

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 14, 2020

Findings Date: April 14, 2020

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: P-11840-20

Facility: FMC Sea Spray

FID #: 120486

County: Carteret

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Relocate no more than 2 dialysis stations from Crystal Coast Dialysis Unit for a total of no more than 12 in-center and home hemodialysis stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to relocate two dialysis stations from Crystal Coast Dialysis Unit (Crystal Coast) to FMC Sea Spray for home hemodialysis training and support services. Upon project completion, FMC Sea Spray will have a total of 12 certified dialysis stations for in-center and home hemodialysis training and support. Crystal Coast will have 19 certified dialysis stations upon completion of this project and Project ID #P-11665-16 (add five stations for a total of 21 stations). Both facilities are located in Carteret County and share BMA, Inc. as a parent company.

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis

stations. According to Table 9D, page 170 of the 2020 SMFP, the county need methodology shows there is no county need determination for additional dialysis stations in Carteret County. Table 9E: Dialysis Station Need Determination by Facility, page 171, shows a facility need determination for one station at FMC Sea Spray; however, this application is not based on the facility need methodology. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

There is one policy in the 2020 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2, on page 20 of the 2020 SMFP states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing 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 State Medical Facilities Plan, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing 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 State Medical Facilities Plan.”*

Both FMC Sea Spray and Crystal Coast are located in Carteret County; thus, the inventory of dialysis stations will not change in Carteret County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion because the relocation of dialysis stations within Carteret County will have no effect on the number of dialysis stations within the county.

- (2) Repealed effective January 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.

CA

The applicant proposes to relocate two dialysis stations from Crystal Coast to FMC Sea Spray. FMC Sea Spray will have a total of 12 certified in-center and home hemodialysis stations at project completion. The applicant states its intent to use the two relocated stations exclusively for home hemodialysis training and support services. FMC Sea Spray is the only provider of home hemodialysis and peritoneal training and support services in Carteret County. Crystal Coast does not provide home training and support services. Crystal Coast will have 19 certified in-center dialysis stations upon completion of this project and Project ID #P-11665-16 (add five stations for a total of 21 stations).

The following tables, summarized from Section A.4, page 8 of the application, show the existing and proposed number of dialysis stations at FMC Sea Spray and Crystal Coast.

FMC Sea Spray		
Stations	Description	Project ID #
10	Total existing certified stations as of December 31, 2018, per 2020 SMFP	
+2	Stations to be added as part of this project	P-11840-20
12	Total stations upon completion of above project	

Crystal Coast		
Stations	Description	Project ID #
16	Total existing certified stations as of December 31, 2018, per 2020 SMFP	
-2	Stations to be deleted as part of another project	P-11840-20
+5	Stations approved to be added but not yet certified	P-11665-19
19	Total stations upon completion of above projects	

As shown in the tables above, upon project completion, FMC Sea Spray will be certified for 12 dialysis stations; and Crystal Coast will be certified for 19 dialysis stations upon completion of this project and Project ID #P-11665-19 (add five stations for a total of 21 stations).

Patient Origin

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” Both facilities involved in this review are located in Carteret County. Thus, the service area for this application is Carteret County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 18, the applicant provides historical patient origin for FMC Sea Spray for in-center (IC), home hemodialysis (HH), and peritoneal (PD) dialysis patients as of December 31, 2019, as follows:

County	# In-Center Patients	% of Total IC	# HH Patients	% of Total HH	# PD Patients	% of Total PD
Carteret	16	50.00%	4	44.44%	8	47.06%
Craven	2	6.25%	2	22.22%	5	29.41%
Guilford	1	3.13%	0	0.00%	0	0.00%
Jones	1	3.13%	0	0.00%	0	0.00%
Onslow	9	28.13%	3	33.33%	4	23.53%
Wake	1	3.13%	0	0.00%	0	0.00%
Other States	2	6.25%	0	0.00%	0	0.00%
Totals	32	100.00%	9	100.00%	17	100.00%

Source: Section C.2, page 18
 Totals may not sum due to rounding

In Section C.3, page 19, the applicant provides a table showing projected patient origin for FMC Sea Spray in the second operating year (CY2022) following project completion, which is summarized below:

County	# IC Patients	% of Total IC	# HH Patients	% of Total HH	# PD Patients	% of Total PD
Carteret	20.2	57.91%	5.1	46.15%	10.1	49.78%
Craven	2.0	5.73%	2.0	18.27%	5.0	24.63%
Jones	1.0	2.87%	0.0	0.00%	0.0	0.00%
Onslow	11.7	33.49%	3.9	35.58%	5.2	25.59%
Totals	35.9	100.00%	10.9	100.00%	19.1	100.00%

Source: Section C.2, page 19
 Totals may not sum due to rounding

However, the totals for projected IC, HH, and PD patients in the table above appear to be miscalculated; thus, the percentages are also off somewhat, as shown in the table below, as calculated by the Agency.

County	# IC Patients	% of Total IC	# HH Patients	% of Total HH	# PD Patients	% of Total PD
Carteret	20.2	57.88%	5.1	46.36%	10.1	49.75%
Craven	2.0	5.73%	2.0	18.18%	5.0	24.63%
Jones	1.0	2.87%	0.0	0.00%	0.0	0.00%
Onslow	11.7	33.52%	3.9	35.45%	5.2	25.62%
Totals	34.9	100.00%	11.0	100.00%	20.3	100.00%

Source: applicant provided number of patients by county
 Totals may not sum due to rounding

As can be seen in the comparison of the two tables above, there is a calculation error in the total number of IC and PD patients. Thus, the percent of total patients by county is incorrect; however, the percent of total patients by county would not differ if rounded to the nearest whole number, therefore, the difference is insignificant.

In Section C, pages 19-22, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 23-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant explains the typical three day per week schedule for in-center patients to receive dialysis and states that failure to receive dialysis services will lead to patient death. In Section A, page 7, the applicant states that at the present time, FMC Sea Spray experiences an unusually high number of transient patients in summer months because of its vacation destination location. The applicant states that in order to serve patients choosing home dialysis, FMC Sea Spray must utilize one of its ten certified dialysis stations to provide home hemodialysis training and support services. Thus, serving patients who choose home hemodialysis inherently limits the number of in-center dialysis patients that can be served. The applicant further states that utilizing a single station for home hemodialysis training and support is not efficient and in a practical sense, limits training to one patient at a time, delaying a second patient’s training until the first patient has completed training.

On page 23, the applicant states:

“This application is primarily focused on relocating two dialysis stations to FMC Sea Spray to be utilized exclusively for home hemodialysis training and support.”

Home dialysis patients – PD and home hemodialysis – require the same regular dialysis treatment regimen. Home PD patients may dialyze on a continuing basis (Continuous Ambulatory Peritoneal Dialysis, or CAPD) or the patients may use a cyclor which is a machine that helps the patient to dialyze overnight. Home hemodialysis patients may use the traditional dialysis regimen of three treatments per week, or as is becoming more and more routine, the home hemodialysis patient may be dialyzing more frequently for shorter periods of time. Some home hemodialysis

patients may dialyze as often as six times per week, others may be doing five or four days per week. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.

...

Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient residence. The patient has total control of the treatment.

Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates.”

The applicant further states that approval of this application will allow BMA to relocate two certified dialysis stations from Crystal Coast, which they plan to use exclusively for home training and support of patients choosing home hemodialysis, enhancing patient training opportunities and ultimately allowing FMC Sea Spray to enable more patients to dialyze at home in a convenient setting, at times which are convenient for the patient.

On pages 24-25, the applicant discusses the nature of home hemodialysis training, stating that HH patients and their care givers are trained on a hemodialysis station for about six hours a day, four days a week, for about six weeks or 25 sessions prior to being discharged to perform hemodialysis at home. The applicant further states that FMC Sea Spray is the only home training program in Carteret County and that the facility has the existing available space to devote to home hemodialysis training in a separate home therapies suite above the in-center dialysis area (Exhibit K-2 Floor Plan). Thus, adding stations at the facility will solve the immediate problem of the limited capacity for home hemodialysis training in Carteret County and enhance patient quality of life by ensuring adequate resources are available to dialysis patients. As an additional consideration, the applicant notes (Section A, page 7) that on July 10, 2019, President Trump issued an Executive Order on Advancing American Kidney Health, which in part, encourages greater use of home dialysis by patients. The order says, “*Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis. ...*” The applicant states that since this announcement, there is a tremendous shift in referral trends within the Fresenius dialysis facilities, toward referrals for home dialysis.

The information is reasonable and adequately supported based on the following:

- The applicant adequately demonstrates the need the existing and proposed patients have for additional in-center and home hemodialysis training and support services.
- The applicant adequately demonstrates the need for additional capacity at FMC Sea Spray to provide adequate in-center and home hemodialysis services to dialysis patients in Carteret County.

Projected Utilization

In-Center

In Section Q, pages 75-76, the applicant provides the assumptions and methodology used to project in-center utilization. The assumptions are provided on page 75 and summarized below:

- The applicant begins the projections for FMC Sea Spray by using the December 31, 2019 in-center patient census: 16 Carteret County in-center patients and nine Onslow County in-center patients.
- The applicant projects the Carteret and Onslow county patient census at FMC Sea Spray will increase by the Carteret and Onslow county Five-Year Average Annual Change Rate (AACR) of 8.1 percent and 9.1 percent, respectively.
- The applicant assumes that the three patients from Craven and Jones counties will continue to dialyze at FMC Sea Spray and are added to the projections without any future growth.
- The applicant assumes that the four patients from Guilford, Wake and other states are transient patients and will not continue to dialyze at FMC Sea Spray in the future.
- Operating Year 1 (OY1) = January 1 through December 31, 2021 (CY2021).
Operating Year 2 (OY2) = January 1 through December 31, 2022 (CY2022).

On page 76, the applicant provides the projected utilization based on the above assumptions, as summarized in the following table:

	Carteret	Onslow
Begin with the Carteret and Onslow county in-center patients as of December 31, 2019.	16	9
Project the Carteret and Onslow county in-center patients forward to December 31, 2020 using the Carteret County AACR of 8.1% and the Onslow County AACR of 9.1%.	$16 \times 1.081 = 17.3$	$9 \times 1.091 = 9.8$
Sum the Carteret and Onslow county patients and add the three patients from Craven and Jones counties. This is the projected starting census for the project.	$17.3 + 9.8 + 3 = 30.1$	
Project the Carteret and Onslow county in-center patients forward one year to December 31, 2021 using the applicable AACR.	$17.3 \times 1.081 = 18.7$	$9.8 \times 1.091 = 10.7$
Sum the Carteret and Onslow county patients and add the three patients from Craven and Jones counties. This is the projected ending census December 31, 2021 (OY1).	$18.7 + 10.7 + 3 = 32.4$	
Project the Carteret and Onslow county in-center patients forward one year to December 31, 2022 using the applicable AACR.	$18.7 \times 1.081 = 20.2$	$10.7 \times 1.091 = 11.7$
Sum the Carteret and Onslow county patients and add the three patients from Craven and Jones counties. This is the ending census as of December 31, 2022 (OY2).	$20.2 + 11.7 + 3 = 34.9$	

The applicant states that the two relocated stations are to be used for home training and support only; therefore, it believes the number of in-center stations should remain constant at ten. However, that is an erroneous assumption. Upon the relocation of two in-center dialysis stations from Crystal Coast to FMC Sea Spray, FMC Sea Spray will be certified for a total of 12 in-center and home hemodialysis stations.

The applicant projects to serve 32.4 in-center patients in OY1, or 2.7 patients per station per week ($32.4 \text{ patients} / 12 \text{ certified stations} = 2.7$).

Projected in-center utilization is reasonable and adequately supported for the following reasons:

- The applicant begins the projections for FMC Sea Spray based on the December 31, 2019 in-center patient census of 16 Carteret County patients and nine Onslow County patients.
- The applicant projects the growth of the Carteret and Onslow county patient census at FMC Sea Spray using the Carteret and Onslow county Five-Year AACR of 8.1 percent and 9.1 percent, respectively, as reported in the 2020 SMFP.
- The applicant assumes that four current patients are transient and will not continue to dialyze at the facility in the future.

- The applicant assumes no growth for the three patients from Craven and Jones counties, whom the applicant assumes will continue to dialyze at FMC Sea Spray.

However, although the applicant states that the two relocated stations will be utilized exclusively for home hemodialysis training and support, upon the relocation of two stations, FMC Sea Spray will be operating 12 in-center and home hemodialysis stations and based on its projected utilization of 32.4 patients in the first year following project completion, the project does not meet the 2.8 patients per station per week requirement in the performance standard in the Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2203. The applicant's projections justify the relocation of only one dialysis station, at a utilization rate of 3.0 patients per station per week (32.4 patients / 11 certified stations = 2.945).

Home Hemodialysis and Peritoneal Dialysis

FMC Sea Spray offers home hemodialysis and peritoneal dialysis training and support services and projects using two stations for home training and support. In Section Q, pages 77-78, the applicant provides the assumptions and methodology used to project home dialysis training utilization. The assumptions are provided on page 77 and summarized below:

- The applicant begins the projections for FMC Sea Spray home training by using the December 31, 2019 HH and PD patient census: HH - four Carteret County patients and 3 Onslow County patients; PD - eight Carteret County patients and 4 Onslow County patients.
- The applicant projects the Carteret and Onslow county patient census at FMC Sea Spray will increase by the Carteret and Onslow county Five-Year AACR of 8.1 percent and 9.1 percent, respectively.
- The applicant assumes that the two HH patients and five PD patients from Craven County will continue to dialyze at FMC Sea Spray and are added to the projections without any future growth.
- Operating Year 1 (OY1) = January 1 through December 31, 2021 (CY2021).
Operating Year 2 (OY2) = January 1 through December 31, 2022 (CY2022).

On page 78, the applicant provides the projected home training utilization based on the above assumptions, as summarized in the following table:

	HH		PD	
	Carteret	Onslow	Carteret	Onslow
Begin with the facility census of Carteret and Onslow home training patients as of December 31, 2019.	4	3	8	4
Project the Carteret and Onslow county patients forward to December 31, 2020 using the Carteret and Onslow county AACR of 8.1% and 9.1%, respectively.	$4 \times 1.081 = 4.3$	$3 \times 1.091 = 3.3$	$8 \times 1.081 = 8.6$	$4 \times 1.091 = 4.4$
Sum the Carteret and Onslow county patients and add the two HH patients and the five PD patients from Craven County. This is the projected starting census for the project.	$4.3 + 3.3 + 2 = 9.6$		$8.6 + 4.4 + 5 = 18.0$	
Project the Carteret and Onslow county patients forward to December 31, 2021 using the Carteret and Onslow county AACR of 8.1% and 9.1%, respectively.	$4.3 \times 1.081 = 4.7$	$3.3 \times 1.091 = 3.6$	$8.6 \times 1.081 = 9.3$	$4.4 \times 1.091 = 4.8$
Sum the Carteret and Onslow county patients and add the two HH patients and the five PD patients from Craven County. This is the projected ending census December 31, 2021 (OY1).	$4.7 + 3.6 + 2 = 10.2$		$9.3 + 4.8 + 5 = 19.1$	
Project the Carteret and Onslow county patients forward to December 31, 2022 using the Carteret and Onslow county AACR of 8.1% and 9.1%, respectively.	$4.7 \times 1.081 = 5.1$	$3.6 \times 1.091 = 3.9$	$9.3 \times 1.081 = 10.1$	$4.8 \times 1.091 = 5.2$
Sum the Carteret and Onslow county patients and add the two HH patients and the five PD patients from Craven County. This is the projected ending census December 31, 2022 (OY2).	$5.1 + 3.9 + 2 = 10.9$		$10.1 + 5.2 + 5 = 20.3$	

Totals may not sum due to rounding

As the tables on page 78 and above show, the applicant projects serving ten home hemodialysis training patients in OY1 and 11 in OY2 two home hemodialysis training stations.

Projected home training utilization is reasonable and adequately supported for the following reasons:

- The applicant begins the projections for FMC Sea Spray home training based on the December 31, 2019 HH and PD patient census of Carteret County patients and Onslow County patients. This assumes that the Carteret and Onslow county current population totals will continue to produce seven HH and 12 PD home training dialysis patients in the future.
- The applicant projects the growth of the Carteret and Onslow county patients at FMC Sea Spray using the Carteret and Onslow county Five-Year AACR of 8.1 percent and 9.1 percent, respectively, as reported in the 2020 SMFP.
- The applicant assumes no growth for the two HH and five PD patients from Craven County, whom the applicant assumes will continue to dialyze at FMC Sea Spray.

Access

In Section C.7, pages 27-28, the applicant states:

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

It is corporate 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.

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

In Section L.3, page 56, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**FMC Sea Spray
Projected Payor Mix CY2022**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	1.51%	0.0%	0.0%
Commercial Insurance*	8.13%	36.56%	25.46%
Medicare*	75.84%	55.34%	66.08%
Medicaid*	1.28%	0.0%	6.95%
Other (Medicare/Commercial)	4.03%	2.82%	0.85%
Other (Misc. incl. VA)	9.21%	5.27%	0.66%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion as modified by Condition (2) of Criterion (4) for the following reasons:

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supports the relocation of one dialysis station to FMC Sea Spray.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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.

CA

The applicant proposes to relocate two certified in-center dialysis stations from Crystal Coast to FMC Sea Spray. The applicant states its intent to use the stations exclusively for home hemodialysis training and support services. Crystal Coast will have 19 certified dialysis stations upon completion of this project and Project ID #P-11665-16 (add five stations for a total of 21 stations).

In Section D, pages 32-35, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced by relocating two stations will be adequately met following completion of the project and the relocation of Crystal Coast. On page 32, the applicant states:

“BMA proposes to relocate two existing and certified dialysis stations from Crystal Coast Dialysis Unit to FMC Sea Spray. Stations are not being eliminated, but are being relocated.

The patients remaining at Crystal Coast Dialysis Unit will not be adversely impacted by this proposal. The 2020 SMFP indicates that Crystal Coast Dialysis Unit qualifies to apply for up to 10 additional dialysis stations in 2020. BMA is preparing an application for two new stations at Crystal Coast Dialysis Unit to be filed on March 16, 2020 for the review commencing on April 1, 2020.”

The applicant states that the new, Crystal Coast physical capacity would be 21 dialysis stations [upon completion of this project and Project ID #P-11665-16 (add five stations)]. The applicant further states that the facility would have room for two new stations.

In Section D, page 34, the applicant provides projected in-center patient utilization of Crystal Coast following completion of the proposed project, as summarized in the table below.

The applicant begins with the Carteret County in-center patients as of December 31, 2019.	58
The applicant projects the Carteret County patients forward to December 31, 2020 using the Carteret County AACR of 8.1 percent.	$58 \times 1.081 = 62.7$
The applicant adds three patients from Craven and Washington counties. This is the ending census on December 31, 2020, the date the stations are projected to relocate.	$62.7 + 3 = 65.7$

The applicant projects the Crystal Coast patient population following the relocation of stations, December 31, 2020, to be 65.7 in-center patients for a utilization of 86% or 3.46 patients per station, per week ($65.7 / 19 = 3.46$; $3.46 / 4 = 0.864$).

Section Q Form D, page 79, shows that Crystal Coast will have 71 in-center patients on December 31, 2020; however, the assumptions provided on pages 80-81 agree with the projections provided in Section D, page 34, as shown in the table above. Furthermore, with the relocation of only one station, on December 31, 2020, Crystal Coast will have a utilization rate of 82.1% ($65.7 / 20 = 3.285 / 4 = 0.8212$).

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant begins its utilization projection with the existing Carteret County patient census currently served at Crystal Coast.
- The applicant projects the Carteret County in-center patient census at Crystal Coast will increase at the Carteret County Five-Year AACR of 8.1 percent, as reported in the 2020 SMFP.
- The applicant projects the number of patients from other counties that are dialyzing at Crystal Coast will remain constant.

On page 34, the applicant states the proposed relocation of the stations from Crystal Coast will not have any effect upon the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care and that the proposed relocation of stations will not have an effect upon access to care for any patient. The applicant also states that BMA has committed to filing a CON application for additional stations.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion as modified by Condition (3) of Criterion (4) for the following reasons:

- The needs of the population currently using the services to be reduced through the relocation of stations will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to relocate two dialysis stations from Crystal Coast to FMC Sea Spray and states its intent to use them exclusively for home hemodialysis training and support services. FMC Sea Spray will have a total of 12 certified in-center and home hemodialysis stations at project completion. The applicant proposes to dedicate two stations to home training and support services. Crystal Coast would be certified for 19 dialysis stations upon completion of this project and Project ID #P-11665-19.

In Section E, pages 36-37, the applicant states that it considered the following alternatives related to serving the needs of the patients in the area:

- Maintain the status quo – the applicant states that failure to relocate stations to FMC Sea Spray is not effective because it limits expansion of the home hemodialysis program at the facility and more capacity is needed to meet the needs of the patients choosing home hemodialysis in Carteret County. Therefore, the applicant called this an ineffective alternative.
- Relocate fewer than two stations –the applicant states that it has established that an effective home hemodialysis training program requires two stations to allow for two patients to be in training simultaneously. The applicant states that more stations, not less, are needed at FMC Sea Spray; therefore, the applicant determined that this was not the most effective alternative.
- Develop a new home therapies program with both peritoneal and home hemodialysis stations – the applicant states that this would require a significant capital expense which causes this alternative to be less cost-effective.

On page 36, the applicant states that there is no other way to adequately provide home hemodialysis training and support at the FMC Sea Spray location, except to apply to relocate existing certified dialysis stations from an operational dialysis center. Crystal Coast is the only other operational dialysis facility in Carteret County.

However, the applicant adequately demonstrates the need to relocate only one dialysis station from Crystal Coast to FMC Sea Spray; therefore, the alternative proposed in this application is the more effective alternative to meet the need, as modified by Condition (2) in Criterion (4), for the following reasons:

- The application is conforming or conditionally conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative; but adequately demonstrates the need to relocate only one dialysis station.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application, as modified by Conditions (2) and (3) below.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than one dialysis station from Crystal Coast Dialysis Unit to FMC Sea Spray for a total of no more than 11 in-center and home hemodialysis stations at FMC Sea Spray upon project completion.**
 - 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify one in-center dialysis station at Crystal Coast Dialysis Unit for a total of no more than 20 in-center dialysis stations at Crystal Coast Dialysis Unit upon completion of this project and Project ID #P-11665-19 (add no more than five stations for no more than 21 stations).**
 - 4. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

The applicant proposes to relocate two dialysis stations from Crystal Coast to FMC Sea Spray. FMC Sea Spray will have a total of 12 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1(a), the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Non-medical Equipment	\$1,500
Furniture	\$6,000
Total	\$7,500

In Section F.3, page 40, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because FMC Sea Spray is an operational facility.

Availability of Funds

In Section F.2, page 38, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SOURCE
Loans	0
BMA, Inc. Accumulated Reserves or OE*	\$7,500
Other (Specify)	0
Total	\$7,500

*OE = Owner's Equity

Exhibit F contains a letter dated January 15, 2020 from Chief Accounting Officer of Fresenius Medical Care, the parent company of Bio-Medical Applications of North Carolina, Inc., authorizing and committing Fresenius Medical Care Holdings, Inc. (FMC) cash reserves of \$11,250 for the capital costs of a project to relocate three dialysis stations from Crystal Coast (\$3,750 per station). However, the application proposes a cost of \$7,500 to relocate two stations (\$3,750 per station). The letter states that FMC's 2018 Consolidate Balance Sheet reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q Form F.2, page 84, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as summarized in the table below.

	OY1 (CY2021)	OY2 (CY2022)
Total In-Center Treatments	8,842.1	9,465.5
Total Gross Revenues (Charges)	\$55,625,822	\$59,547,270
Total Net Revenue	\$3,515,272	\$3,759,722
Average Net Revenue per Treatment	\$398	\$397
Total Operating Expenses (Costs)*	\$3,001,068	\$3,147,529
Average Operating Expense per Treatment	\$339	\$333
Net Income	\$514,204	\$612,193

*Total operating costs for OY1 and OY2 are understated by \$51,357 and \$17,676, respectively. It appears the applicant confused the column years when transferring the salary entries from Form H to Form F.4 Operating Costs. However, the shortage is more than covered by the net income in both years. Because total operating expenses are understated, average operating expense per treatment is slightly understated and results in an irrelevant difference.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates sufficient funds for the capital needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal.

- (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

The applicant proposes to relocate two dialysis stations from Crystal Coast to FMC Sea Spray to be used exclusively for home hemodialysis training and support services. FMC Sea Spray will have a total of 12 certified dialysis stations at project completion. Crystal

Coast will have 19 certified dialysis stations upon completion of this project and Project ID #P-11665-19. Both facilities are in Carteret County.

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are in Carteret County. Thus, the service area for this application is Carteret County. Facilities may serve residents of counties not included in their service area.

Currently, there are two existing and approved dialysis facilities in Carteret County, both of which are owned by BMA, as shown in the following table:

Carteret County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Crystal Coast Dialysis Unit*	BMA	Morehead City	16	106.25%
FMC Sea Spray^^	BMA	Cedar Point	10	80.00%

Source: 2020 SMFP, Table B.

*Approved for the relocation of entire 21 station facility upon completion of Project ID #P-11538-18 (relocate entire 16 station facility) and Project ID #P-11665-19 (add five stations)

^^ Designated as a small facility per Condition 1.a. in the facility need determination methodology

In Section G, page 43, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Carteret County. The applicant states it is not proposing to develop new services but instead to relocate two existing certified in-center dialysis stations within Carteret County.

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates that existing home dialysis training and support services in Carteret County is limited to FMC Sea Spray.
- The proposal would not result in an increase or decrease in the number of certified in-center dialysis stations in Carteret County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the FMC Sea Spray service, as summarized in the following table:

POSITION	FTE Positions As of 12/31/19	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.00	1.00	1.00
RN	1.50	1.50	1.50
Home Training Nurse	2.00	2.50	2.50
Patient Care Technician (PCT)	5.00	5.00	5.00
Dietician	0.50	0.50	0.50
Social Worker	0.50	0.50	0.50
Maintenance	0.50	0.50	0.50
Administration/Business Office	1.00	1.00	1.00
FMC Director Operations	0.20	0.20	0.20
In-Service	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
Total	12.50	13.00	13.00

Source: Section Q Form H

The assumptions and methodology used to project staffing are provided in Section Q Form H Staffing. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Section Q Form F.4, except for the total salary expense from Form H Staffing, which was inaccurately transferred to Section Q Form F.4 Operating Costs; however, there is more than adequate net income to cover the shortage. The discussion regarding salaries and operating expenses in the financial feasibility section in Criterion (5) is incorporated herein by reference. In Section H, pages 44-45, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 40, the applicant identifies Dr. Stuart Jennings as the medical director. In Exhibit H-4, the applicant provides a letter from Stuart Jennings, MD indicating his intent to continue serving as medical director and expressing his support for the project.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I.1, page 46, the applicant includes a list of providers of the necessary ancillary and support services.

FMC SEA SPRAY ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training (in-center)	On site by the applicant
HH/PD training and follow-up	On site by the applicant
Isolation – hepatitis	On site by the applicant
Psychological counseling	RHA Health Services in Morehead City
Nutritional counseling	On site by the applicant
Social Work services	On site by the applicant
Laboratory services	On site by the applicant
Acute dialysis in an acute care setting	Carteret General Hospital
Emergency care	On site staff until ambulance arrives
Blood bank services	Carteret General Hospital
Diagnostic and evaluation services	Carteret General Hospital
X-ray services	Carteret General Hospital
Pediatric nephrology	Vidant Health
Vascular surgery	Vascular Care of New Bern
Transplantation services	Vidant Health
Vocational rehabilitation & counseling	Vocational Rehab Services Morehead City
Transportation	Carteret County Area Transportation

In Section I.1 and I.2, pages 46-47, the applicant adequately explains how each ancillary and support service is and will continue to be made available and provides some supporting documentation in Exhibits I.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective January 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

The applicant does not propose to construct any new space associated with the relocation of two stations as proposed in this application. Therefore, Criterion (12) is not applicable to this review.

- (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 L, page 54, the applicant provides the historical payor mix for the last full operating year for its existing FMC Sea Spray and Crystal Coast services, as summarized in the tables below.

**FMC Sea Spray
 Historical Payor Mix CY2018**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	1.51%	0.00%	0.00%
Commercial Insurance*	8.13%	36.56%	25.46%
Medicare*	75.84%	55.34%	66.08%
Medicaid*	1.28%	0.00%	6.95%
Medicare/Commercial	4.03%	2.82%	0.85%
Other (Misc. incl. VA)	9.21%	5.27%	0.66%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

**Crystal Coast Dialysis Unit
 Historical Payor Mix CY2018**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	0.57%	0.00%	0.00%
Commercial Insurance*	7.25%	0.00%	0.00%
Medicare*	77.47%	0.00%	0.00%
Medicaid*	3.56%	0.00%	0.00%
Medical/Commercial	7.85%	0.00%	0.00%
Other (Misc. incl. VA)	3.31%	0.00%	0.00%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding
 *Including any managed care plans

In Section L.1(a), page 53, the applicant provides comparison of the demographical information on FMC Sea Spray patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total FMC Sea Spray Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	36.2%	51.0%
Male	63.8%	49.0%
Unknown	0.0%	0.0%
64 and Younger	13.8%	75.0%
65 and Older	86.2%	25.0%
American Indian	0.0%	0.6%
Asian	1.7%	1.3%
Black or African-American	41.4%	5.8%
Native Hawaiian or Pacific Islander	1.7%	0.2%
White or Caucasian	58.6%	86.5%
Other Race	0.0%	5.6%
Declined / Unavailable	0.0%	0.0%

* The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 55, that it has no obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 55, the applicant states that no patient civil rights access complaints have been filed against any BMA North Carolina facilities within the last five years.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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 L.3, page 56, the applicant projects the following payor mix for the proposed services during the second full operating year following completion of the project, as summarized in the table below.

**FMC Sea Spray
Projected Payor Mix CY2022**

Payment Source	% of IC Patients	% of HH Patients	% of PD Patients
Self-pay	1.51%	0.00%	0.00%
Commercial Insurance*	8.13%	36.56%	25.46%
Medicare*	75.84%	55.34%	66.08%
Medicaid*	1.28%	0.00%	6.95%
Medicare/Commercial	4.03%	2.82%	0.85%
Other (Misc. incl. VA)	9.21%	5.27%	0.66%
Total	100.00%	100.00%	100.00%

Totals may not sum due to rounding

*Including any managed care plans; however, the table provides by the applicant separates out Medicare/Commercial

As shown in the table above, during the second year of operation, the applicant projects that 1.51% of in-center dialysis services will be provided to self-pay patients, 79.87% to patients having some or all their services paid for by Medicare, and 1.28% to Medicaid patients. Regarding home hemodialysis services, 58% of those patients will have all or part of their services paid by Medicare.

On page 56, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of

the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of FMC Sea Spray.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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 L.5, page 57, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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 M, page 58, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective January 1, 1987.
 - (16) Repealed effective January 1, 1987.
 - (17) Repealed effective January 1, 1987.
 - (18) Repealed effective January 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 relocate two in-center dialysis stations from Crystal Coast to FMC Sea Spray. FMC Sea Spray will have a total of 12 certified in-center and home hemodialysis stations at project completion.

On page 113, the 2020 SMFP defines the service area for the county need methodology for dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* Both facilities referred to in this application are in Carteret County. Thus, the service area for this application is Carteret County. Facilities may serve residents of counties not included in their service area.

Currently, there are two existing and approved dialysis facilities in Carteret County, both of which are owned by BMA, as summarized in the following table:

Carteret County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Crystal Coast Dialysis Unit*	BMA	Morehead City	16	106.25%
FMC Sea Spray^^	BMA	Cedar Point	10	80.00%

Source: 2020 SMFP, Table B.

*Approved for the relocation of entire 21 station facility upon completion of Project ID #P-11538-18 (relocate entire 16 station facility) and Project ID #P-11665-19 (add five stations)

^^ Designated as a small facility per Condition 1.a. in the facility need determination methodology

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 59, the applicant states that it does not expect the station relocation to have any effect on

the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. The applicant further states:

“There are currently two dialysis facilities within Carteret County offering in-center dialysis; both are operated by BMA. With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at FMC Sea Spray.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 59, the applicant states:

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

...

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

Regarding the impact of the proposal on quality, in Section N, page 60, the applicant states:

“Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 60, the applicant states:

“It is corporate 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.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would be a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits).
- Quality (see Sections C, N and O of the application and any exhibits).
- Access to medically underserved groups (see Sections C, D, L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and

- information publicly available and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective January 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

In Section Q Form A, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies over 100 dialysis facilities owned, operated, or managed by a BMA related entity located in North Carolina.

In Section O.2, page 65, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility was found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*”. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective January 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.

CA

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-NA- FMC Sea Spray is an existing facility.

- (b) An applicant proposing to increase the number of dialysis stations in:
 - (1) an existing dialysis facility; or
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

-CA- In Section Q Form C, the applicant projects that FMC Sea Spray will serve 32.4 in-center patients per station per week. With the proposed relocation of two stations for a total of 12 in-center and home hemodialysis stations, the utilization rate of 2.7 patients per station per week, as of the end of the first operating year following project completion, does not meet the minimum performance standard of 2.8 patients per station per week. However, the relocation of one station results in a utilization rate of 3.0 patients per station per week ($32.4 / 11 = 2.945$), which exceeds the minimum performance standard of 2.8 patients per station per week.

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

-C- In Section C, pages 20-21, the applicant provides the assumptions and methodology it used to project in-center utilization at the facility.