

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 28, 2013

PROJECT ANALYST: Jane Rhoe-Jones
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-10051-12 / Biomedical Applications of North Carolina, Inc d/b/a FMC Sea Spray / Develop FMC Sea Spray, a new dialysis facility, by relocating ten dialysis stations from BMA Crystal Coast in Morehead City for a total of ten certified dialysis stations upon project completion / 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 FMC Sea Spray, whose parent company is Fresenius Medical Care Holdings, Inc. (FMC), purposes to relocate ten existing certified dialysis stations from BMA Crystal Coast in Morehead City to FMC Sea Spray in Cape Carteret for a total of ten dialysis certified stations at FMC Sea Spray upon completion of the project. In addition to an isolation station, the new facility will offer home training and support for peritoneal dialysis and home hemodialysis. Both the current and proposed facilities are in Carteret County. The applicant does not propose to add new dialysis stations. Therefore, neither the county or facility need methodologies in the 2012 State Medical Facilities Plan (SMFP) are applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a facility pursuant to a need determination in the 2012 SMFP. However, Policy ESRD-2: Relocation of Dialysis Stations, on page 33, is applicable to this review. The policy states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of Need applicants

proposing to relocate dialysis stations shall:

- (A) *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- (B) *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate ten existing dialysis stations within Carteret County. Consequently, there is no change in the dialysis station inventory in Carteret County, therefore, the application is consistent with Policy ESRD-2 and 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. (BMA) d/b/a FMC Sea Spray, proposes to relocate ten existing dialysis stations from BMA Crystal Coast in Morehead City to FMC Sea Spray for a total of ten certified dialysis stations at FMC Sea Spray upon completion of the project. In addition to an isolation station, the new facility will offer home training and support for peritoneal dialysis and hemodialysis. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. In Section II.7, page 13, the applicant states:

“The BMA Crystal Coast facility can not be easily expanded. The current facility does not have space for home training.”

Population to be Served

In Section III.7, page 50, the applicant projects the number of in-center and home dialysis patients to be served in the first two years of operation following project completion, as illustrated in the following table:

County	Operating Year 1			Operating Year 2			County Patients as % of Total	
	In-Center	Home		In-Center	Home		Year 1	Year 2
		Home Hemodialysis	Peritoneal Dialysis		Home Hemodialysis	Peritoneal Dialysis		
Carteret	28	9	5	30	9	5	91.3%	91.7%
Craven	3	0	0	3	0	0	6.5%	6.2%
Onslow	1	0	0	1	0	0	2.2%	2.1%
TOTAL	32	9	5	34	9	5	100%	100%

In Section II.7, pages 13-17 and in Section III.7, pages 47-51, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize the FMC Sea Spray facility, as follows:

“This project is scheduled for completion and certification at June 20, 2014. Operating Year 1 is the period from July 1, 2014 through June 30, 2015. Operating Year 2 is the period from July 1, 2015 through June 30, 2016.

As of June 30, 2012 BMA Crystal Coast was providing in-center dialysis for 70 dialysis patients. Those patients reside in the following counties:

BMA Crystal Coast In-center Dialysis	
County	June 30, 2012 Census
Carteret	66
Craven	3
Onslow	1
Total	70

BMA projects that 30 in-center patients will transfer their care to the new facility upon certification of the stations.

BMA projects that all of the home patients of Carteret County will transfer their care to the new facility due to patient convenience issues. [home training is currently provided at FMC Craven County]. FMC Craven County is approximately 37 miles from the BMA Crystal Coast facility. However, the proposed FMC Sea Spray is only 20 miles from BMA Crystal Coast. Patients generally choose a location which is closer. In this case the difference is as much as 34 miles round trip. ...

...

BMA will project the home patient population to increase commensurate with the Carteret County five year average annual change rate. Subsequent to growth projections, BMA assumes that 63.6% of the forecasted patients will dialyze via home hemo-dialysis [sic] and 36.4% of the patients will be peritoneal dialysis patients.

BMA will project changes for the Carteret County patient population only. BMA will project growth of this patient population at a rate commensurate with the Carteret County five year average annual change rate as published in the July 2012 SDR. That rate is 7.7%.

Both Craven and Onslow Counties have dialysis facilities. Thus BMS assumes that the patients from Craven and Onslow Counties are dialyzing at BMA Crystal Coast as a function of patient choice. However, BMA also projects these patients to transfer to the new facility in Cape Carteret as the new facility will be closer to the patient residence location.

- a) For example, the patient from Onslow County would actually drive past the proposed location to reach the BMA Crystal Coast facility. In as much as the patient will have the same physician and dialysis will be delivered in the same manner, BMA assumes that the patient will choose the closer location.*
- b) Similarly, BMA believes that the patients from Craven County would transfer to the new facility based upon a shorter commute and thus patient convenience.*
- c) BMA will add the patients from Onslow and Craven Counties at appropriate points in time.*

BMA will not project any increase in the patient populations residing in Onslow or Craven Counties (total, four in-center patients). Rather BMA assumes that those patients will choose to dialyze with the FMC Sea Spray facility upon certification of the facility. BMA will add these patients to the projected census at the appropriate points in time.”

The applicant adequately identifies the population to be served.

Need Analysis

In Section III.3, page 39, the applicant states that cost containment is a key factor for this project. This project, the applicant states, also affords BMA the opportunity to provide home training to residents of Carteret County in Carteret County. The applicant also states geographic access is an additional key factor in developing this project. The applicant discusses the number of end stage renal disease patients residing in western Carteret County (which lacks dialysis options) who utilize BMA Crystal Coast. BMA provides maps on pages 28-29, 40-41 and 44-45, which illustrate the options for dialysis care in the service area which is comprised of Carteret, Craven, Greene and Onslow counties.

Exhibit 22 of the application contains over 40 support letters from patients indicating that FMC Sea Spray is closer to their residence and they are willing to consider transferring to FMC Sea Spray. The letters of support state in part:

“Patients on dialysis have many hardships, especially arranging transportation three days per week. The proposed location for the new FMC Sea Spray facility is much more convenient for me and is closer to my home. Dialyzing at FMC Sea Spray would mean less time involved in transportation and more time for me, and my needs.”

In Section II.7, page 15 and III.7, page 48, the applicant states:

“BMA will project changes in the Carteret County patient population only. BMA will project growth of this patient population at a rate commensurate with the Carteret County five year average annual change rate as published in the January 2012 SDR. That rate is 7.7%.”

The following tables from page 16-17 and 40-50, illustrate the applicant’s assumptions and methodology used to project the utilization at FMC Sea Spray for in-center and home dialysis patients.

FMC Sea Spray In-Center Dialysis	
BMA begins with the patient population of Carteret County projected to transfer to the new facility upon certification of the stations, June 30, 2014.	26
BMA projects this population forward for one year to June 30, 2015. This is the end of Operating Year 1.	$(26 \times .077) + 26 = 28$
BMA adds the four patients from Craven and Onslow counties. This is the projected ending census for Operating Year 1.	$28 + 4 = 32$
BMA again projects the Carteret patient population forward one year to June 30, 2016.	$(28 \times .077) + 28 = 30$
BMA adds the four patients from Craven and Onslow counties. This is the projected ending census for Operating Year 2.	$30 + 4 = 34$

The applicant projects to serve 32 in-center patients by the end of Year One or 3.2 patients per station [$32/10 = 3.2$]; and 34 in-center patients by the end of Year Two or 3.4 patients per station [$34/10 = 3.4$]. The projected utilization rate is 80% at the end of Year One [$32/(4 \times 10) = 0.80$] and 85% in Year Two [$34/(4 \times 10) = 0.85$]. Projected in-center utilization at FMC Sea Spray is based on reasonable, credible and supported assumptions.

FMC Sea Spray Home Dialysis	
BMA begins with the home dialysis patient population of Carteret County as of December 31, 2011 (based upon the July 2012 SDR). (These patients must use facilities in	

other counties.)	11
BMA projects this population forward for six months to June 30, 2012.	$[11 \times (.077/12 \times 6)] + 11 = 11$
BMA projects this population forward for 12 months to June 30, 2013.	$(11 \times .077) + 11 = 12$
BMA projects this population forward for 12 months to June 30, 2014, which is the date FMC Sea Spray is expected to open.	$(12 \times .077) + 12 = 13$
BMA projects this population forward for 12 months to June 30, 2015. This is the end of Operating Year 1.	$(13 \times .077) + 13 = 14$
BMA projects this population forward for 12 months to June 30, 2016. This is the end of Operating Year 2.	$(14 \times .077) + 14 = 15$

The applicant projects to serve 14 home dialysis patients by the end of Year One and 15 home dialysis patients by the end of Year Two. Projected home dialysis utilization at FMC Sea Spray is based on reasonable, credible and supported assumptions.

The applicant adequately identifies the population to be served and adequately demonstrates the need the population to be served has for the proposed facility. 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.

C

The applicant proposes to transfer ten existing dialysis stations from BMA Crystal Coast to FMC Sea Spray. In Section III, pages 42-44, the applicant discusses how the needs of dialysis patients at BMA Crystal Coast will continue to be met after the transfer of stations. BMA Crystal Coast is currently certified for 20 dialysis stations and will have 10 stations at the conclusion of this project.

In Section II, page 13, the applicant states:

“BMA is proposing to develop a new 10 station dialysis facility. The facility will offer in-center dialysis and home training and support for peritoneal and home hemodialysis [sic].

The BMA Crystal Coast facility is the current location of the proposed home program. BMA had an approved CON to add six dialysis stations to BMA Crystal Coast, CON Project ID# P-8598-10 (See July 2012 SDR, Table A). However, ... BMA elected to surrender that CON and pursue a course of action designed to enhance access to care for the dialysis patient population of Carteret County. BMA will file a CON application in September 2012 seeing to add three dialysis stations to

BMA Crystal Coast via Facility Need methodology.

The BMA Crystal Coast facility can not be easily expanded. The current facility does not have space for home training. BMA considered both of these factors in making the decision to split the BMA Crystal Coast facility and bring home therapies to Carteret County.”

In Section III, page 42, the applicant states:

“... In order to demonstrate the effects upon the remaining patient population BMA must project the facility census forward to the point of the projected certification of this project, June 30, 2014.

In projecting the patient population forward BMA will begin with the patient population of BMA Crystal Coast as of June 30, 2012. BMA notes that four patients were residents of either Craven County (three) or Onslow County (one). BMA will not project these patient populations to increase. Both Craven and Onslow Counties have dialysis facilities. Thus, BMA believes that these patients are dialyzing at BMA Crystal Coast as a function of patient choice. Further, BMA has projected that these patients would transfer to the new facility upon certification of the project.”

BMA Crystal Coast	
BMA begins with the Carteret County patients at BMA Crystal Coast as of June 30, 2012.	66
BMA projects this patient population forward for one year to June 30, 2013.	$(66 \times .077) + 66 = 71$
BMA projects this patient population forward for another year to June 30, 2014. This is the projected certification date of this project.	$(71 \times .077) + 71 = 77$
At this point BMA subtracts the 26 Carteret patients projected to transfer to the new facility. This is the census projected to be remaining at the BMA Crystal Coast facility.	$77 - 26 = 51$

Thus, the applicant projects to serve 51 in-center patients by June 30, 2014 at BMA Crystal Coast. This is a utilization rate of five patients per station [$51/10 = 5.1$].

The applicant states:

“BMA recognizes that utilization rates exceeding four patients per station necessarily result in an evening dialysis shift. Evening dialysis is not always favorable for the patient.

In this case, BMA notes that the BMA Crystal Coast dialysis facility does qualify for additional dialysis stations through Facility Need methodology.”

The following table illustrates the number of stations BMA of Crystal Coast could have applied for in the October 1, 2012 review if BMA had chosen to do so.

Assuming an October 1 Review	
Required SDR Utilization	80%

Center Utilization Rate as of 12/31/2011		85.0%
Certified Stations		20
Pending Stations		0
Total Existing and Pending Stations		20
In-Center Patients as of 12/31/2011 (SDR2)		68
In-Center Patients as of 6/30/2011(SDR1)		65
Step	Description	
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change.	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/11	0.0923
(ii)	Divide the result of Step (i) by 12	0.0077
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/10 to 12/31/11)	0.0923
(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	74.2769
(v)	Divide the result of Step (iv) by 3.2 patients per station	23.2115
	and subtract the number of certified and pending stations as recorded in SDR2 [20] to determine the number of stations needed	3

The applicant further states:

“As the calculations demonstrate, BMA Crystal Coast can apply for up to three dialysis stations ... BMA will apply for three stations. BMA will project these stations to be certified effective June 30, 2014, the same date as certification of the Sea Spray project. Thus BMA would have 13 dialysis stations at BMA Crystal Coast. Utilization is then a function of 51 patients dialyzing on 13 stations. The result is 3.9 patients per station. The above demonstrates that no patient would be adversely affected by the relocation of these 10 stations to FMC Sea Spray.”

Effective March 7, 2011, BMA Crystal Coast was authorized to add six stations for a total of 26 stations. By letter dated September 17, 2012, BMA relinquished that certificate in order to be able to file the present application instead. BMA will be able to file a CON application if necessary to expand BMA Crystal Coast. This project does not reduce the total number of stations in Carteret County; it merely splits them into two separate facilities owned and operated by the same provider.

The applicant demonstrates that the needs of the population presently served at BMA Crystal Coast will be adequately met following relocation of ten stations to FMC Sea Spray. Therefore, the application is conforming to this criterion.

- (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.

In Section III.9, pages 51-52, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo. This was not considered a viable alternative. The applicant states due to space constraints, the current facility cannot be expanded to offer home dialysis training and support in Carteret County. Home training is not available for residents of Carteret County in Carteret County. Furthermore, the applicant states BMA Crystal Coast is not readily accessible to the growing population of dialysis patients residing in western Carteret County.
- 2) Add six stations to BMA Crystal Coast. This was not considered a viable alternative. The applicant states in Section III, page 39, that it would have been more expensive to add six stations at \$81,000 per station than to develop the ten-station FMC Sea Spray facility at \$68,000 per station.
- 3) Relocate BMA Crystal Coast. This was not considered a viable alternative. The applicant states patients live in a wide geographic area that would have made it difficult to find an appropriate location which is readily accessible to all residents of Carteret County.
- 4) Transfer 10 stations to develop the FMC Sea Spray facility. In Section III, page 52, the applicant states this alternative will meet the needs of *“a growing patient population. ... the wide ranging residence locations of the dialysis patients of BMA warrant development of the new facility. Further, the new facility will be able to offer home dialysis training and support which can not be offered from the BMA Crystal Coast facility. Relocation of the peritoneal dialysis program is the most cost efficient method of meeting the needs of the ESRD patient population of the area.”* In addition, the applicant states this alternative is more cost effective than adding six stations to BMA Crystal Coast as discussed in Alternative 2 above.

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Sea Spray shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Sea Spray shall install plumbing and electrical wiring through the walls for no more than ten certified stations which shall include any home hemodialysis training and isolation stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify ten stations at BMA Crystal Coast for a total of no more than ten certified dialysis stations at BMA Crystal Coast upon project completion.**

4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Sea Spray 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 69-70, the applicant states that the capital cost is projected to be \$1,369,725, as shown below in the table.

FMC Sea Spray Capital Costs	
Construction Contract	\$ 966,309
(RO) Water Treatment Equipment	50,570
Equipment/Furniture	188,411
Architect/Engineering Fees	74,368
Contingency	90,067
Total Capital Costs	\$1,369,725

In Section IX.3, page 76, the applicant projects that the total working capital (start-up and initial operating expenses) associated with the proposed project will be \$1,229,890, as shown below in the table.

FMC Sea Spray Total Working Capital	
Start Up Expenses	\$23,837
Initial Operating Expenses	\$1,206,053
Total Working Capital	\$1,229,890

Exhibit 24 includes a letter dated September 17, 2012 from the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“As Vice President, I am authorized and do hereby authorize the relocation of these stations and development of the new FMC Sea Spray dialysis facility for capital costs of \$1,369,725. Further, I am authorized and do hereby authorize and commit all necessary cash and cash reserves for the start up and working capital which may be needed for this project.”

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 77, the applicant provides the allowable charges per treatment for each payment source for BMA Crystal Coast as follows:

BMA Crystal Coast	
Payor	Charge Per treatment (in-center and home)
Commercial Insurance	\$1,375
Medicare	\$234
Medicaid	\$137
VA	\$193

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 78-83, the applicant reports projected revenues and expenses for FMC Sea Spray as follows:

FMC Sea Spray		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,082,415	\$2,177,875
Total Operating Costs	\$1,809,080	\$1,893,863
Net Profit	\$273,335	\$284,012

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 of the application for the applicant’s assumptions.

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Sea Spray proposes to relocate ten existing certified dialysis stations from BMA Crystal Coast in Morehead City to establish a new facility (FMC Sea Spray) in Cape Carteret. BMA Crystal Coast is the only kidney disease treatment center located in Carteret County with 20 certified stations. This proposal would split the existing stations into two 10-station facilities. The new facility, FMC Sea Spray would provide a more convenient location for some of the residents now

using BMA Crystal Coast. The proposal will not result in an increase in the number of certified dialysis stations located in Carteret County. The applicant also proposes to offer peritoneal and hemodialysis home training, a service not currently offered in Carteret County due to space constraints at BMA Crystal Coast.

Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant discusses projections for the in-center patient population in Section II.7, pages 13-17, and Section III.7, pages 47-51, of the application. The applicant projects to serve 32 in-center patients at FMC Sea Spray by the end of Year One or 3.2 patients per station [$32/10 = 3.2$]; and 34 in-center patients by the end of Year Two or 3.4 patients per station [$34/10 = 3.4$]. The projected utilization rate is 80% at the end of Year One [$32/(4 \times 10) = 0.80$] and 85% in Year Two [$34/(4 \times 10) = 0.85$]. The growth projections are based on Carteret County projected average annual growth rate in the number of dialysis patients. Projected utilization at FMC Sea Spray is based on reasonable and supported assumptions. Furthermore, utilization at BMA Crystal Coast following project completion is also expected to remain high. The 20 existing stations are expected to remain well utilized after being divided into two 10-station facilities.

The applicant adequately demonstrates the need to relocate ten dialysis stations from BMA Crystal Coast and develop the proposed FMC Sea Spray. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved certified dialysis stations 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 66, the applicant provides projected staffing for FMC Sea Spray upon project completion, as illustrated in the following table:

FMC Sea Spray	
Full-Time Equivalent (FTE) Positions	
RN	1.75
Tech	4.5
Clinical Mgr.	1.00
Area Mgr.	.15
Dietician	.30
Social Worker	.30
Home Training Nurse	1.00
Medical Records	.50
Chief Tech	.10
Equip Tech	.20
In-Service	.20
Clerical	.50

Total FTEs	10.50
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The applicant projects a total of 10.5 FTE positions upon project completion and states on page 67 that there is no difficulty expected in recruiting staff. In Section V.4, page 59, the applicant identifies the Medical Director for FMC Sea Spray as W. Joseph Newman, MD. In Exhibit 21 the applicant provides a letter from Dr. Newman indicating his willingness to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 55, the applicant lists the providers of the necessary ancillary and support services. Exhibits 16-19 contain documentation on service agreements. 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.

C

In Section XI, pages 85-92, the applicant discusses the site for the proposed FMC Sea Spray dialysis facility and states it plans to lease space for the proposed new facility.

The applicant states that the site is close to NC Highway 24, the main highway through Cape Carteret; and also convenient to the dialysis patients living in western Carteret County. On page 90, the applicant states the facility will be 7,656 square feet with energy saving features as described on page 89. The applicant projects the construction upfit cost will be \$966,309 and architect and engineering fees will be \$74,368, which is a total of \$1,040,677. Thus, the per square foot cost is projected to be \$136 ($\$1,040,677 / 7,656 = \136). See Section VIII.1, pages 69-70 and Section XI.6(h), page 90. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 90:

FMC Sea Spray	
Facility Area	Estimated Total Sq. Ft.
Ancillary Areas:	
Administration	1037
Public Lobby	416
Mechanical Equipment	75
Housekeeping	37
General Storage	788
Exam/Treatment	114
Staff Lounge	210
RO	250
Other: Toilets/Circulation/Med Waste	1934
Sub-Total Support	4,861
Treatment Areas:	
Nurses Station (incl in overall treatment area space)	0

Dialysis Stations	2,130
Patient Home Training	4,77
Isolation Room(s)	132
Other: Med/Lab Prep	2,386
Sub-Total Treatment	2,795
Total Square Feet	7,656

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed dialysis services if the project were approved. Therefore, the application is conforming to this criterion.

(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 61 the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. The patient population of the FMC Sea Spray Program facility is expected to be similar to the BMA Crystal Coast home [sic] program and will likely be comprised of the following:

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC Sea Spray	28.6%	52.9%	87.1%	31.4%	40.0%

This Medicare percentage represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 87.1% of the facility treatment reimbursement is from Medicare.

In Section VI.1., page 62, the applicant states that the projected payor mix at FMC Sea Spray is the same as the current payor mix for BMA Crystal Coast. Also in Section, VI.1., page 62, the applicant provides the projected payor mix for FMC Sea Spray which is illustrated in the following table. The Project Analyst assumes this is also the current payor mix at BMA Crystal Coast.

FMC Sea Spray (projected payor source)		
Source of Payment	In-center	Home

Medicare	84.5%	91.9%
Commercial Insurance	7.4%	4.1%
VA	7.3%	4.0%
Medicaid	0.7%	0.0%
Total	100.0%	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 FMC Sea Spray 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%

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 64, 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 62, the applicant provides the projected payor mix for the proposed services at FMC Sea Spray, as shown in the table below. The applicant projects no change from the current payor mix BMA Crystal Coast.

FMC Sea Spray (projected payor source)
--

Source of Payment	In-center	Home
Medicare	84.5%	91.9%
Commercial Insurance	7.4%	4.1%
VA	7.3%	4.0%
Medicaid	0.7%	0.0%
Total	100.0%	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 63, the applicant states,

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

The applicant adequately demonstrates that FMC Sea Spray 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 58, the applicant states that Exhibit 19 includes a letter from FMC’s director of operations, inviting the Carteret Community College Department of Nursing to include FMC Sea Spray in its clinical rotation schedule for student nurses. The applicant also states that other BMA facilities have such relationships with similar training programs and it is expected that FMC Sea Spray will as well.

The information provided in Section V.3 is reasonable and credible for a new 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 transfer ten dialysis stations from BMA Crystal Coast (the existing 20-station facility) to FMC Sea Spray (the new 10-station facility), for a total of ten certified stations at both facilities upon completion of the proposed project. BMA is the sole provider of dialysis services in Carteret County. FMC Sea Spray will offer home training and support for peritoneal dialysis and hemodialysis; not currently provided in Carteret County. The utilization rate at BMA Crystal Coast currently exceeds 81%.

In Section V.7, page 60, 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 in part:

“BMA does not expect this proposal to have any effect on the competitive environment within Carteret County. At the present time the only provider of dialysis services within the County is BMA. The facility will have added value stemming from the strength of our relationship with the nephrology physicians already referring to BMA at the BMA Crystal Coast dialysis facility.

BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that 85.3% of the patients will be relying upon Medicare and Medicaid. The facility must capitalize upon every opportunity for efficiency.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need to relocate ten dialysis stations to Cape Carteret and to offer home training for hemodialysis and peritoneal dialysis. The

applicant also adequately demonstrates that the proposed project is a cost-effective alternative to meet the need.

- 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.1, V.2, V.4, V.5 and VII is reasonable and credible and demonstrates the provision of quality services.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. In Section VI.1, page 61 the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. The patient population of the FMC Sea Spray Program facility is expected to be similar to the BMA Crystal Coast home [sic] program and will likely be comprised of the following:

Facility	Medicaid/ Low Income	Elderly (65+)	Medicare	Women	Racial Minorities
FMC Sea Spray	28.6%	52.9%	87.1%	31.4%	40.0%

This Medicare percentage represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 87.1% of the facility treatment reimbursement is from Medicare.

... 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 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, as promulgated in 10A NCAC 14C .2200, are applicable to this review. The application is conforming to all applicable criteria which are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

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

-C- See Section II.1, pages 11-12, and Section IV, pages 53-54, and Exhibit 2 (copy of the July 2012 SDR, Tables A and B). As of June 30, 2011, the utilization rate was 81.3% at BMA Crystal Coast.

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

-C- See Section II.1, page 11, and Section IV, page 53. The mortality rates for BMA Crystal Coast were 22.7% in 2009, 18.3% in 2010, and 21.4% in 2011.

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

-C- See Section II, page 11, and Section IV, page 53. Home training is proposed in this application. BMA Crystal Coast does not offer home training. Patients desiring home training are referred to FMC Craven County in New Bern.

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

-C- See Section II, page 11, and Section IV, page 53. In 2011 there were 16 transplant referrals and two transplants performed.

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

-C- See Section II, page 11, and Section IV, page 54. There are 15 patients on the transplant waiting list.

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

-C- See Section II, page 12 and Section IV, page 54. In 2011 there were 90 hospital admissions; none of which were dialysis related.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- See Section II, page 12, and Section IV, page 54. The applicant reported no patients with infectious diseases and no infectious disease conversions.

(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.*

-C- See Exhibit 16 for a letter of intent to sign a written agreement between FMC Sea Spray and CarolinaEast Medical Center, in New Bern.

.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.*

-C- See Exhibit 17 for a copy of the transplantation agreement with Duke University Medical Center.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-C- See Exhibit 30 for documentation that power and water will be available at the primary site located at 400 Taylor Notion Road, Cape Carteret. See also Exhibit 31 for documentation that power and water will be available at the secondary site located at 904 and 906 WB McLean Boulevard, Cape Carteret.

.2202(b)(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 the emergency disaster manual; which includes a section on power failure.

.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.*

-C- See Exhibit 30 for documentation that the primary site located at 400 Taylor Notion Road, Cape Carteret is available for a build to suit lease to FMC. See Exhibit 31 for documentation that the current owner of the secondary site located at 904 and 906 WB McLean Boulevard, Cape Carteret, is willing to sub-divide the property and sell it to FMC. That applicant states that if the primary site is not available once the CON application is approved, then BMA will pursue the secondary site. The applicant also states that the two sites are located in the same parcel of land.

.2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Section II, page 13, Section VII, page 67, Section XI.6(g), page 90, and Exhibits 11 and 12. In Section II, page 13, the applicant states, “BMA will provide all services approved by the [sic] Certificate of Need in conformity with applicable laws and regulations. ...”

.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, pages 13-7, and Section III.7, page 50, FMC Sea Spray provides projected patient origin which is based on historical experience at BMA Crystal Coast, as shown in the below table:

FMC SEA SPRAY								
County	Operating Year 1			Operating Year 2			County Patients as % of Total	
	In-Center	Home		In-Center	Home		Year 1	Year 2
		Home Hemo-dialysis	Peritoneal Dialysis		Home Hemo-dialysis	Peritoneal Dialysis		
Carteret	28	9	5	30	9	5	91.3%	91.7%
Craven	3	0	0	3	0	0	6.5%	6.2%

Onslow	1	0	0	1	0	0	2.2%	2.1%
TOTAL	32	9	5	34	9	5	100%	100%

.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.*

-C- In Section II, page 18, the applicant provides a map of the service area and states: “BMA reasonably expects that greater than 100% of the patient population of the facility resides within 30 miles of the facility. Thirty miles from the primary location for FMC Home Dialysis covers the majority of Carteret. Cape Carteret is situated on the western side of Carteret County. To the extent that some patients on the far eastern side of Carteret County would have to travel further than 30 miles, BMA notes that those patients would also have to bypass the BMA Crystal Coast facility in order to reach the proposed facility. Thus, BMA does not expect to serve patients from the far eastern end of the county.”

.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, page 18, 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.*

-C- In Section II, page 19, the applicant states: “BMA has proposed to relocate 10 dialysis stations to the new location. Further, BMA has proposed to serve 32 in-center patients at the end of the first operating year. This equates to a utilization of 3.2 patients per station.” See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

.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.

-NA- FMC Sea Spray is a new ESRD facility.

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

-C- In Section II, pages 14-17 and 19-23, and Section III, pages 39-52, 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- In Section V, page 55, the applicant states that diagnostic and evaluation services will be provided by CarolinaEast Medical Center or Carteret General Hospital.

.2204(2) *Maintenance dialysis;*

-C- In Section V, page 55, the applicant states that maintenance dialysis will be provided at FMC Sea Spray.

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

-C- In Section II, pages 14 and 24, and Section V, page 55, the applicant states that accessible self-care training will be provided at FMC Sea Spray.

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

-C- In Section II, page 24, the applicant states that an accessible follow-up program for support of patients dialyzing at home will be provided by FMC Sea Spray. The applicant also states that FMC Sea Spray will offer both peritoneal and home hemodialysis training and support.

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

-C- In Section V, page 55, the applicant states that X-ray services will be provided by CarolinaEast Medical Center or Carteret General Hospital.

.2204(6) *Laboratory services;*

-C- In Section V, page 55, the applicant states that laboratory services will be provided on the FMC Sea Spray premises by SPECTRA.

- .2204(7) *Blood bank services;*
-C- In Section V, page 55, the applicant states that blood bank services will be provided by CarolinaEast Medical Center.
- .2204(8) *Emergency care;*
-C- In Section V, page 55, the applicant states, “All BMA staff trained to respond and fully stocked crash cart available; Ambulance transport to local Hospital.”
- .2204(9) *Acute dialysis in an acute care setting;*
-C- In Section V, page 55, the applicant states that acute dialysis in an acute care setting will be provided by CarolinaEast Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients*
-C- See Section V, page 55, the applicant states, “Eastern Nephrology Associates Vascular Access Center; Coastal Surgical will provide vascular surgery.”
- .2204(11) *Transplantation services;*
-C- In Section V, page 55, the applicant states that transplantation services will be provided by Duke University Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
-C- In Section V, page 55, the applicant states that referrals will be made to Carteret County Vocational Rehabilitation for vocational rehabilitation counseling and services.
- .2204(13) *Transportation*
-C- In Section V, page 55, the applicant states that transportation will be provided by Carteret County Area Transportation System.

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- See Section II, page 25. Also, in Section VII, page 66, the applicant provides the proposed staffing. The applicant states on page 67 that the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. 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- In Section II, page 25 and Section VII, page 67, the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 14 contains the training outline and Exhibit 15 contains the outline for continuing education programs.