

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 9, 2019

Findings Date: January 9, 2019

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: L-11580-18

Facility: BMA East Rocky Mount

FID #: 970528

County: Edgecombe

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

Project: Add two dialysis stations for a total of 26 stations upon completion of this project, Project ID# L-11374-17 (relocate 10 stations) and Project ID# L-11483-18 (add four stations)

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. (BMA) d/b/a BMA East Rocky Mount proposes to add two dialysis stations for a total of 26 stations upon completion of this project, Project ID# L-11374-17 (relocate 10 stations to FKC Boice-Willis) and Project ID# L-11483-18 (add four stations). The parent company of BMA is Fresenius Medical Care Holdings, Inc. (FMC).

Need Determination

The 2018 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 D in the July 2018 Semiannual Dialysis Report (SDR), there is a surplus of seven dialysis stations in Edgecombe County. Therefore, there is no county need determination for new dialysis stations in Edgecombe County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA East Rocky Mount in the July 2018 SDR is 3.8667 patients per station per week. This utilization rate was calculated based on 116 in-center dialysis patients and 30 certified dialysis stations as of December 31, 2017 (116 patients / 30 stations = 3.8667 patients per station per week; $3.8667 / 4 = .9667$ or 96.67 % facility utilization). Application of the facility need methodology indicates that two additional stations are needed for this facility, as illustrated in the following table.

BMA EAST ROCKY MOUNT OCTOBER 1 REVIEW - JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		96.67%
Certified Stations		30
Pending Stations		4
Total Existing and Pending Stations		34
In-Center Patients as of 6/30/17 (SDR2)		116
In-Center Patients as of 12/31/16 (SDR1)		116
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.0000
(ii)	Divide the result of step (i) by 12	0.0000
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0000
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	116.0000
(v)	Divide the result of step (iv) by 3.2 patients per station	36.2500
	and subtract the number of certified and pending stations to determine the number of stations needed	2.250

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. *Policy GEN-3*, on page 33, 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3(a and d), pages 8, 10-11, Section O, pages 54-57, and Exhibit O-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.3(b and d), pages 9-11, Section L, pages 47-51, and Exhibit L-1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3(c) and (d), pages 10-11, Section C, pages 17-18, and Section N, page 53. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of 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 for the above stated reasons.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

BMA proposes to add two dialysis stations to the BMA East Rocky Mount facility for a total of 26 stations upon completion of this project, Project ID# L-11483-18 (add four stations) and Project ID# L-11374-17 (relocate 10 stations to FMC Boice-Willis). The applicant is not proposing to offer home hemodialysis (HHD) or peritoneal dialysis (PD) training and support.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for in-center (IC) patients at BMA East Rocky Mount.

BMA EAST ROCKY MOUNT				
Patient Origin				
	Current		OY2	
	December 31, 2017		Calendar Year 2021	
	In-center	% of Total	In-center	% of Total
Edgecombe	43.3	49.6%	43.7	49.8%
Halifax	2	2.3%	2	2.3%
Nash	39	44.7%	39	44.5%
Pitt	1	1.1%	1	1.1%
Washington	1	1.1%	1	1.1%
Wilson	1	1.1%	1	1.1%
Total	87.3	100.0%	87.7	100.0%

Source: Current Year Table in Section C.8, page 19 of the application. Source: OY2 Table in Section C.1, page 14 of the application. Note: The applicant incorrectly stated the calendar years for OY1 and OY2; but provided clarifying information on November 26, 2018.

In Section C, pages 14-16, 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 16-17, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 14-15, the applicant provides the assumptions for projecting utilization of the proposed services, summarized as follows:

1. The applicant assumes that the BMA East Rocky Mount facility serves patients who are part of the Edgecombe County ESRD patient population and will increase at a rate of 0.9% which is the Edgecombe County Five Year Average Annual Change Rate (AACR) published in the July 2018 SDR.
2. The applicant assumes that the BMA East Rocky Mount facility serves patients who are part of the Nash County ESRD patient population; however, the applicant will not increase the growth of this out of county population segment from Nash County. The Nash County patient population at BMA East Rocky Mount has been constant during the past several years.
3. As of December 31, 2017, the patient census of Edgecombe County residents at BMA East Rocky Mount was 66 in-center patients.
4. As of June 30, 2018, there were 39 Nash County patients being served at BMA East Rocky Mount and five patients from other NC counties and other states, as follows:
 - a. Two in-center patients from Halifax County; wherein no growth is projected for these two patients.
 - b. One in-center patient each from Pitt, Washington and Wilson counties. BMA assumes that these patients will continue dialyzing at BMA East Rocky Mount however, no patient growth is projected for this segment of the patient population.
5. In the certificate of need application to relocate 10 dialysis stations to the new FKC Boice-Willis dialysis facility, the applicate assumes that 24 Edgecombe County patients dialyzing at BMA East Rocky Mount would transfer their care to Boice-Willis. The applicant states that the Boice-Willis project has been delayed and the facility is projected to be certified at the end of 2019; thus the applicant will subtract the 24 patients at that time.
6. The applicant projects the first two full operating years of the project will be January 1, 2020 – December 31, 2020 (CY2020) and January 1, 2021 – December 31, 2021 (CY2021), per clarifying information received from the applicant on November 26, 2018.

Projected Utilization

In Section C, page 16, the applicant provides the methodology used to project utilization for in-center patients as shown in the following table.

BMA EAST ROCKY MOUNT	
Begin with Edgecombe County patients dialyzing at the facility as of June 30, 2018.	66
Project Edgecombe County patient census forward one year to December 31, 2018 using one half of the Edgecombe County Five Year Average Annual Change Rate.	$66 \times 1.0045 = 66.3$
Project Edgecombe County patient census forward one year to December 31, 2019.	$66.3 \times 1.009 = 66.9$
Subtract the 24 patients projected to transfer to FMC Boice-Willis.	$66.9 - 24 = 42.9$
Add the 44 patients from other North Carolina counties. This is the starting census for OY1 (CY2020).	$42.9 + 44 = \mathbf{86.9}$
Project the Edgecombe County patient census forward one year to December 31, 2020.	$42.9 \times 1.009 = 43.3$
Add the 44 patients from other counties. This is the ending census for OY1 (CY2020).	$43.3 + 44 = \mathbf{87.3}$
Project the Edgecombe County patient census forward one year to December 31, 2021.	$43.3 \times 1.009 = 43.7$
Add the 44 patients from other North Carolina counties. This is the ending census for OY2 (CY2021).	$43.7 + 44 = \mathbf{87.7}$

Source: Table in Section C.5, page 16.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) the facility is projected to serve 87 in-center patients, and at the end of OY2 (CY2021) the facility is also projected to serve 87 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- **OY1 and OY2:** 3.35 patients per station per week or 83.6% (87 patients / 26 stations = $3.346 / 4 = 0.835$ or 83.6%).

The projected utilization of 3.346 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 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:

- BMA East Rocky Mount is currently operating at 96.73% capacity.
- The applicant begins its utilization projection with the existing patients of BMA East Rocky Mount.
- No growth is projected for the non-Edgecombe County patients that are existing patients at the facility.

- The projection of the future utilization of services is based upon the facility's historical patient utilization, adjusted for all approved relocation of stations and transfer of patients.
- The applicant assumes a projected annual rate of growth of 1.091 percent for the in-center Edgecombe County patient census at BMA East Rocky Mount, which is consistent with the Edgecombe County Five Year Average Annual Change Rate as published in the July 2018 SDR, Table D.
- The resulting utilization rate at BMA East Rocky Mount by the end of the first year exceeds the minimum standard of 3.2 patients per station per week.

Access

In Section C.3, page 17, the applicant states each of BMA's 114 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.1, page 48, the applicant projects the following payor mix during the second full fiscal year of operation (CY2020) following completion of the project, as illustrated in the following table.

BMA EAST ROCKY MOUNT	
PAYOR SOURCE	% OF TOTAL PATIENTS
Self-Pay/Indigent/Charity	0.24%
Medicare	76.98%
Medicaid	11.03%
Commercial Insurance	4.87%
Medicare/Commercial	5.58%
Miscellaneous (Incl. VA)	1.30%
Total	100.00%

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 to reduce or eliminate a service, nor does the applicant propose to relocate 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

BMA proposes to add two dialysis stations to BMA East Rocky Mount for a total of 26 stations upon completion of this project, Project ID# L-11374-17 (relocate ten stations to FMC Boice-Willis), and Project ID# L11483-18 (add four stations).

In Section E.1, page 23, the applicant describes the alternatives 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 due to the fact that BMA East Rocky Mount is projected to need the additional stations to assure patients access to dialysis care at a convenient location and times.
- Apply for fewer than two additional stations - Pursuant to the Facility Need Methodology, BMA East Rocky Mount showed a need for two additional dialysis stations. Fewer stations would result in higher utilization rates which could affect patient access.
- Relocate stations from the FMC Tarboro facility in Edgecombe County - However, FMC Tarboro only has 10 dialysis stations, the minimum number of dialysis stations required at a facility. Therefore, it is not the most effective alternative to relocate stations from another BMA facility in Edgecombe County.

On page 23, the applicant states that its proposal is the most effective alternative because this project as proposed does not require a capital expenditure and with this project, BMA is ensuring adequate access for its patients at BMA East Rocky Mount.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the reasons stated below:

- the facility is operating at above 80% capacity,
- the facility need methodology indicates a need for additional stations at the facility,
- maintaining the status quo does not address the need for additional stations at the facility and will result in higher utilization rates and potentially restrict patient admissions, and
- applying for fewer than two stations would not be appropriate when utilization is projected to be 3.346 patients per station per week.

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. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount shall materially comply with all representations made in the certificate of need application and any clarifying responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount shall develop no more than two additional dialysis stations for a total of no more than 26 certified stations at BMA East Rocky Mount upon completion of this project, Project ID# L-11374-17 (relocate 10 stations to FMC Boice-Willis) and Project ID# L-11483-18 (add four stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount shall take the necessary steps to decertify ten dialysis stations at BMA East Rocky Mount (relocating ten stations to FMC Boice-Willis) for a total of no more than 26 dialysis stations at BMA East Rocky Mount.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount 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

BMA proposes to add two dialysis stations to BMA East Rocky Mount for a total of 26 stations upon completion of this project, Project ID# L-11374-17 (relocate ten stations to FMC Boice-Willis), and Project ID# L-11483-18 (add four stations).

Capital and Working Capital Costs

BMA East Rocky Mount is an existing facility that has relocated stations in and out of the facility. In Section R, pages 24 and 26-27, the applicant projects no capital costs for the project, start up nor initial operating expenses. Therefore, no working capital is needed.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form B, page 75, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown below in the table.

BMA EAST ROCKY MOUNT		
	1st Full Fiscal Year Jan 1, 2020 - Dec 31, 2021	2nd Full Fiscal Year Jan 1, 2021 - Dec 31, 2021
Total Treatments* (Form C. Adjusted for missed treatments)	12,893	12,893
Total Gross Revenues (Charges)	\$51,417,284	\$51,417,284
Total Net Revenue	\$3,545,715	\$3,545,715
Average Net Revenue per Treatment	\$275	\$275
Total Operating Expenses (Costs)	\$3,538,734	\$3,458,955
Average Operating Expense per Treatment	\$275	\$268
Net Income	\$6,981	\$86,760

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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 for the following reasons:

- The applicant adequately demonstrates that there are no capital and working capital costs based on reasonable and adequately supported assumptions.
 - 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

BMA proposes to add two dialysis stations to BMA East Rocky Mount for a total of 26 stations upon completion of this project, Project ID# L-11374-17 (relocate ten stations to FMC Boice-Willis), and Project ID# L-11483-18 (add four stations).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR, there are five existing and approved dialysis facilities in Edgecombe County, listed as follows:

EXISTING and APPROVED DIALYSIS FACILITIES in EDGECOMBE COUNTY				
Facility Name	Provider Name	Location	#Stations	Utilization
BMA East Rocky Mount	FMC	Rocky Mount	30	96.67%
Fresenius Medical Clinic Tarboro	FMC	Tarboro	10	45%
FMS ENA Home LLC*	FMC	Tarboro	NA	NA
Fresenius Kidney Care Boice-Willis**	FMC	Rocky Mount	NA	NA
Dialysis Care of Edgecombe County	DaVita	Tarboro	35	66.43%

*FMS ENA Home is a freestanding Peritoneal Dialysis Facility with no dialysis stations. **FKC Boice-Willis is an approved facility under development. (Sources: Application, page 32 and July 2018 SDR, Table B, 41)

In Section G, page 32, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Edgecombe County. The applicant states:

- “*The BMA East Rocky Mount facility is very heavily utilized, with utilization rates nearing 100%.*”
- “*The BMA East Rocky Mount facility is situated on the western side of Edgecombe County, located approximately 13 road miles from the existing DC of Edgecombe facility, and approximately 14 miles from the recently certified FMC Tarboro location. Tarboro is located at the approximate center of Edgecombe County. Thus, the BMA East Rocky Mount facility is not as likely to serve patients from the center of the county, or eastern areas of Edgecombe County.*” (The applicant provides a map with the locations of the dialysis centers in the service area on page 33.)

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

- The applicant adequately demonstrates the need for two additional dialysis stations at BMA East Rocky Mount pursuant to the facility need methodology in the 2018 SMFP.
- The applicant adequately demonstrates that the proposed two new dialysis stations at BMA East Rocky Mount is needed in addition to the existing or approved dialysis stations.
- Projected utilization at the end of OY1 exceeds the minimum standard for in-center patients per week required by 10A NCAC 14C .2203(b).

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 for the reasons above stated reasons.

- (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 H. page 34, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services as illustrated in the following table.

BMA EAST ROCKY MOUNT Current and Projected Staffing		
Position	Current Jan 1, 2017 – Dec 31, 2017	2nd Full Calendar Year Jan 1, 2021 Dec 31, 2021
RN	5.00	5.00
LPN	1.00	1.00
Patient Care Tech	14.00	14.00
Dietician	1.00	1.00
Social Worker	1.40	1.40
Clinical Manager	1.00	1.00
Administrator	0.10	0.10
In-service	0.20	0.20
Clerical	1.00	1.00
Chief Tech	0.15	0.15
Equip Tech	0.85	0.85
TOTAL	25.70	25.70

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, pages 72-73, which is found in Section R. In Section H, page 35, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 38, the applicant identifies the current medical director. In Exhibit I.5, the applicant provides a letter from the current medical director indicating an interest to continue to serve as medical director for the proposed services.

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 37, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.1 - I.5.

BMA EAST ROCKY MOUNT Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	BMA East Rocky Mount (on site)
Self-care training (in-center)	Referral - FMC South Rocky Mount or BMA Rocky Mount
Home training HH PD Accessible follow-up program	Referral - FMC South Rocky Mount or BMA Rocky Mount
Psychological counseling	Referral – Eastpointe, Rocky Mount
Isolation – hepatitis	BMA East Rocky Mount (on site)
Nutritional counseling	BMA East Rocky Mount (on site)
Social Work services	BMA East Rocky Mount (on site)
Acute dialysis in an acute care setting	UNC Nash or Vidant Edgecombe
Emergency care	UNC Nash or Vidant Edgecombe
Blood bank services	UNC Nash
Diagnostic and evaluation services	UNC Nash
X-ray services	UNC Nash
Laboratory services	SPECTRA
Pediatric nephrology	Vidant Medical Center
Vascular surgery	Eastern Nephrology Access Center; Triangle Vascular Access; Nash Day Hospital – Rocky Mount
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation – Rocky Mount
Transportation	Tar River Transit; K&L Transport; Bostic Transport; Eastern Medical Transportation; Nash &/or Edgecombe Rescue

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.

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 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 any new space nor renovate any existing space. 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.7, page 51, the applicant provides the historical payor mix during CY 2017 at BMA East Rocky Mount, as shown below in the table.

BMA EAST ROCKY MOUNT	
PAYOR CATEGORY	% OF TOTAL PATIENTS
Self-Pay/Indigent/Charity*	-0.18%
Medicare	76.85%
Medicaid	10.45%
Commercial Insurance	6.55%
Medicare/Commercial	0.00%
Miscellaneous (Incl. VA)	1.51%
Total	100.00%

Numbers may not sum due to rounding. *Source: Footnote under the table on Page 51 and represents an accounting function which has since been corrected.

On page 51, the applicant states,

“The above table reflects a negative percentage in the Self Pay/Indigent/Charity line. This is the result of an accounting function and does not accurately portray the treatment volumes or payor mix for 2017 at the facility. At some point in 2017, the accounting department made a correction to the accounting records for a prior period.”

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Edgecombe	19%	54%	64%	24%	13%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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, in Section L, page 50, the applicant states,

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.”

In Section L, page 50, 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.

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

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, page 51, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

BMA EAST ROCKY MOUNT PROJECTED PAYOR MIX	
PAYOR SOURCE	% OF TOTAL PATIENTS
Self-Pay/Indigent/Charity	0.24%
Medicare	82.56%
Medicaid	11.03%
Commercial Insurance	4.87%
Medicare/Commercial	5.58%
Miscellaneous (Incl. VA)	1.30%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.24% of total services will be provided to self-pay/indigent/charity patients, 82.56% to Medicare patients and 11.03% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for BMA East Rocky Mount.

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, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed 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 52, 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-1.

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

BMA proposes to add two dialysis stations to BMA East Rocky Mount for a total of 26 stations upon completion of this project, Project ID# L-11374-17 (relocate ten stations to FMC Boice-Willis), and Project ID# L-11483-18 (add four stations).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

According to the July 2018 SDR, there are five existing and approved dialysis facilities in Edgecombe County, listed as follows:

EXISTING and APPROVED DIALYSIS FACILITIES in EDGECOMBE COUNTY				
Facility Name	Provider Name	Location	#Stations	Utilization
BMA East Rocky Mount	FMC	Rocky Mount	30	96.67%
Fresenius Medical Clinic Tarboro	FMC	Tarboro	10	45%
FMS ENA Home LLC*	FMC	Tarboro	NA	NA
Fresenius Kidney Care Boice-Willis**	FMC	Rocky Mount	NA	NA
Dialysis Care of Edgecombe County	DaVita	Tarboro	35	66.43%

*FMS ENA Home is a freestanding Peritoneal Dialysis Facility with no dialysis stations. **FKC Boice-Willis is an approved facility under development. (Sources: Application, page 32 and July 2018 SDR, Table B, 41)

In Section N.1, pages 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 53, the applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Edgecombe County. The applicant does not project to serve dialysis patients currently being served by another provider.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

- (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 Exhibit A.4, the applicant lists more than 100 Fresenius related dialysis facilities located in North Carolina.

In Section O.3, page 57, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, BMA East Rocky Mount; the facility which is the subject of this application to add two dialysis stations. The applicant states that BMA East Rocky Mount is currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS conditions for Coverage for the BMA East Rocky Mount facility in Exhibit O-2. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided 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 application is conforming to all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility.

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

-C- In Section C, pages 14 and 16, the applicant demonstrates that BMA East Rocky Mount will serve 87 in-center patients at the end of OY1 (CY2020) for a utilization rate of 83.7% or 3.2549 patients per station per week ($87 \text{ patients} / 26 \text{ stations} = 3.3461 / 4 = 0.8365$ or 83.7%). 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, pages 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.