

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 23, 2013

PROJECT ANALYST: Jane Rhoe-Jones
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: P-10097-13 / Bio-Medical Applications of North Carolina, Inc.
d/b/a BMA Crystal Coast / Add three dialysis stations for a
total of 13 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. (BMA) d/b/a BMA Crystal Coast, 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 completion of this project and Project ID# P-10051, FMC Sea Spray (proposal to relocate 10 stations from BMA Crystal Coast [3332 Bridges Street, Morehead City] to develop a new 10-station dialysis facility in Carteret County – FMC Sea Spray, Cape Carteret). The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Carteret 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 BMA Crystal Coast in the January 2013 SDR is 3.5 patients per station. This utilization rate was calculated based on 70 in-center dialysis patients and 20 certified dialysis stations (70 patients / 20 stations = 3.5 patients per station).

A certificate of need application was approved February 28, 2013 for BMA to transfer 10 stations from BMA Crystal Coast to FMC Sea Spray, a proposed new dialysis facility in Carteret County.

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

APRIL 1 REVIEW --- BMA Crystal Coast ---P-10097-13		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/12		87.5%
Certified Stations		20
Pending Stations		0
Total Existing and Pending Stations		20
In-Center Patients as of 6/30/12(SDR2)		70
In-Center Patients as of 12/31/11 (SDR1)		68
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	0.0588
(ii)	Divide the result of step (i) by 12	0.0049
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January 2013 SDR (6/30/12) until the end of calendar year 2012 (6 months)	0.0294
(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	72.0588
(v)	Divide the result of step (iv) by 3.2 patients per station	22.5184
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	3

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed 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, pages 42-43 of the 2013 SMFP is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

In Section I.13, pages 4-7, the applicant discusses the quality of services provided at BMA Crystal Coast, attributing much of its success in providing quality services to its corporate structure, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments and other management resources 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:
 - Revenue Operations – draws experience through interaction with numerous Medicare intermediaries and third-party carriers
 - Accounting and Budgeting – tailored to ensure effective financial management of dialysis treatment centers

- Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities
- Human Resources – develops productivity standards, job descriptions, staff performance review, personnel policies and procedures and employee relations
- Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care
- Marketing and Managed Care – competitive analysis and continuous development of dialysis services
- Health, Safety and Risk Management – provides regulatory information used to ensure compliance in the dialysis setting and provides risk management services
- Regional Vice Presidents – provide operational direction and monitoring of daily operations

The applicant also credits its quality services to quality staffing and staff training. In Section II.3, page 28, the applicant states that each new employee is required to complete an eight-week training program. Staff is trained in 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.

In Section II.1, page 20, the applicant states:

“BMA is a high quality health care provider. ... BMA’s parent company, Fresenius Medical Care, encourages all BMA facilities to attain the FMC ‘UltraCare’ certification. This is not a one time test, but rather is an ongoing process aimed at encouraging all staff, vendors, physicians, and even patients to be a part of the quality care program. Facilities are evaluated annually for ‘UltraCare’ certification.”

See Exhibit 13 for a copy of the BMA Continuous Quality Improvement process. In Section II.3, page 28, the applicant states:

“BMA Crystal Coast has a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method [sic] of review is [sic] patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation [sic]. Other audits include Patient Satisfaction Surveys and chart audits. CQI membership includes the Medical Director, Area Manager, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual

projects to gather data as needed to conduct the ‘Check, Plan, Do, and Check, Act’ process for addressing improvement opportunities.”

In Section V.7, page 44, the applicant states that BMA facilities have contained operating costs while continuing to provide patient care and treatment which is outstanding. The applicant further states that the proposed project will not adversely affect quality, but will enhance the quality of life for ESRD patients.

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

Promote Equitable Access

In Section II.1, pages 21-22, 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 84.6% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. Thus 84.6% 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. BMA continually strives to develop facilities and dialysis stations in close proximity to the patient residence. At this time, Carteret County has only one operational dialysis facility: BMA Crystal Coast. The January 2013 SDR reports that Carteret County ESRD patient population is growing at an Average Annual Change Rate of 7.7%. As the dialysis patient population of Carteret County continues to increase, the need for dialysis stations will continue to increase. ... BMA is planning to add three stations so that an adequate supply of necessary health resources remains in closer proximity to the residence location of patients residing in this area of Carteret County.”

The applicant also states on page 22,

“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. A patient in need of dialysis is always welcomed at a BMA facility; the only requirement is proper referral from a physician.”

In Section VI.1, page 45, the applicant states that in North Carolina BMA has a long history of providing dialysis services to the underserved populations. On page 46, the applicant states that the sources of government payors are Medicare at 84.1%, Medicaid at .46% and the VA at 7.4%. Thus, if the VA is included, approximately 92% of the in-center revenue is derived from government payors.

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section II.1, page 22, the applicant states:

“BMA is not projecting a capital expenditure for this project. BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... 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 2013 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 BMA Crystal Coast, proposes to add three dialysis stations to its existing facility for a total of 13 certified stations upon completion of this project and Project ID# P-10051-12, FMC Sea Spray (relocate 10 stations from BMA Crystal Coast to FMC Sea Spray).

Population to be Served

In Section IV.1, page 37, the applicant identifies the current population served, as illustrated in the table below.

BMA Crystal Coast Current Patient Origin		
COUNTY	6/30/2012 In-center Patients	Percent of Total
Carteret	66	94.3%
Craven	3	4.3%

Onslow	1	1.4%
Total	70	100.0%

In Section III.7, page 34, the applicant states that the four BMA Crystal Coast patients from Craven and Onslow counties will transfer their care to FMC Sea Spray (Project ID# P-10051-12), once that facility is operational. In Section III.7, page 35, the applicant identifies the patient population that is proposed to be served for the first two years of operation following project completion. The patient population only includes Carteret County as illustrated in the following table.

BMA Crystal Coast Projected Patient Origin				
			County Patients as a Percentage	
County	Operating Year 1	Operating Year 2	Year 1	Year 2
Carteret	54.4	58.6	100.0%	100.0%
Total	54.4	58.6	100.0%	100.0%

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III, pages 32-33, the applicant states the application is filed pursuant to the Facility Need Methodology. The applicant utilizes data from the January 2013 SDR and proposes to add three dialysis stations to BMA Crystal Coast for a total of 13 stations at the facility upon project completion.

In Section III.7, pages 33-34, the applicant provides the following assumptions for the proposed project:

1. *BMA is proposing to add three dialysis stations for FMC [sic] Crystal Coast for a facility total of 13 dialysis stations upon completion of this project and CON Project ID # P-10051-12 ... In order to be conforming with Rule 10A NCAC 14C .2203 (b), BMA must prove 3.2 patients per station at the end of Operating Year 1. Thus BMA must project to serve 41.6 rounded to 42 patients.*
2. *BMA assumes that BMA Crystal Coast facility census will increase at a rate commensurate with the Carteret County Five Year Average Annual Change Rate as published in the January 2013 SDR. That rate is 7.7%.*
3. *In CON Project ID # P-10051-12, BMA proposal for FMC Sea Spray, BMA asserted that 26 Carteret County patients would transfer their care from BMA Crystal Coast to FMC Sea Spray upon completion of that project. BMA assumes the same for this proposal.*
4. *Within the application for FMC Sea Spray, BMA asserted that the four patients from Craven and Onslow Counties, who are currently dialyzing at BMA Crystal Coast,*

would transfer their care to the FMC Sea Spray facility upon completion of that project. BMA will continue with that assertion in this CON application. As a consequence, BMA Crystal Coast is projected to be serving only patients from Carteret County through Operating Years 1 and 2 of this proposal.

5. BMA will not deny treatment to patients residing in other counties when referral to BMA Crystal Coast is by a nephrology physician with admitting privileges at BMA Crystal Coast.
6. FMC Sea Spray is scheduled for completion at June 30, 2014 This project is scheduled to follow FMC Sea Spray. Thus:

*Operating Year 1 is July 1, 2014 through June 30, 2015
 Operating Year 2 is July 1, 2015 through June 30, 2016*

In Section III.7, pages 34-35, the applicant provides the following methodology for the proposed project:

“BMA will project growth of the Carteret County patients only. Growth of the Carteret County dialysis patients dialyzing at BMA Crystal Coast is projecting using the 7.7% growth rate as discussed above. Calculations of growth are as follows:”

<i>BMA begins with the Carteret County patients as of June 30, 2012.</i>	66
<i>This segment of the facility census is projected forward for one year to June 30, 2013.</i>	$(66 \times .077) + 66 = 71.1$
<i>BMA projects growth of the Carteret County patients forward for one year to June 30, 2014.</i>	$(71.1 \times .077) + 71.1 = 76.6$
<i>BMA subtracts the 26 patients forecast to transfer to FMC Sea Spray upon completion of that project.</i>	$76.6 - 26 = 50.6$
<i>BMA projects growth of the Carteret County patients forward for one year to June 30, 2015. This is the end of Operating Year 1.</i>	$(50.6 \times .077) + 50.6 = 54.4$
<i>BMA again projects growth of the Carteret County patients forward for one year to June 30, 2016. This is the end of Operating Year 2.</i>	$(54.4 \times .077) + 54.4 = 58.6$

The applicant projects to serve 54 in-center patients or 4.2 patients per station ($54 / 13 = 4.15$) by the end of Year 1 and 58 in-center patients or 4.5 patients per station ($58 / 13 = 4.46$) by the end of Year 2 for the proposed 13 station facility. 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.

Access to Services

In Section VI, pages 45-46, the applicant states that BMA currently operates 93 facilities in 40 North Carolina Counties which include low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 92% of its patients will be covered by Medicare, Medicaid and VA. The applicant adequately demonstrates 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.

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 services proposed. Therefore, the application is conforming to this criterion.

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

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

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In Section III.9, page 36, the applicant states the alternatives considered by BMA Crystal Coast prior to the submission of this application, which include:

- 1) Maintain the Status Quo – Do Nothing. This alternative is not consistent with the growing patient population in Carteret County. Therefore, this alternative was not a suitable option.
- 2) Add fewer than three stations. This alternative is not cost-effective nor is it consistent with the growing patient population in Carteret County. BMA has demonstrated the need for three stations.
- 3) Add three stations. BMA chose this alternative as most effective and least costly to meet the needs of the patients receiving treatment at the BMA Crystal Coast facility.

The applicant adequately demonstrates the need for three additional stations based on the continued growth of the ESRD patient population in Carteret 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 BMA Crystal Coast, shall materially comply with all representations made in the certificate of need application and in the supplemental information requested by the Certificate of Need Section. In those instances where representations conflict, Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Crystal Coast, shall materially comply with the last-made representation.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast, shall develop and operate no more than three additional stations for a total of 13 certified following completion of this project and Project ID# P-10051-12, FMC Sea Spray, which shall include any isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast, shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 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, pages 53-54, the applicant states that there is no capital cost for the BMA Crystal Coast project. In Section IX.3, page 57, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project.

Exhibit 24 includes a letter dated September 15, 2013 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA proposes to add three dialysis stations to the BMA Crystal Coast dialysis facility. This project does not call for any capital expense on behalf of BMA.”

In Exhibit 10, the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. for the fiscal year ended December 31, 2011. As of December 31, 2011,

FMC had \$204,142,000 in cash and cash equivalents, \$13,864,539,000 in total assets and \$8,388,027,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 58, the applicant provides the allowable charges per treatment for each payment source for BMA Crystal Coast as follows:

BMA Crystal Coast	
Payor	Allowable Charge Per In-center Treatment
Commercial Insurance	\$1,375
Private Pay	\$1,375
Medicare	\$234
VA	\$147
Medicaid	\$137

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 (\$234). This fee 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 Section X.2-X.4, pages 59-62, the applicant projects revenues and expenses for BMA Crystal Coast as follows:

BMA Crystal Coast		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,223,565	\$2,397,643
Total Operating Costs	\$2,061,080	\$2,170,296
Net Profit	\$162,485	\$227,347

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 59-62, for the applicant’s assumptions.

In summary, the applicant states that there are no capital and working capital costs for this project. 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.

three dialysis stations to its existing facility for a total of 13 stations upon project completion. Currently BMA Crystal Coast is the only kidney disease treatment center located in Carteret County, as per the January 2013 SDR. Upon completion of CON Project ID# P-10051-12, FMC Sea Spray, a second dialysis facility will be developed by the applicant by relocating 10 of its 20 certified dialysis stations from BMA Crystal Coast in Morehead City to establish a new facility in Cape Carteret).

The January 2013 SDR shows there is a deficit of one dialysis station in Carteret 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 BMA Crystal Coast based on the proposed number of in-center patients. Per the January 2013 SDR, as of June 30, 2012, the 20 station BMA Crystal Coast facility was operating at 87.5% capacity ($70 / 20 = 3.5$; $3.5 / 4 = .875$ or 87.5%). The target utilization 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 54 patients at the end of Year 1 (7/1/2013-6/30/2015) which is a utilization rate of 100% ($54 / 13 = 4.15$; $4.15 / 4 = 1.038$ or 100%). Therefore, the applicant is conforming to the requirement in 10A NCAC 14C .2203.

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

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

C

In Section VII.1, page 50, the applicant provides projected staffing for BMA Crystal Coast upon project completion, as illustrated in the following table:

BMA Crystal Coast Full-Time Equivalent (FTE) Positions	
RN	3.00
Tech	8.00
Clinical Mgr.	1.00
Area Mgr.	.15
Dietician	.33
Social Worker	.33
Chief Tech	.10
Equip Tech	.70
In-Service	.20
Clerical	1.00
Total FTEs	14.81

The applicant projects a total of 14.8 FTE positions upon project completion and states on page 51 that there is no difficulty expected in recruiting staff. In Section VII.1, page 50, the applicant states that the RN and PCT to be added will be hired to work the evening shift. In Section VII.10, page 52, the applicant states that additional staff will be added as the census increases. In Section V.4, page 59, the applicant identifies the Medical Director for BMA Crystal Coast as W. Joseph Newman, MD. In Exhibit 21 the applicant provides a letter from Dr. Newman indicating 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.

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In Section V.1, page 39, the applicant lists the providers of the necessary ancillary and support services. Exhibits 16-18 contain documentation on service agreements. See also the BMA's response to 10A NCAC 14C .2204, Section II, pages 17-18. The applicant adequately demonstrates that necessary ancillary and support services are 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 45 the applicant states:

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

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Crystal Coast	1.4%	52.2%	84.1%	36.2%	39.1%

This Medicare percentage represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 84.1%* of the facility treatment reimbursement is from Medicare. * Confirmed by the applicant in clarifying information that the Agency requested of the applicant.

In Section, VI.1, page 46, the applicant provides the current and projected payor mix for BMA Crystal Coast. The applicant expects no change in the current payor mix once this project is implemented. The current payor mix is illustrated in the following table.

BMA Crystal Coast (current payor source)	
Source of Payment	In-center

Medicare	84.0%
Commercial Insurance	7.9%
VA	7.4%
Medicaid	0.5%
Other: Self/Indigent	0.2%
Total	100.0%

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.

	CY 2009 Total # of Medicaid Eligibles as % of Total Population *	CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Carteret County	17%	6.7%	19.7%
Statewide	14%	6.6%	19.5%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the BMA Crystal Coast Dialysis Center facility. In fact, only 5.8% of all newly diagnosed ESRD patients (incident ESRD patients) in North Carolina's Network 6 were under the age of 35.

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 and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

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

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

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks

comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010: “On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.” Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

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

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

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

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

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

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%

Other	219	2.3%
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Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicant demonstrates that medically underserved populations have adequate access to the services provided at BMA Crystal Coast. 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 49, the applicant states there have been no civil rights access complaints filed against BMA 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 46, the applicant provides the projected payor mix for the proposed services at BMA Crystal Coast, as shown in the table below. The applicant projects no change from the current payor mix BMA Crystal Coast.

BMA Crystal Coast (projected payor source)	
Source of Payment	In-center
Medicare	84.0%
Commercial Insurance	7.9%
VA	7.4%
Medicaid	0.5%
Other: Self/Indigent	0.2%
Total	100.0%

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 48, the applicant states,

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA 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 applicant adequately demonstrates that BMA Crystal Coast 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 41, the applicant states that Exhibit 19 includes a letter to the healthcare program chair of the Craven Community College, to include BMA Crystal Coast in its clinical rotation schedule for student nurses.

- (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

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Crystal Coast proposes to add three dialysis stations to its existing facility for a total of 13 stations upon project completion and completion of CON Project ID# P-10051-12, FMC Sea Spray (wherein the applicant will relocate 10 of its 20 certified dialysis stations from BMA Crystal Coast in Morehead City to establish a new facility - FMC Sea Spray in Cape Carteret).

The January 2013 SDR shows there is a deficit of one dialysis station in Carteret County; however, in this application, the applicant is applying for additional stations based on the

facility need methodology. According to the January 2013 SDR, BMA Crystal Coast is the only kidney disease treatment center located in Carteret County. Per the January 2013 SDR, as of June 30, 2012, the 20 station BMA Crystal Coast facility was operating at 87.5% capacity ($70 / 20 = 3.5$; $3.5 / 4 = .875$ or 87.5%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility.

In Section V.7, pages 43-44, 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 BMA Crystal Coast facility will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need, based on facility need, to add three dialysis stations for a total of 13 certified dialysis stations upon completion of the proposed project and Project ID# P-10051-12, FMC Sea Spray. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to BMA Crystal Coast 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 39-44), and VII. (pages 50-52), 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 45, the applicant states:

“It is clear that BMA Crystal Coast projects to provide service to historically underserved populations. It is BMA policy to provide all

services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

The applicant provides the following table to demonstrate that medically underserved populations will continue to have adequate access to BMA services, as illustrated below.

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
BMA Crystal Coast	1.4%	52.2%	84.1%	36.2%	39.1%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 84.1% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI, page 45, 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.

The applicant currently provides dialysis services at BMA Crystal Coast. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, BMA Crystal Coast 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 87.5% with 3.5 patients per station ($70 / 20 = 3.5$) as reported in the January 2013 SDR.

(2) Mortality rates;

-C- In Section II.1, page 10, the applicant provides the mortality rates as 14.1%, 21.4% and 13.0% for 2010, 2011 and 2012, 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 Crystal Coast does not have a home dialysis program. Patients who are candidates for home dialysis are referred to BMA Craven County, in New Bern.*"

(4) The number of transplants performed or referred;

-C- In Section II.1, page 10, the applicant states BMA Crystal Coast referred 16 transplants in 2011 and 102 in 2012. Two transplants were performed in 2011 and one in 2012.

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

-C- In Section II.1, page 10, the applicant states, "*BMA Crystal Coast has eight patients 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 76 hospital admissions in 2012, 103 of which were dialysis related and 66 that 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 2011 or 2012 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- BMA Crystal Coast is an existing facility. The applicant, however, provides a copy of the hospital affiliation agreement with CarolinaEast Medical Center in Exhibit 16.

(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- BMA Crystal Coast is an existing facility.

(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.

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

-C- See Exhibit 12 for a copy of the Emergency/Disaster Manual (which has policies and procedures for back-up electrical service in the event of a power outage) for BMA Crystal Coast.

(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.

(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 BMA Crystal Coast.*”

(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 12-14, and Section III.7, pages 33-35, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

BMA Crystal Coast				
County	Operating Year 1 2015	Operating Year 2 2016	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Carteret	54.4	58.6	100.0%	100.0%
Total	54.4	58.6	100.0%	100.0%

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- BMA Crystal Coast 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 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.*”

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- BMA Crystal Coast does not propose to establish a new End Stage Renal Disease 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- BMA Crystal Coast projects utilization of 4.155 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12-14, and Section III.7, pages 33-35.

(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 12-14, and Section III.7, pages 33-35. The applicant projects a 7.7% increase in its current Carteret County patient utilization using the county five year average annual change rate.

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 17, the applicant states, *“Patients will be referred to Carteret General Hospital.”*
- (2) maintenance dialysis;
- C- In Section II.1, page 17, the applicant states, *“The facility will provide in-center dialysis.”*
- (3) accessible self-care training;
- C- In Section II.1, page 17, the applicant states, *“Patients desiring self care training will be referred to the BMA Craven County facility for [sic] home training department for home training and follow-up care.”*
- (4) accessible follow-up program for support of patients dialyzing at home;
- C- In Section II.1, page 17, the applicant states, *“Patients desiring to dialyze at home will be referred to the BMA Craven County facility home training department for on [sic] home training and follow-up care. The BMA Craven County Home Training Department as a complete home training program.”*
- (5) x-ray services;
- C- In Section II.1, page 17, the applicant states, *“Patients will be referred to Carteret General Hospital.”*
- (6) laboratory services;
- C- In Section II.1, page 17, the applicant states, *“BMA provides on site laboratory services through contract with Spectra Labs.”* See Exhibit 18 for the laboratory services agreement with Spectra Laboratories.
- (7) blood bank services;
- C- In Section II.1, page 15, the applicant states, *“Patients in need of blood transfusion will be referred to Carolina East Medical Center.”*
- (8) emergency care;
- C- In Section II.1, page 18, 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 18, the applicant states, “*Patients in need of hospital admission will be referred to Carolina East Medical Center, at 2000 East Boulevard, Morehead City, N.C. 28561 [sic].*”

(10) vascular surgery for dialysis treatment patients;

-C- In Section II.1, page 18, the applicant states, “*Patients will be referred to Eastern Nephrology Access Center. Patients may also be referred to Coastal Surgical, 2203 Neuse Boulevard, New Bern, NC.*”

11) transplantation services;

-C- In Section II.1, page 18, the applicant states, “*BMA Crystal Coast has a transplant agreement with UNC Hospital.*” See Exhibit 17 for a copy of the transplant agreement with UNC Hospital.

(12) vocational rehabilitation counseling and services; and

-C- In Section II.1, page 18, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the Division of Vocational Rehabilitation of Carteret County*”

(13) transportation.

-C- In Section II.1, page 19, the applicant states, “*Transportation services will be provided by Carteret Area Rural Transit System, CARTS.*”

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 19, the applicant states that sufficient staffing for each shift is provided. BMA will add a third shift in the second year of operation at BMA Crystal Coast. In Section VII.2, page 51, 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 19, and Section VII.5, page 51, 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, 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 14 contains an outline of the training program and Exhibit 15 contains the outline of the continuing education information.