in 42 North Carolina Counties. The applicant states each facility has a population which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 86.2% of its patients will be covered by Medicare and Medicaid, based on the current payor mix at FMC Anson County. The applicant adequately demonstrates the need this population has for the dialysis 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.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for three additional stations and the extent to which all residents of the area are likely to have access to the dialysis services proposed at FMC Anson County. 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.

- (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, page 41, the applicant describes the alternatives considered by FMC Anson County prior to the submission of this application, which include:

- 1) Apply for fewer stations – the applicant states this option seems to ignore the growing patient census at FMC Anson County, and the fact that the Facility Need Methodology calculated a 42.9% growth rate at the facility. Therefore, this alternative was not a suitable option.
- 2) Do nothing – the applicant states this alternative will eventually remove choice for patient options in Anson County. The growth rate at the facility seems likely to continue, and the utilization is projected to be over 80%. BMA demonstrated a need for three additional stations at FMC Anson County.
- 3) Add three stations. BMA chose this alternative as most effective and least costly to meet the needs of the patients currently receiving treatment and projected to receive treatment at FMC Anson County.

The applicant adequately demonstrates the need for three additional stations based on the continued growth of the ESRD patient population in Anson County and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County, shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County, shall develop and operate no more than three additional stations for a total of 13 certified stations following completion of this project.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County, shall install plumbing and electrical wiring through the walls for no more than three additional stations for a total of no more than 13 stations, which shall include any home hemodialysis or isolation stations.**



Medicare	\$239.00
Medicaid	\$137.29
VA	\$146.79
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
Other: Self/Indigent	\$1,425.00

The applicant states that the commercial charge listed does not reflect actual reimbursement. In addition, the applicant states that BMA has “*opted in*” completely to Medicare’s “*bundling*” reimbursement program, which provides one basic fee per dialysis treatment, which the applicant states on page 65 is “*approximately \$240 per treatment.*” This fee “*bundles,*” or includes all ancillary services which were previously billed separately.

The applicant projects revenues in Section X.2 and operating expenses in Section X.4 of the application. In Sections X.2 - X.4, pages 66 - 75, the applicant projects revenues and expenses for FMC Anson County as follows:

FMC ANSON COUNTY		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$2,130,191	\$2,273,135
Total Operating Costs	\$1,886,598	\$1,992,667
<b>Net Profit</b>	<b>\$ 243,593</b>	<b>\$ 280,468</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, page 68, for the applicant’s assumptions regarding in-center revenue, and Section X, page 70, for the applicant’s assumptions with regard to home revenue.

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County proposes to add three dialysis stations to its existing facility for a total of 13 stations upon project completion. The January 2014 SDR identifies two dialysis facilities in Anson County: FMC Anson County and Dialysis Care of Anson County, operated by DaVita, Inc. As of June 30, 2013, the reporting date for the January 2013 SDR, Dialysis Care of Anson County was dialyzing

32 in-center patients on 15 certified stations, which is a utilization of 53.33% [ $32 / 15 = 2.13$ ;  $2.13 / 4 = 0.533$ ].

The January 2014 SDR, Table B, shows there is a surplus of one dialysis station in Anson County; however, in this application, the applicant is applying for additional stations based on the facility need methodology. The applicant adequately demonstrates the need for three additional stations at FMC Anson County based on the number of in-center patients projected to be served. As reported in the January 2014 SDR, as of June 30, 2013, the 10 station FMC Anson County facility was operating at 85.0% capacity, with 34 in-center patients ( $34 / 10 = 3.4$ ;  $3.4 / 4 = 0.85$  or 85.0%). The target utilization for dialysis stations, pursuant to 10A NCAC 14C §.2203(b), is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 13 stations serving up to 42 patients at the end of Year 1, which is a utilization rate of 81% ( $42 / 13 = 3.23$ ;  $3.23 / 4 = 0.8077$  or 81%). Therefore, the applicant is conforming to the requirement in 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Anson County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 56, the applicant provides projected staffing for FMC Anson County upon project completion, as illustrated in the following table:

<b>FMC ANSON COUNTY FULL-TIME EQUIVALENT (FTE) POSITIONS</b>			
	<b>CURRENT</b>	<b>ADD</b>	<b>TOTAL</b>
RN	1.50	0.50	2.00
Tech	4.00	1.00	5.00
Clinical Manager (DON)	1.00	-	1.00
FMC Director of Operations	0.15	-	0.15
Dietician	0.40	-	0.40

Social Worker	0.40	-	0.40
Home Training Nurse	0.00	0.33	0.33
Chief Tech	0.10	-	0.10
Equip Tech	0.40	-	0.40
In-Service	0.15	-	0.15
Clerical	0.80	-	0.80
<b>Total FTEs</b>	<b>8.90</b>	<b>1.83</b>	<b>10.73</b>

The applicant projects a total of 10.73 FTE positions upon project completion. In Section VII.4, on page 57, the applicant states it anticipates no difficulty recruiting additional staff for the facility. In Section V.4(b), on page 46, the applicant states the current Medical Director for FMC Anson County is Andrew O'Connor, MD. In Exhibit 21 the applicant provides a February 3, 2014 letter of support from Dr. O'Connor which also indicates his willingness to continue to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 a table in Section V.1, on page 44, the applicant identifies the providers of the necessary ancillary and support services for FMC Anson County. The applicant provides further detail of the ancillary and support services in Section V, on pages 45 – 49. In Exhibits 19, 25, and 26 the applicant provides documentation to support the statements regarding the provision of necessary ancillary and support services. The applicant adequately demonstrates that necessary ancillary and support services are available and will continue to be available, and that the proposed services will be coordinated with the existing healthcare 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, page 50 the applicant states:

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. ... The patient population of the FMC Anson County facility is comprised of the following:”*

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Anson County	5.9%	23.5%	85.3%	64.7%	91.2%

The applicant states:

*“The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 85.3% of the facility treatment reimbursement is from Medicare.”*

In Section, VI.1, page 51, the applicant provides the current and projected payor mix for FMC Anson County. The applicant expects no change in the current payor mix once the three stations are added. The payor mix is illustrated in the following table.

FMC ANSON COUNTY CURRENT PAYOR MIX	
PAYOR SOURCE	IN-CENTER
Commercial Insurance	13.76%
Medicare	75.52%
Medicaid	4.52%
Medicare / Commercial	6.16%
Other: Self/Indigent	0.04%
Total	100.0%

On page 51, the applicant provides a table to show projected in-center and home dialysis reimbursements.

FMC ANSON COUNTY CURRENT PAYOR MIX		
PAYOR SOURCE	IN-CENTER	HOME
Commercial Insurance	13.76%	38.00%
Medicare	75.52%	54.60%
Medicaid	4.52%	1.90%
Medicare/Medicaid	0.00%	0.00%
Medicare / Commercial	6.16%	2.70%
VA	0.00	1.80%
Other: Self/Indigent	0.04%	1.00%
Total	100.0%	100.0%

Currently, FMC Anson County does not have home peritoneal dialysis or home hemo-dialysis trained patients; however, on page 51, the applicant states it projects to provide training to home dialysis patients following the addition of three stations. The applicant states:

*“BMA notes that the facility is approved for the provision of home dialysis training and support. However, the facility did not have any home trained patients in 2013.*

...

*BMA expects the percentage of home dialysis patients with commercial insurance to increase as more patients choose home dialysis. This expected change is not based upon specific historical data for the facility, but rather is a reflection of changes within the home dialysis patient population. ... while*



*the ESRD patient population of North Carolina continues to increase at a rate of approximately 3% annually, the home patient population is increasing at significantly higher rates.”*

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 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>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Anson County	23.3%	10.9%	22.3%
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 dialysis services offered by FMC Anson County. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina’s Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

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 or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*<sup>1</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

---

<sup>1</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 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 report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$45.5 billion, including Medicare Part D (p. 118).

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

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

\*Source: Southeastern Kidney Council (SKC) Network 6.

Table includes North Carolina statistics only.<sup>2</sup>

The 2012 United States Renal Data System (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%

<sup>2</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

<b>TOTAL</b>	<b>\$49.2</b>	<b>100.0%</b>
--------------	---------------	---------------

\*Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 327.

The applicant demonstrates that medically underserved populations have adequate access to the services provided at FMC Anson County. Therefore, the application is conforming to this criterion.

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

C

In Section VI.6(a), page 54, the applicant states there have been no civil rights access complaints filed against any North Carolina BMA facilities in 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 51, the applicant provides the projected payor mix for the proposed services at FMC Anson County, as shown in the table below. The applicant projects no change in the current payor mix for in-center patients at FMC Anson County, but does project to serve home dialysis patients following the addition of the three dialysis stations.

<b>FMC ANSON COUNTY CURRENT PAYOR MIX</b>		
<b>PAYOR SOURCE</b>	<b>IN-CENTER</b>	<b>HOME</b>
Commercial Insurance	13.76%	38.00%
Medicare	75.52%	54.60%
Medicaid	4.52%	1.90%
Medicare/Medicaid	0.00%	1.80%
Medicare / Commercial	6.16%	0.00%
State Kidney Program	0.00%	2.70%
Other: Self/Indigent	0.04%	1.00%
Total	100.00%	100.00%

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 54, the applicant states,

*“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Anson County 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 FMC Anson County will offer a range of means by which a person can access its 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 45, 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.”*

In Exhibit 19 the applicant provides a January 29, 2014 letter to the Dean of the nursing program at South Piedmont Community College, requesting to include FMC Anson County in its clinical rotation schedule for student nurses.

The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

NC

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anson County proposes to add three dialysis stations to its existing facility for a total of 13 stations upon project completion.

The January 2014 SDR shows there is a surplus of one dialysis station in Anson County; however, in this application, the applicant is applying for additional stations based on the facility need methodology. According to the January 2014 SDR, there are two dialysis facilities in Anson County, both of which are located in Wadesboro. The January 2014 SDR, Table A reports that, as of June 30, 2013, the 10 station FMC Anson County facility was operating at 85.0% capacity, with 34 patients on 10 stations ( $34 / 10 = 3.4$ ;  $3.4 / 4 = 0.850$ , or 85.0%). The target utilization, pursuant to 10A NCAC 14C §2203(b) is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. The other dialysis facility, Dialysis Care of Anson County, operated by DaVita, Inc., was operating at 53.33% capacity, with 32 patients on 15 stations ( $32 / 15 = 2.13$ .  $2.13 / 4 = 0.533$ ).

In Section V.7, page 49, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states that there are no other providers of dialysis in the county. The applicant states its proposal to add three dialysis stations will not adversely affect quality, but rather, enhance the quality of life for the ESRD patients. The applicant further states:

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

...

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.”*

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding three dialysis stations to the existing FMC Anson County dialysis facility will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis service because:

- The applicant adequately demonstrates the need, based on the facility need methodology, to add three dialysis stations for a total of 13 certified dialysis stations upon completion of the proposed project. Furthermore, the applicant demonstrates that the proposed

project is a cost-effective alternative to meet the need to provide additional access to dialysis services for FMC Anson County patients;

- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 44 – 45 and 46 - 48), and VII. (pages 57 - 58), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 50, the applicant states:

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

The applicant provides the following table to demonstrate that medically underserved populations will continue to have adequate access to dialysis services provided by FMC Anson County, as illustrated below.

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Anson County	5.9%	23.5%	85.3%	64.7%	91.2%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 85.3% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI.1(a), page 50, that BMA has a long history of providing dialysis services to all segments of the population, regardless of race, ethnicity, Medicaid and Medicare recipients, gender, or other considerations. The application is conforming to this criterion.

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

C

The applicant currently provides dialysis services at FMC Anson County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Anson County has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

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

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

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

*(1) Utilization rates;*

-C- In Section II.1, page 10, the applicant provides the utilization rate of 85.0% with 3.4 patients per station ( $34 / 10 = 3.4$ ) as reported in the January 2014 SDR.

*(2) Mortality rates;*

-C- In Section II.1, page 10, the applicant provides the mortality rates as 8.9%, 10.7% and 6.3% for 2011, 2012 and 2013, respectively.

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

-NA- In Section II.3, page 10, the applicant states, “BMA has not yet provided home training services to patients of the FMC Anson County facility. No patients of the facility have been identified as viable candidates for home training and no patients of the facility have requested to dialyze at home.”

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

- C- In Section II.1, page 10, the applicant states FMC Anson County referred 0 transplants in 2012 and 3 in 2013. No transplants were performed in 2012 and one was performed in 2013.
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section II.1, page 10, the applicant states, “FMC Anson County has one patient on the transplant waiting list.”
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section II.1, page 11, the applicant states that there were 70 hospital admissions in 2013, 14 of which were dialysis related and 56 of which were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section II.1, page 11, the applicant states that there were no patients at the facility in 2012 or 2013 or at the time of the application with an infectious disease.

*(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:*

*(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- FMC Anson County is an existing facility. The applicant, however, provides a copy of the hospital affiliation agreement with Duke University Medical Center in Exhibit 26.

*(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with 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- FMC Anson County is an existing facility.

*(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- FMC Anson County is an existing facility.

*(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- In Exhibit 12 the applicant provides a copy of the *Emergency Management and Disaster Planning* policy, which provides procedures for back-up electrical service in the event of a power outage for FMC Anson County.

*(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- FMC Anson County is an existing facility.

*(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- In Section II.1, page 12, the applicant states, “*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC Anson County.*”

*(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, pages 12 - 15, and Section III.7, pages 35 - 40, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A % OF TOTAL	
	In-Ctr.	Home	In-Ctr.	Home	Year 1	Year 2
Anson	41.2	1	43.2	2	97.69%	97.84%
Chesterfield, SC	1.0	0	1.0	0	2.31%	2.16%
Total	42.2	0	44.2	2	100.00%	100.00%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

*(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC Anson County is an existing facility.

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

-C- In Section II.1, pages 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.”

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

*(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- FMC Anson County is an existing facility.

*(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- FMC Anson County projects utilization of 3.23 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 17 - 21, and Section III.7, pages 35 - 40.

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

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 17 - 21, and Section III.7, pages 35 - 40.

#### **10A NCAC 14C .2204 SCOPE OF SERVICES**

*To be approved, the applicant must demonstrate that the following services will be available:*

*(1) diagnostic and evaluation services;*

- C- In Section II.1, page 21, the applicant states, *“Patients will be referred to Anson Community Hospital, or Carolinas Medical Center - Union.”*

*(2) maintenance dialysis;*

- C- In Section II.1, page 21, the applicant states, *“The facility will provide in-center dialysis.”*

*(3) accessible self-care training;*

- C- In Section II.1, page 21, the applicant states, *“Patients who are candidates for self-care will be referred to the facility home training department.”*

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

- C- In Section II.1, page 21, the applicant states, *“Patients who are candidates for home dialysis will be referred to the facility home training department.”*

*(5) x-ray services;*

- C- In Section II.1, page 22, the applicant states, *“Patients will be referred to Anson Community Hospital, or Carolinas Medical Center - Union.”*

*(6) laboratory services;*

- C- In Section II.1, page 22, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 15 for the laboratory services agreement with Spectra Laboratories.
- (7) *blood bank services;*
- C- In Section II.1, page 22, the applicant states, “*Patients in need of blood transfusion will be referred to Anson Community Hospital, or Carolinas Medical Center - Union.*”
- (8) *emergency care;*
- C- In Section II.1, page 22, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*”
- (9) *acute dialysis in an acute care setting;*
- C- In Section II.1, page 22, the applicant states, “*Patients admitted to hospital [sic] will be referred to Carolinas Medical Center - Union.*”
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section II.1, page 22, the applicant states, “*Patients will be referred to Metrolina Nephrology Associates Access Center, Piedmont Surgical or Sanger Heart and Vascular Clinic. The surgeons of these locations will coordinate with the patient and schedule vascular surgery.*”
- (11) *transplantation services;*
- C- In Section II.1, page 22, the applicant states, “*FMC Anson County has a transplant agreement with CMC.*” See Exhibit 26 for a copy of the transplant agreement with Carolinas Medical Center.
- (12) *vocational rehabilitation counseling and services; and*
- C- In Section II.1, page 22, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Division of Vocational Rehabilitation of Anson County and Carolinas Medical Center – Union.*”
- (13) *transportation.*

- C- In Section II.1, page 22, the applicant states, “*Transportation services are provided by Anson County Transportation.*”

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

*(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 II., page 23, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 57, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

*(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 II.1, page 23, and Section VII.5, page 57, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten-week training program, and that staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 9 contains an outline of the training program and Exhibit 10 contains the outline of the continuing education information.