

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 16, 2014

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: P-10257-14/ Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast/ Add three dialysis stations for a total of 16 dialysis stations upon completion of this project, Project I.D. #P-10051-12 (relocation of 10 stations to develop FMC Sea Spray) and Project I.D. #P-10097-13 (add three dialysis stations)/ Carteret 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 Crystal Coast proposes to add three in-center dialysis stations to the existing facility for a facility total of 16 in-center dialysis stations upon completion of this project, Project I.D. #P-10051-12 (relocation of 10 stations to develop FMC Sea Spray) and Project I.D. #P-10097-13 (add three dialysis stations).

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 January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Carteret County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported

in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, BMA Crystal Coast demonstrates a need for three additional stations in its existing facility based on the facility need methodology, because the utilization rate reported in the January 2014 SDR is 3.75 patients per station, or 93.75%. This utilization rate was calculated based on 75 in-center dialysis patients and 20 certified dialysis stations as of June 30, 2013 (75 patients/20 stations = 3.75 patients per station). Effective April 3, 2013, BMA was approved to relocate 10 stations to develop FMC Sea Spray (Project I.D. #P-10051-12). Effective June 25, 2013, BMA was approved to add three dialysis stations to BMA Crystal Coast (Project I.D. #P-10097-13) for a total of 16 stations upon completion of the project.

Application of the facility need methodology indicates three additional stations are needed for this facility, as illustrated in the following table. Therefore, there will be a total of 16 stations at the completion of this project, Project I.D. #P-10051-12 and Project I.D. #P-10097-13.

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		93.75%
Certified Stations		20
Pending Stations		3
<b>Total Existing and Pending Stations</b>		<b>23</b>
In-Center Patients as of 6/30/13 (SDR2, January 2014 SDR)		75
In-Center Patients as of 12/31/12 (SDR1, July 2013 SDR)		68
Difference (SDR2 - SDR1)		7
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12 (SDR1)	0.2059
(ii)	Divide the result of Step (i) by 12	0.0172
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January 2014 SDR (6/30/13) until the end of calendar year 2013 (6 months)	0.1032
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	82.7400
(v)	Divide the result of Step (iv) by 3.2 patients per station	25.8563
	and subtract the number of certified and pending stations as recorded in SDR2 [23] to determine the number of stations needed	2.8563

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations after rounding to the nearest whole number. Rounding to the nearest whole number is discussed in the SMFP, page 364. The applicant is proposing to add only three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: BASIC PRINCIPLES in the 2014 SMFP is also 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 (SMFP) 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

The applicant, BMA Crystal Coast, is a subsidiary of Fresenius Medical Care Holdings, Inc. (FMC). The applicant describes how its proposal will promote safety and quality in Section I, pages 4-8, and Section II, pages 12, 22-24, and 26-28. The applicant states in Section I, pages 4-5,

*“FMC’s commitment to the quality and availability of dialysis services is evidenced in its organizational structure. The **Clinical Services Department**, within the Dialysis Division (Bio-Medical Applications, or BMA) serves as a central resource for the entire FMC network of health care providers. The department is devoted to assuring all FMC facilities are provided with the best procedures and equipment available and consistently meet the highest possible standards. Professional staff is available to assist facility managers and medical personnel with questions and concerns relative to clinical operations. Additionally, the department provides such services as an ongoing Clinical Review Program, guidelines for the comprehensive training of staff members, a Quality Assurance Program and a full range of services to support home care.*

*Another important resource for the provision of quality care is FMC’s **Technical Services Department**. The primary focus of this department is to oversee the technical and mechanical aspects of dialysis. The department is further supported by [sic] a research and quality control team that consistently leads the industry in dealing with technically complex issues facing dialysis providers.*

...

*The result of these services support the commitment and assurance that every patient receives care of the highest standards each time he or she is treated at an FMC facility.”*

In addition, in Section II, page 12, the applicant states it will provide all services in conformity with applicable laws and regulations, stating it consistently meets Federal and state guidelines for dialysis staffing. Furthermore, it states that all fire, water supply, and other relevant health and safety equipment will be appropriately maintained at the facility.

In Section II, pages 19-20, the applicant states BMA’s parent company, FMC, “*encourages all BMA facilities to attain the FMC UltraCare® certification*”, an ongoing quality care program focused on delivering optimum care to patients through “*Clinical Leadership ▪ Continuous Quality Improvement ▪ Superior Customer Service Team Approach to Care ▪ Innovative Technology ▪ Patient-Centered Care.*”

Moreover, in Section II, pages 26-28, the applicant discusses its various programs used to ensure quality of care. These include: a quality improvement program, staff orientation and training, in-service education, technical audits, continuous quality improvement, external surveys, and single use dialyzers. In addition, BMA Crystal Coast participates in the “*Core Indicators Project*” which includes goals for quality indicators that are more stringent than those of the Federal Centers for Medicare and Medicaid Services for assessing the quality of dialysis treatment outcomes. The following table is provided, on page 28, to illustrate BMA Crystal Coast’s averages on three quality indicators,

<b>Core Indicator</b>	<b>Measurement</b>	<b>Result</b>
Dialysis Adequacy	% of patients with Ekt/V > 1.2	98.3%
Nutrition	% of patients with Albumin > 3.5	89.2%
Vascular Access	% of patients with AV Fistula	75.4%
	% of patients with Catheter	12.3%

The applicant notes, on page 28, that a higher percentage of patients with AV Fistula and a lower percentage of patients with catheters “*are a positive indication.*”

### Promote Equitable Access

The applicant describes how its proposal will promote equitable access in Section II, pages 20-21, and in Section VI, page 41. The applicant states in Section II, pages 20-21, that the majority of its dialysis patients are covered by Medicare and Medicaid and projects that 84.3% of its in-center dialysis treatments will be covered by these two payors. The applicant projects that an additional 8.4% of in-center dialysis treatments will be covered

by VA, bringing the projected total for government payors up to 92.7%. In Section VI, page 41, the applicant states,

*“BMA of North Carolina has historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age, or any other grouping/category or basis for being an underserved person.”*

In addition, the applicant states, on page 43, that there are some patients who do not have sufficient financial resources to pay for the services rendered and that *“BMA allocates these un-collectables to a ‘Bad Debt’ account.”* The applicant reports that the amount of bad debt for BMA Crystal Coast was \$265,674 for FY 2013. Although BMA’s admission policy requires some type of insurance prior to receiving dialysis services, the applicant states on page 42, *“...the Regional Vice President does have the authority to override the policy. The Social Worker and Business office staff will assist the patient by identifying available sources of funding and completing the required information necessary to obtain assistance.”*

Moreover, the applicant states in Section II, page 21, that it is sensitive to time and distance barriers and that it will *“apply to develop new dialysis facilities when needed”* to address the growing dialysis population in Carteret County. By applying for three additional dialysis stations at BMA Crystal Coast, it is addressing a growing need for dialysis services in the county.

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

#### Maximize Healthcare Value

The applicant describes how its proposal will maximize health care value for resources expended in Section II, page 21. The applicant states that 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.”* Since the majority of BMA Crystal Coast’s patients are covered by government payors using fixed rates of reimbursement, BMA *“must work diligently to control costs of delivery for dialysis. BMA does.”*

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

- (2) Repealed effective July 1, 1987.

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast proposes to add three in-center dialysis stations to the existing facility, pursuant to a Facility Need Determination, for a facility total of 16 stations upon completion of this project, Project I.D. #P-10051-12 (relocation of 10 stations to develop FMC Sea Spray, and Project I.D. #P-10097-13 (add three stations).

Population to be Served

In Section III.7, page 32, the applicant provides BMA Crystal Coast’s projected patient origin during the first two operating years as illustrated below:

COUNTY	OPERATING YEAR 1 CY 2016	OPERATING YEAR 2 CY 2017	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1 (CY 2016)	YEAR 2 (CY 2017)
Carteret	54.6	60.0	100.0%	100.0%
<b>Total</b>	<b>54.6</b>	<b>60.0</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III, pages 31-32, the applicant provides the assumptions and methodology used to project patient utilization and the need for three additional dialysis stations, summarized as follows:

- Based on the data reported in Table A, page 15 of the January 2014 SDR, BMA Crystal Coast had 75 in-center patients as of June 30, 2013. There are 20 certified dialysis stations at the facility and a utilization rate of 93.75%.
- Based on information provided by the applicant in Section III.2, page 29, and illustrated in a table provided by the analyst (see Criterion 1), the facility demonstrates a need for three additional stations based on facility need methodology.

- The applicant assumes that the number of patients utilizing the facility will increase by 9.9%, equal to the Five Year Average Annual Change Rate (AACR) for Carteret County as stated in the January 2014 SDR.
- BMA Crystal Coast is projected to have 54.6 in-center patients by the end of Operating Year One (January 1, 2016 - December 31, 2016) and 60.0 in-center patients by the end of Operating Year Two (January 1, 2017 – December 31, 2017). The applicant illustrates this in Section III, page 31, applying the Five Year AACR of 9.9% for Carteret County as follows:
- BMA Crystal Coast census as of December 31, 2013 = 66 in-center patients
- January 1, 2014 – December 31, 2014 -  $(66 \times .099) + 66 = 72.5$  in-center patients
- January 1, 2015 – December 31, 2015 –  $(72.5 \times .099) + 72.5 = 79.7$  in-center patients for the projected starting census for this project.
- BMA subtracts 30 patients expected to transfer to FMC Sea Spray for Project I.D. #P-10051-12 (relocation of 10 stations) by December 31, 2015 –  
 $79.7 - 30 = 49.7$  in-center patients
- January 1, 2016 – December 31, 2016 –  $(49.7 \times .099) + 49.7 = 54.6$  in-center patients at the end of Operating Year One
- January 1, 2017 – December 31, 2017 –  $(54.6 \times .099) + 54.6 = 60.0$  in-center patients at the end of Operating Year Two

The applicant states, on page 32, *“In financial projections and utilization projections for this application, BMA has rounded down to the whole number.”* Therefore, for Operating Year One, 54 patients would be dialyzing on 16 stations for a total of 3.38 patients per station ( $54/16 = 3.38$ ) which exceeds the minimum of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for three additional dialysis stations at the BMA Crystal Coast facility. Consequently, 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

The applicant proposes to add three in-center dialysis stations to its existing facility, for a facility total of 16 in-center dialysis stations following completion of this project, and Project I.D. #P-10051-12 (relocation of 10 stations to develop FMC Sea Spray), and Project I.D. #P-10097-13 (add three stations).

In Section III.9, page 33, the applicant states that it considered the alternative of applying for fewer additional stations at the facility, however this alternative would not address the growing patient census at the facility. The applicant states, *“The Facility Need Calculations demonstrate that the facility is growing at 23.9% annually, significantly more than the Carteret County Five Year Average Annual Change Rate.”*

The applicant further states on page 33, that patient choice would be adversely affected if the stations were not added, and that the facility is projected to exceed 80% utilization. Furthermore, the applicant states, on page 33, *“Failure to expand potentially denies patients a choice of dialysis at BMA Crystal Coast.”* The applicant adequately explains why it chose the selected alternative over the status quo. Furthermore, the application is conforming to all other applicable statutory review criteria. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified facility need for three additional dialysis stations at BMA Crystal Coast. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast shall materially comply with all representations made in its certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast shall develop and operate no more than three additional dialysis stations for a total of 16 certified stations upon completion of this project, Project I.D. #P-10051-12 (relocation of 10 stations to develop FMC Sea Spray, and Project I.D. #P-10097-13 (add three stations) which shall include any home hemodialysis training or isolation stations.**

- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of 16 dialysis stations which shall include any home hemodialysis training or isolation stations.**
  - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast 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(b), page 49, the applicant states that there will be no capital cost for the project. In Section IX, page 52, the applicant states that there are no start-up or initial operating expenses since BMA Crystal Coast is an existing facility.

Exhibit 24 includes a letter of commitment dated March 17, 2013 from the Vice President of Fresenius Medical Care Holdings, Inc. verifying the project does not require any capital expenditure.

In Exhibit 4, the applicant provides a copy of the most recent audited financial reports for FMC, Inc. and Subsidiaries. As of December 31, 2012, Fresenius Medical Care Holdings, Inc. and Subsidiaries had cash and cash equivalents totaling \$341,071,000 with \$17,841,509,000 in total assets and \$9,469,431,000 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 53, the applicant lists the following charges per treatment for each payment source,

**BMA Crystal Coast Projected  
 Allowable  
 In-Center Charges per Treatment**

SOURCE OF PAYMENT	IN-CENTER CHARGE
Private Pay	\$1,425.00
Commercial Insurance*	\$1,425.00
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

\*Includes Blue Cross/Blue Shield

\*\*Includes Medicare Advantage program

The applicant states, on pages 53-54, that it is using a Medicare rate of \$239 to reflect Medicare’s ‘*Bundling*’ of the dialysis treatment with all ancillary services and to account for additional reimbursement due to some co-morbid conditions. The applicant states, on page 53, that “...*the basic rate for Medicare reimbursement has been approximately \$240 per treatment.*” Further, the applicant notes, on page 54, that there will be cuts to Medicare reimbursement for dialysis treatment which will be phased in over several years, amounting to a 12% reduction in revenues. The applicant provides the following projected Medicare reimbursement by calendar year, stating, “*BMA will use these rates within the application and its projections of revenues.*”

**BMA Crystal Coast  
 Anticipated Medicare Reimbursement by Year**

Year	Medicare Rate
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Sections X.2 through X.4, pages 55-60, the applicant reports projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$2,259,742	\$2,417,958
Total Operating Costs	\$2,131,348	\$2,260,738
Net Profit	\$128,394	\$157,220

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, pages 55-61 of the application, for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

### C

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast proposes to add three in-center dialysis stations to the existing facility. As reported by the applicant in Section II, page 13, as of December 31, 2013, BMA Crystal Coast was serving 66 patients, six days a week, with 20 certified stations. Ten stations will be relocated from BMA Crystal Coast to create a new dialysis facility, FMC Sea Spray in Carteret County (Project I.D. #P-10051-12), and three stations will be added to BMA Crystal Coast (Project I.D. #P-10097-13). Upon completion of both projects, Project I.D. #P-10051-12 and Project I.D. #P-10097-13, and the proposed project, BMA Crystal Coast will have 16 dialysis stations  $[(20-10) + 3 + 3 = 16]$ . Dialysis facilities that operate two shifts per week (2 patients dialyzing per day at each station on alternate days) have a capacity of four patients per station. For BMA Crystal Coast, this equates to 3.75 patients per station, which is 93.75% of capacity ( $75 \text{ patients}/20 \text{ stations} = 3.75$ ;  $3.75 \text{ patients per station}/4 \text{ patients per station} = 93.75\%$ ). The applicant provides reasonable projections for the in-center patient population it proposes to serve as discussed in Section II, page 13 of the application. At the end of operating year one, with 16 dialysis stations (includes the relocation of 10 stations upon completion of Project I.D. #P-10051-12 and the addition of three stations upon completion of Project I.D. #P-10097-13), and 54 in-center patients projected, the applicant's projected utilization will be 3.38 patients per station ( $54 \text{ patients}/16 \text{ stations} = 3.38$ ). The target utilization rate is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility required by 10A NCAC 14C .2203(b). Therefore, BMA Crystal Coast proposes to exceed the minimum target utilization.

At the end of operating year two, with 16 dialysis stations and 60 in-center patients projected, the applicant's projected utilization will be 3.75 patients per station, operating at 93.8% of capacity ( $60 \text{ patients}/16 \text{ stations} = 3.75$ ;  $3.75 \text{ patients per station}/4 \text{ patients per station} = 0.938$ ). These utilization projections are based on applying the Five Year AACR for Carteret County of 9.90% in dialysis patients utilizing BMA Crystal Coast. Therefore, projected utilization is based on reasonable and supported assumptions regarding continued growth.

According to the January 2014 SDR there are two dialysis facilities in Carteret County, however only one, BMA Crystal Coast, is operational. It has 20 certified stations and is located in Morehead City. The other dialysis facility, FMC Sea Spray, will have 10 stations pending certification and is located in Cape Carteret. The applicant states, in Section II, page 12,

*“Within the CON application for FMC Sea Spray, CON Project ID # P-10051-12, BMA projected 30 patients from BMA Crystal Coast to transfer their care upon certification of the project. BMA maintains those projections in this project. FMC Sea Spray is now targeted for completion by December 31, 2015...”*

FMC Sea Spray is approximately 19 miles from BMA Crystal Coast.

According to estimates from the U.S. Census Bureau, Carteret County’s population grew 1.0% from July 1, 2012 to July 1, 2013 and had 68,434 residents as of July 1, 2013<sup>1</sup>.

The applicant adequately demonstrates the need to add three dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Carteret 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 46, the applicant provides current and projected staffing for the BMA Crystal Coast facility following the addition of three stations. The applicant does not plan to add any FTE positions for the proposed project.

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<sup>1</sup> Annual Estimates of the Resident Population: July 1, 2012 to July 1, 2013, U.S. Census Bureau, Population Division, <http://factfinder2.census.gov>

POSITION	CURRENT FTES	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	3.00	0	3.00
Technician	8.00	0	8.00
Clinical Manager/ Director of Nursing	1.00	0	1.00
Administrator (FMC Director of Operations)	0.25	0	0.25
Dietician	0.40	0	0.40
Social Worker	0.25	0	0.25
Chief Technician	0.10	0	0.10
Equipment Technician	1.00	0	1.00
In-Service	0.25	0	0.25
Clerical	1.00	0	1.00
<b>Totals</b>	<b>15.25</b>	<b>0</b>	<b>15.25</b>

In Exhibit 21 of the application, the applicant provides a letter from Dr. W. Joseph Newman, Eastern Nephrology Associates, stating that he will continue to serve as the Medical Director of BMA Crystal Coast. The information provided in Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a medical director, for the provision of 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 36, the applicant provides a table listing all ancillary and support services, indicating whether they are provided on the premises or off site, and if off site, by whom. Carolina East Medical Center will provide acute dialysis services when needed, and blood bank services. Diagnostic evaluation services and x-ray services will be provided by Carteret General Hospital. The applicant indicates, on page 36 and in Exhibit 26, that both Duke University Medical Center and University of North Carolina (UNC) Healthcare will provide transplantation services. Pediatric nephrology services will be provided by referral to either East Carolina University or UNC Healthcare. Vascular surgical services will be provided by Carolina East Medical Center or Eastern Nephrology Associates Vascular Access Center. Psychological counseling will be provided by Le' Chris Health Systems in Morehead City. Isolation for hepatitis, dialysis/maintenance, nutritional counseling, and social work services will be provided onsite. Self care training for

hemodialysis, intermittent peritoneal dialysis, CAPD, and CCPD will be referred to BMA Craven County. All laboratory services will be provided on site by Spectra Laboratories. All other ancillary services will be provided by stated providers.

The applicant states, on page 38, that it has existing professional relationships with local physicians for referrals and that it does not expect referral patterns to change. In addition, the applicant states, in Section V.6(a), page 39,

*“As an active facility in Carteret County, BMA Crystal Coast enjoys the support of the medical community and community leadership. The applicant keeps the medical community apprised of developments through the relationship with Nephrology physicians who refer patients to the facility.”*

In addition, the applicant provides a patient petition of support in Exhibit 22.

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 care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section VI.1(a), page 41, the applicant states,

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 100 facilities in 42 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has eight facilities under development or pending CON approval. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.*

...

*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.”*

In addition, in Section VI.1(b), page 42, the applicant provides the current in-center dialysis payor mix at BMA Crystal Coast as of December 31, 2013, as shown in the table below:

<b>BMA CRYSTAL COAST PAYOR SOURCE</b>	<b>PERCENT OF TOTAL</b>
Medicare	84.04%
Medicaid	0.29%
Medicare/Medicaid	0%
Commercial Insurance	6.97%
VA	8.37%
Medicare/Commercial	0.33%
Private Pay	0%
Other: Self/Indigent	0%
<b>Total</b>	<b>100.00%</b>

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 Carteret County and statewide.

<b>COUNTY</b>	<b>2010 TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION</b>	<b>2010 TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION</b>	<b>2008-2009 % UNINSURED (ESTIMATE BY CECIL G. SHEPS CENTER)</b>
Carteret	13.9%	6.6%	19.5%
Statewide	17.0%	6.7%	19.7%

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 with respect to dialysis services offered by BMA Crystal Coast. 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.

The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistic 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. 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,

*“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 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:

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

<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>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;

C

In Section VI.6 (a), page 44, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities 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

<sup>3</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.1(c), page 42, the applicant provides the projected payor mix for the proposed services at BMA Crystal Coast. The applicant projects no change from the current payor mix for dialysis visits, however it states “...the payor mix is dynamic and not fixed.”

**BMA CRYSTAL COAST  
PROJECTED PAYOR MIX**

<b>PAYOR SOURCE</b>	<b>IN-CENTER</b>
Private Pay	0%
Commercial Insurance	6.97%
Medicare	84.04%
Medicaid	0.29%
Medicare/Medicaid	0%
Medicare/Commercial	0.33%
State Kidney Program	0%
VA	8.37%
Other: Self/Indigent	0%
<b>Total</b>	<b>100.00%</b>

In Section VI.1(c), page 42, 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.’*

The applicant demonstrates it will provide adequate access to medically underserved populations, including the elderly. 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 Sections VI.5(a) and (b), page 44, the applicant states that patients have access to dialysis services through Nephrologists who apply for and receive

medical staff privileges to admit patients to the facility. Further, the applicant states,

*“BMA Crystal Coast 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 Nephrologists expect to continue receiving referrals from the local physician community, home health agencies, and acute care facilities.”*

The applicant adequately demonstrates that BMA Crystal Coast will provide 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(a), pages 37-38, the applicant states that all health related training programs are welcome to learn about the facility and receive instruction on ESRD, its prognosis and treatment. In addition, Exhibit 19 contains a letter from FMC’s Craven County Area Manager to Carteret Community College’s Nursing Program inviting the school to participate in clinical rotations for its nursing students at the BMA Crystal Coast facility. The information provided in Section V.3 and Exhibit 19 is reasonable and credible for an existing facility 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

The applicant proposes to add three dialysis stations to its existing dialysis facility for a total of 16 certified stations upon completion of the proposed project. The January 2014 SDR shows that there is no need for additional dialysis stations in Carteret County, however, the applicant demonstrates a need for three additional dialysis stations based on the facility need methodology in the 2014 SMFP. The utilization rate for BMA Crystal Coast currently exceeds 93%. BMA Crystal Coast is the only operational in-center dialysis service in Carteret County. One other in-center dialysis service in Carteret County, FMC Sea Spray, has been conditionally approved but has not yet been certified.

In Section V.7, pages 39-40, 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 it *“has added value”* due to its strong relationship with Eastern Nephrology Associates, a large group of nephrologists practicing in eastern North Carolina. In addition, the facility is compelled to operate efficiently since it relies heavily on Medicare and Medicaid payors to cover treatment expenses at fixed rates. Moreover, the applicant states that its combined efforts to contain operating costs and to provide outstanding care to patients contribute to the overall success of the facility and that its proposal to add three dialysis stations will *“enhance the quality of the ESRD patients’ lives.”*

See also 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 BMA Crystal Coast facility will have a positive impact on cost-effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need, based on ‘Facility Need,’ to add three dialysis stations for a total of 16 certified dialysis stations following completion of this project, Project I.D. #P-10051-12, and Project I.D. #P-10097-13. The applicant also demonstrates that the proposed project will provide additional access to Carteret County residents and is a cost-effective alternative;
- The applicant adequately demonstrates it 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 and VII is reasonable and credible and demonstrates the provision of quality services.
- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 41, the applicant states,

*“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent*

*company to BMA, currently operates 100 facilities in 42 North Carolina Counties...*

*Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. ”*

The applicant provides the following table from Section VI.1(a), page 41, representing the patient population at BMA Crystal Coast, to demonstrate that medically underserved populations will continue to have adequate access the facility’s dialysis services, as illustrated below:

<b>Facility</b>	<b>Medicaid/ Low Income</b>	<b>Elderly (65+)</b>	<b>Medicare</b>	<b>Women</b>	<b>Racial Minorities</b>
BMA Crystal Coast	22.7%	54.5%	90.0%	34.8%	40.9%

*“Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 90% of the facility treatment reimbursement is from Medicare.”*

The applicant further states on page 41,

*“It is clear that BMA Crystal Coast 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 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. Therefore, 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 Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, BMA Crystal Coast 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 proposal 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- The utilization rate as of June 30, 2013 as shown in the January 2014 SDR, is 93.75%. See Exhibit 5 (copy of the January 2014 SDR, Table A, page 8).

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

- C- In Section IV.2, page 34, the applicant reports the 2011, 2012 and 2013 facility mortality rates, which were 21.4%, 12.9%, and 14.8%, respectively.

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

- NA- The applicant states, in Section IV.3, on page 34, that it is not certified to provide home dialysis.

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

- C- In Section IV.4, page 34, the applicant states that BMA Crystal Coast referred 65 patients for transplant evaluation in 2013. One patient received a transplant in 2013.

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

- C- In Section IV.5, page 34, the applicant states that BMA Crystal Coast has 17 patients on the transplant waiting list.

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

-C- The applicant reports, in Section IV.6, page 35, that there were a total of 89 hospital admissions in 2013; 13.5% were dialysis-related and 86.5% were non-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 35, the applicant reports that in 2013 there were no patients with Hepatitis B and no patients who converted to infectious status with Hepatitis B in 2013. The applicant states, "BMA does not identify patients with AIDS or other infectious disease. All other patients with infectious disease such as AIDS will receive their dialysis care and treatment in the in-center treatment area."

*(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 Crystal Coast 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 Crystal Coast 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 Crystal Coast 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 excerpts from Fresenius Medical Care’s written policies and procedures which includes back up for electrical service in the event of a power outage. Fresenius Medical Care (FMC) is the parent company of Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast.

.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 Crystal Coast 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- The applicant provides documentation that it provides its services in conformity with all applicable laws and regulations in Sections VII.2, page 47, XI.6(e), page 66, and XI.6(g), page 66.

.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- In Section II, page 15, BMA Crystal Coast provides its projected patient origin. The projected patient origin for the first two years of operation following completion of the project is provided as follows:

County	Operating Year One 1/01/2016 – 12/31/2016	Operating Year Two 1/01/2017 – 12/31/2017
	IN-CENTER PATIENTS	IN-CENTER PATIENTS
Carteret	54.6	60.0
<b>Total</b>	<b>54.6</b>	<b>60.0</b>

Assumptions and methodology are provided in Section II, pages 12-17.

*.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 Crystal Coast 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 14, 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 Crystal Coast is an existing facility.

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

-C- In Section III.7, page 32, the applicant states it projects to serve 54 in-center patients by the end of Operating Year 1, which is 3.38 patients per station ( $54/16 = 3.38$ ) or 84.5% of capacity ( $3.38/4 = .845$ ).

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

-C- In Section II, pages 12-17 and Section III.7, pages 31-32, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

#### **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-         See Section V.1, page 36. Diagnostic evaluation services are provided by Carteret General Hospital.
- .2204(2)     *Maintenance dialysis;*
- C-         See Section V.1, page 36. BMA Crystal Coast provides maintenance dialysis.
- .2204(3)     *Accessible self-care training;*
- C-         See Section V.1, page 36. Self-care training in hemodialysis, intermittent peritoneal dialysis, CAPD, and CCPD is provided through referral to BMA Craven County.
- .2204(4)     *Accessible follow-up program for support of patients dialyzing at home;*
- C-         See Section V.2(d), page 37. The applicant states that patients dialyzing at home are followed by the BMA Craven County home training program.
- .2204(5)     *X-ray services;*
- C-         See Section V.1, page 36. X-ray services are provided by Carteret General Hospital.
- .2204(6)     *Laboratory services;*
- C-         See Section V.1, page 36 and Exhibit 15. All laboratory services are provided on the premises by Spectra Laboratories, Inc.
- .2204(7)     *Blood bank services;*
- C-         See Section V.1, page 36. Blood bank services are provided by Carolina East Medical Center.
- .2204(8)     *Emergency care;*
- C-         See Section V.1, page 36. Emergency care is provided by fully trained BMA Crystal Coast staff and ambulance transport is available to the nearest hospital.
- .2204(9)     *Acute dialysis in an acute care setting;*
- C-         See Section V.1, page 36. Acute dialysis in an acute care setting is provided by Carolina East Medical Center.

- .2204(10) *Vascular surgery for dialysis treatment patients;*
- C- See Section V.1, page 36. Vascular surgery for dialysis treatment patients is provided by Carolina East Medical Center or Eastern Nephrology Associates Vascular Access Center.
- .2204(11) *Transplantation services;*
- C- See Section V.1, page 36 and Exhibit 26. Transplantation services are provided by Duke University Medical Center and UNC Healthcare.
- .2204(12) *Vocational rehabilitation counseling and services; and*
- C- See Section V.1, page 36. Vocational rehabilitation counseling and services are provided by Carteret County Social Services.
- .2204(13) *Transportation*
- C- See Section V.1, page 36. Transportation is provided by Carteret County Area Transportation System (CCATS).

#### **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 46, the applicant provides the proposed staffing. In Section VII.2, page 47, the applicant states the proposed facility does and will comply with all staffing requirements set forth in 42 C.F.R. Section 494. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

- C- See Section VII.3, page 47, for discussion of training and certifications held or required for the BMA Crystal Coast direct patient care staff. In addition, the applicant states that BMA Crystal Coast continually updates its training and corporate staff monitors policies and procedures to keep up to date with federal and state regulations. Moreover, see Exhibit 9 for FMC's Core Curriculum for the Dialysis Technician Training Program Outline and Exhibit 10 for FMC's continuing education programs outlines and requirements.