

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 31, 2020

Findings Date: July 31, 2020

Project Analyst: Kim Meymandi

Team Leader: Fatimah Wilson

Project ID #: P-11873-20

Facility: Crystal Coast Dialysis Unit

FID #: 970506

County: Carteret

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

Project: Add no more than two dialysis stations pursuant to facility need for a total of no more than 22 stations upon completion of this project, Project ID# P-11840-20 (relocate one station) and Project ID# P-11665-19 (add 5 stations) which is a change of scope

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

Bio-Medical Applications of North Carolina, Inc (hereinafter referred to as “the applicant” or BMA) proposes a change of scope (COS) for Project ID# P-11665-19 (add 5 stations). Additionally, the applicant proposes to add no more than two dialysis stations to the existing Crystal Coast Dialysis Unit pursuant to the facility need determination for a total of no more than 22 stations upon completion of this project, Project I.D. # P-11665-19 (add 5 stations) and Project I.D. # P-11840-20 (relocate one station).

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (2020 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 not a county need determination for new dialysis stations in Carteret County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility based on Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Crystal Coast Dialysis Unit on page 152 of the 2020 SFMP is 106.25% or 4.25 patients per station per week, based on 68 in-center dialysis patients and 16 certified dialysis stations ($68 / 16 = 4.25$; $4.25 / 4 = 1.0625$ or 106.25%).

As shown in Table 9E on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Crystal Coast Dialysis Unit is up to 10 additional stations; thus, the applicant is eligible to apply to add up to 10 additional stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

In this review, the applicant proposes to add two new stations, five stations pursuant to P-11665-19 and relocate one station to FMC Sea Spray pursuant to Project ID #P-11840-20 (2+5-1=6); therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations in the 2020 SMFP.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. Policy GEN-3: Basic Principles, on pages 30-31 of the 2020 SMFP, Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B.5 (a) and (d), pages 14-17, Section N, pages 50-51; Section O, pages 53-56; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B.5 (b) and (d), pages 15-17, Section C.7, pages 22-23; Section L, pages 45-48; Section N.2(c), page 51 and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B.5 (c) and (d), pages 16-17; Section C pages 19-22; Section N.2(a), pages 50-51; and referenced exhibits. The information provided by the applicant regarding its efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal will maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of safety and quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on the following:

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3 because the proposal promotes safety and quality, equitable access and maximizes healthcare value.

- (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.

The applicant proposes a COS for Project ID# P-11665-19 (add five stations). The applicant proposes to add no more than two dialysis stations to the existing Crystal Coast Dialysis Unit pursuant to the facility need determination for a total of no more than 22 stations upon completion of this project, Project I.D. # P-11665-19 (add five stations) and Project I.D. # P-11840-20 (relocate one station).

The following table, summarized from page 7 of the application, shows the current and projected number of dialysis stations at Crystal Coast Dialysis Unit upon project completion.

Crystal Coast Dialysis Unit

# of Stations	Description	Project ID #
16	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
2	# of stations to be added as part of this project	
	# of stations to be deleted as part of this project	
5	# of stations previously approved to be added but not yet certified	P-11665-19
	# of stations previously approved to be deleted but not yet certified	
	# of stations proposed to be added in an application still under review	
-2	# of stations proposed to be deleted in an application still under review	P-11840-20
21	Total # of stations upon completion of all facility projects	

As outlined in the table above, the applicant proposes to add two dialysis stations for a total of 21 stations upon the project completion.

However, due to the conditional approval (CA) of P-11840-20 the applicant was approved to relocate only one station not two stations, making the table provided by the applicant incorrect. Therefore, the table has been revised by the Project Analyst to reflect the correct number of stations upon completion of all projects and is shown below.

# of Stations	Description	Project ID #
16	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
2	# of stations to be added as part of this project	P-11873-20
	# of stations to be deleted as part of this project	
5	# of stations previously approved to be added but not yet certified	P-11665-19
	# of stations previously approved to be deleted but not yet certified	F-11452-18
	# of stations proposed to be added in an application still under review	
-1	# of stations proposed to be deleted in an application still under review	P-11840-20
22	Total # of stations upon completion of all facility projects	

Patient Origin

On page 113, the 2020 SMFP defines the service area 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.*” Thus, the service area for this facility is Carteret County. Facilities may serve residents of counties not included in their service area.

In Section C., pages 19-20, the applicant provides current and projected patient origin for in-center (IC) patients at Crystal Coast Dialysis Unit for the last full operating year (CY2019) and the second full operating year (CY2022), as summarized in the table below.

Crystal Coast Current and Projected Patient Origin				
County	Last Full Operating Year (OY) 01/01/2019 to 12/31/2019		Second Full Operating Year (OY) 01/01/2022 to 12/31/2022	
	# of In-Center Patients	% of Total	# of In-Center Patients	% of Total
Carteret	58	89.23%	73.3	96.07%
Craven	2	3.08%	2	2.62%
Guilford	1	1.54%	0	0.00%
Wake	1	1.54%	0	0.00%
Washington	1	1.54%	1	1.31%
South Carolina	1	1.54%	0	0.00%
Other States	1	1.54%	0	0.00%
Total	65	100.0%	76.3	100%

In Section C, pages 20-21, the applicant provides the assumptions and methodology it used to project in center patient origin. In Section I, page 38, the applicant states that it will not be offering home hemodialysis (HHD) or peritoneal dialysis (PD) services at this facility. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.3, page 20, the applicant describes its assumptions for projecting in-center utilization of the facility, summarized as follows:

- The 2020 SMFP, Table 9 states that the applicant is eligible to apply for up to 10 additional stations. The proposed application is to add two additional stations.
- The applicant states that it projects patients forward from the December 31, 2019 census data. The applicant states that it assumes the patients from Crystal Coast Dialysis Unit on December 31, 2019 will continue to dialyze there and will increase at a rate equal to the Carteret County Five Year Average Annual Change Rate (AACR) of 8.1% as published in the 2020 SMFP.
- The applicant assumes the December 31, 2019 patients from Guilford and Wake counties as well as those from South Carolina and other states are transient patients and will not carry these patients forward.

- The applicant states that it is reasonable to conclude that they will continue to serve three patients residing in Craven and Washington Counties. However, they do not project any patient growth from this population and will only carry the number forward at the appropriate time.
- The project is scheduled for completion on December 31, 2020. Therefore, Operating Year (OY) 1 is calendar year (CY) 2021, January 1-December 31, 2021 and OY2 is CY2022, January 1-December 31, 2022.

In-Center Projected Utilization

In Section C.3, page 21, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table.

BMA begins with the Carteret County in-center patients as of December 31, 2019.	58
BMA projects the Carteret County in-center patients forward one year to December 31, 2020 using the Carteret County AACR.	$58 \times 1.081 = 62.7$
BMA adds 3 patients residing in Craven and Washington Counties for a projected starting census for this project.	$62.7 + 3 = 65.7$
BMA projects the Carteret County patient population forward one year to December 31, 2021 using the Carteret County AACR.	$62.7 \times 1.081 = 67.8$
BMA adds 3 patients residing in Craven and Washington Counties for a projected year-end census as of December 31, 2021 (OY1).	$67.8 + 3 = 70.8$
BMA projects the Carteret County in-center patient population forward one year to December 31, 2022 using the Carteret County AACR.	$67.8 \times 1.081 = 73.3$
BMA adds 3 patients residing in Craven and Washington Counties for a projected year-end census as of December 31, 2022 (OY2).	$73.3 + 3 = 76.3$

The applicant projects to serve 70.8 in-center patients in OY1 and 76.3 in-center patients in OY2. Thus, the applicant projects that Crystal Coast Dialysis will have a utilization rate of 84.0% or 3.37 patients per station per week ($70.8 \text{ patients} / 21 \text{ stations} = 3.37 / 4 = 0.84$ or 84.0%) in OY1 and a utilization rate of 91% or 3.63 patients per station per week ($76.3 \text{ patients} / 21 \text{ stations} = 3.63 / 4 = 0.91$ or 91%) in OY2.

However, given that Project ID # P-11840-20 granted conditional approval for the relocation of only one station rather than two stations, the projections by the applicant are incorrect and should be adjusted to account for the conditional approval of Project ID# P-11840-20. Given this corrected number of total stations, the utilization rate for OY1 is 80.45% or 3.22 patients per station per week ($70.8 \text{ patients} / 22 \text{ stations} = 3.22 / 4 = 0.8045$ or 80.45%) and for OY2 is 86.7% or 3.47 patients per station per week. The corrected utilization rates of 3.22 patients per station per week in OY1 exceeds the minimum standard of 2.8 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins the projections with the existing Crystal Coast Dialysis Unit in-center patient census as of December 31, 2019.
- The applicant projects the Carteret County patient census at Crystal Coast Dialysis Unit will increase by the Carteret County Five Year AACR of 8.1 percent, as reported in the 2020 SMFP.
- The applicant adds three patients residing in Craven and Washington Counties who currently use the facility, however, no growth is projected for this population segment in the first two operating years of the project.
- The utilization rate by the end of OY1 exceeds the minimum standard of 2.8 patients per station per week as required by 10A NCAC 14C .2203(b).

Access

In Section C.7, pages 22-24, 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 or, payor 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 patients regardless of income, racial or ethnic background, gender, handicap, age, ability to pay or any other factor that would classify a patient as underserved”

In Section L.3, page 47, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the proposed project, as illustrated in the following table.

Crystal Coast Dialysis Unit Projected Payor Mix CY2022

Primary Payor Source at Admission	In-center Dialysis	
	# of Patients	% of Total
Self-Pay	0.74	0.97%
Insurance*	4.93	6.47%
Medicare*	59.35	77.82%
Medicaid*	2.43	3.19%
Other: Medicare/Commercial	6.38	8.36%
Other: Misc. incl. VA	2.43	3.19%
Total	76.3	100%

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 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 supported.
- 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.

NA

The applicant does not propose a reduction, elimination or relocation of a facility or service; therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add two dialysis stations to the existing Crystal Coast Dialysis Unit for a total of 22 stations upon completion of this project, Project ID # P-11840-20 (relocate one station) and Project I.D. # P-11665-19 (add 5 stations) which is a change of scope.

In Section E, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.
- *Apply for more than two stations* – The applicant states that this is not an effective alternative because the new space cannot accommodate more than 21 stations.
- *Apply for fewer than two stations*-The applicant states this is not an effective option because the projected utilization exceeds the minimum required utilization. Thus, more stations are needed, not fewer.

Given that Project I.D. # P-11840-20 provided conditional approval for the relocation of only one station not two stations from Crystal Coast Dialysis Unit and given that the applicant has stated that the facility cannot accommodate more than 21 stations, the applicant adequately demonstrates the need to add only one dialysis station. 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 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 add only one dialysis station.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.**
 - 2. Pursuant to the facility need determination in the 2020 SMFP, Bio-Medical Applications of North Carolina, Inc. shall develop no more than one additional dialysis station for a total of no more than 21 stations upon completion of P-11665-19 (add five stations) and P-11840-20 (relocate one station).**
 - 3. 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 add two dialysis stations to the existing Crystal Coast Dialysis Unit for a total of 22 stations upon completion of this project, Project ID # P-11840-20 (relocate one station) and Project I.D. # P-11665-19 (add five stations) which is a change of scope.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, the applicant projects no capital costs associated with this project. In Section F.3, pages 31-33, the applicant states there will be no start-up or initial operating expenses associated with the proposed project because this is an existing facility that is already operational.

Financial Feasibility

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

Crystal Coast Dialysis Unit Projected Revenue and Operating Expenses

	OY 1 CY2021	OY 2 CY2022
Total In-Center Treatments	10,099.1	10,881.2
Total Gross Revenue (charges)	\$63,533,538	\$68,453,505
Total Net Revenue	\$2,988,841	\$3,220,293
Total Net Revenue/Treatment	\$295.95	\$295.95
Total Operating Expenses (costs)	\$2,487,135	\$2,610,104
Average Operating Expense per Treatment	\$246	\$240
Net Income / Profit	\$501,706	\$610,189

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
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the

proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 add two dialysis stations to the existing Crystal Coast Dialysis Unit for a total of 22 stations upon completion of this project, Project ID # P-11840-20 (relocate one station) and Project I.D. # P-11665-19 (add 5 stations) which is a change of scope.

On page 113, the 2020 SMFP defines the service area 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.”* Thus, the service area for this facility is Carteret County. Facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis facilities in Carteret County. The following table shows the existing and approved dialysis facilities in Carteret County, from Table 9B of the 2020 SMFP:

Carteret County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/18	In-Center Patients	Percent Utilization	Patients per Station
Crystal Coast Dialysis Unit	16	68	106.25%	4.2500
FMC Sea Spray	10	32	80.00%	3.2000
Total	26	100		

Source: 2020 SMFP, Table 9B.

In Section G.2, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Carteret County. The applicant states:

“This is a proposal to add two dialysis stations to an existing dialysis facility. The stations are needed by the patient population projected to be served by the facility. The projections of future patient populations to be served begins with the current patient population of the facility and an increase of that population at a rate of 8.1%. The applicant has not projected to serve patients currently served in another facility or served by another provider. The stations are needed at Crystal Coast Dialysis Unit to support the rapidly growing patient census at the facility.”

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:

- There is a facility need determination at Crystal Coast Dialysis Unit, as calculated using the methodology in the 2020 SMFP, for the proposed two additional dialysis stations.

- The applicant adequately demonstrates that the two proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 Staffing, the applicant provides a table showing current and projected staffing in full time equivalent (FTE) positions for Crystal Coast Dialysis Unit, as summarized below.

POSITION	FTE Positions as of 11/15/2019	FTE POSITIONS OY1	FTE POSITIONS OY2
Administrator	1.0	1.0	1.0
Registered Nurse	2	2.5	2.5
Technicians (PCT)	6	6.5	6.5
Maintenance	0.5	0.5	0.5
Dietitian	0.5	0.66	0.66
Social Worker	0.5	0.66	0.66
Administration/Business Office	1.0	1.0	1.0
Other: FMC Director Operations	0.2	0.2	0.2
Other: In-Service	0.15	0.15	0.15
Other: Chief Tech	0.15	0.15	0.15
Total	12.00	13.32	13.32

Source: Section Q, Form H

The medical Director is not an FTE of the facility, but is a contracted position. The Medical Director expenses are included as a separate line item on the Form F.4 Operating Costs. The Medical Director expense is reported a Consultant Fees.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 Operating Costs. In Section H, pages 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. Exhibit H contains documentation of its continuing education programs. In Section H.4, page 37, the applicant identifies three nephrologists of Eastern Nephrology Associates who have agreed to provide medical coverage at the facility, with Dr. Walter Newman serving as the Medical director for the facility. In Exhibit H-4, the applicant provides a letter from medical director indicating his support for the facility.

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

Conclusion

The Agency reviewed the:

- Application
- 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, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

ANCILLARY AND SUPPORT SERVICES		
SERVICES	PROVIDER	
Self-care training	Referral to FMC Sea Spray home therapies department	
Home training Home Hemodialysis Home Peritoneal dialysis Accessible follow-up program		
Isolation – hepatitis B positive patients		Provided on site by the applicant
Nutritional counseling		
Social Work services		
Laboratory services		
Vascular surgery	Referral to Vascular Care of New Bern	
Pediatric nephrology	Referral to Vidant Health	
Acute dialysis in an acute care setting	Referral to Carteret General Hospital	
Transplantation Services	Referral to Vidant Health	
Emergency care	Provided by facility staff until Ambulance arrives	
Blood bank services	Referral to Carteret general Hospital	
X-ray, Diagnostic and evaluation services	Referral to Carteret General Hospital	
Psychological Counseling	Referral to RHA Health Services in Morehead City	
Vocational Rehabilitation counseling and services	Referral to Division of Vocational Rehabilitation Services in Morehead City	
Transportation	CCATS-Carteret County Area Transportation	

Source: Table in Section I, page 38

In Section I, page 39, the applicant describes its existing relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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.

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 July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct or renovate any space associated with replacing dialysis stations which are being relocated to FMC Sea Spray. 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 46, the applicant provides the historical payor mix for Crystal Coast Dialysis Unit patients during CY2019 for its existing services, as shown in the table below.

Crystal Coast Dialysis Unit Historical Payor Mix (CY2019)

Primary Payor Source at Admission	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	0.63	0.97%
Insurance*	4.20	6.47%
Medicare*	50.59	77.82%
Medicaid*	2.07	3.19%
Other: Medicare/Commercial	5.43	8.36%
Other: Misc. incl. VA	2.07	3.19%
Total	65.0	100.0%

*Including any managed care plans

In Section L.1(a), page 45, the applicant provides comparison of the demographical information on Crystal Coast Dialysis Unit patients and the service area patients during CY2019, as summarized below.

Crystal Coast Dialysis Unit	Percentage of Total Patients Served during the Last Full OY	Percentage of the Population of the Service Area where the Stations will be located or Services Offered*
Female	46.6%	51.0%
Male	53.4%	49.0%
Unknown		
64 and Younger	46.6%	75%
65 and Older	53.4%	25%
American Indian	0.0%	0.6%
Asian	1.7%	1.3%
Black or African-American	39.7%	5.8%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	53.4%	86.5%
Other Race	5.2%	5.6%
Declined / Unavailable	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
- 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 46, that it has no obligation in any of its facilities to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 47, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- 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 47, 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.

**Crystal Coast Dialysis Unit
Projected Payor Mix for Second Full Operating Year CY2022**

Primary Payor Source at Admission	In-Center Dialysis	
	# of Patients	% of Total
Self-pay	0.74	0.97%
Insurance*	4.93	6.47%
Medicare*	59.35	77.82%
Medicaid*	2.43	3.19%
Other: Medicare/Commercial	6.38	8.36%
Other: Misc. incl. VA	2.43	3.19%
Total	76.3	100.0%

*Including any managed care plans

As shown in the table above, in the second full year of operation, the applicant projects that 0.97% of in-center dialysis services will be provided to self-pay patients, 77.82% to Medicare patients, 8.36% to Medicare/Commercial and 3.19% to Medicaid patients.

On page 47, 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, stating the payor mix is based upon recent facility history of actual treatment volumes.

The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of Crystal Coast Dialysis Unit.

Conclusion

The Agency reviewed the:

- Application
- 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, pages 48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- 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 49, 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
- 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 July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add two dialysis stations to the existing Crystal Coast Dialysis Unit for a total of 22 stations upon completion of this project, Project ID # P-11840-20 (relocate one station) and Project I.D. # P-11665-19 (add 5 stations) which is a change of scope.

On page 113, the 2020 SMFP defines the service area 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.”* Thus, the service area for this facility 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. The following table shows the existing and approved dialysis facilities in Carteret County, from Table 9B of the 2020 SMFP:

Carteret County Dialysis Facilities

Dialysis Facility	Owner	Location	# of In-Center Patients	# of Certified Stations	Percent Utilization
Crystal Coast Dialysis Unit*	BMA	Morehead City	68	16	106.25%
FMC Sea Spray^^	BMA	Cedar point	32	10	80%

Source: 2020 SMFP, Table 9B.

*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) and Project ID #P-11840-20 (delete 1 station).

^^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.1, page 50, the applicant states that it does not expect the addition of 2 stations to have any effect on the competitive climate in Carteret County nor do they project to serve patients currently being served by another provider. Furthermore, the applicant states:

“There are currently two dialysis facilities with in-center dialysis stations within Carteret County. 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 Crystal Coast Dialysis Unit.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 51, the applicant states:

“Approval of this application will allow the Crystal Coast Dialysis Unit facility to continue serving patients who reside in the area. Consequently, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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 51, 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 have 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 L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 based on the reasons stated above.

- (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

In Section Q Form A Facilities, 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, pages 56, 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 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 July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as 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- The applicant is not proposing to establish a new kidney disease treatment center or dialysis 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.

-C- In Section C.3, page 21, the applicant projects that Crystal Coast Dialysis Unit will serve 70.8 in-center patients on 22 stations, or a rate of 3.21 patients per station per week, as of the end of the first operating year (CY2021) following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C.3, pages 20-23, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.