

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 23, 2018

Findings Date: July 23, 2018

Project Analyst: Jane Rhoe-Jones

Team Leader: Gloria C. Hale

Assistant Chief: Lisa Pittman

Project ID #: L-11483-18

Facility: BMA East Rocky Mount

FID #: 970528

County: Edgecombe

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

Project: Add no more than four dialysis stations for a total of no more than 24 dialysis stations upon completion of this project and Project ID #L-11374-17 (relocate 10 stations to the new FMC Boice-Willis facility)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. (BMA), the applicant, currently operates a 30-station dialysis facility, BMA East Rocky Mount, located at 2330 S. Fairview Road, Rocky Mount, Edgecombe County. The applicant proposes to add four dialysis stations to its existing facility for a total of 24 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-11374-17 (relocate 10 stations to the new FMC Boice-Willis facility).

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 January 2018 Semiannual Dialysis Report (SDR), there is a surplus of 11

dialysis stations in Edgecombe County. The county need methodology, as discussed on page 365 of the 2018 SMFP, requires a deficit of 10 stations or greater and the utilization of all facilities in the county to be 80% or greater to identify a county need for an additional facility. Therefore, there is no county need determination for new dialysis stations for Edgecombe County.

However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for BMA East Rocky Mount in the January 2018 SDR is 3.8667 patients per station. This utilization rate was calculated based on 116 in-center dialysis patients and 30 certified dialysis stations. (116 patients / 30 stations = 3.8667 patients per station per week). The facility need methodology requires a facility's utilization rate in the latest SDR to be at least 3.2 patients per station to be eligible to apply for additional stations based on facility need. Therefore, the applicant is eligible to apply for additional stations based on the facility need methodology.

Application of the facility need methodology indicates that up to a maximum of four additional stations are needed for this facility, as illustrated in the following table from Section B.2, page 6.

BMA EAST ROCKY MOUNT APRIL 1 REVIEW-JANUARY 2018 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		96.67%
Certified Stations		30
Pending Stations		0
Total Existing and Pending Stations		30
In-Center Patients as of 6/30/17 (SDR2)		116
In-Center Patients as of 12/31/16 (SDR1)		125
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-9
	Multiply the difference by 2 for the projected net in-center change	-18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	-0.1440
(ii)	Divide the result of step (i) by 12	-0.0120
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	-0.0720
(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	107.6480
(v)*	Divide the result of step (iv) by 3.2 patients per station	33.6400
	and subtract the number of certified and pending stations to determine the number of stations needed	4
Pending Stations: INCLUDE all previously approved stations to be added to this facility, which includes any stations certified after the cutoff date. Do NOT subtract any stations to be transferred from this facility.		

*Rounding is allowed in Step (v).

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. The applicant proposes to add four stations. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application 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, on page 33 of the 2018 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 would promote safety and quality in Section B.4(a), page 8, Section O, pages 52-56, and referenced exhibits. 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.4(b), page 9, Section C.3, pages 15-16, Section L, pages 45-49, and referenced exhibits. 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.4(c) and (d), pages 9-11, and Section N, page 51. 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. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to add four stations to its existing facility for a total of 24 stations at BMA East Rocky Mount upon completion of this project and Project ID #L-11374-17 (relocate 10 stations to the new FMC Boice-Willis facility).

The following table, summarized from page 4 of the application, illustrates the current and projected number of dialysis stations at BMA East Rocky Mount.

BMA EAST ROCKY MOUNT		
Stations	Description	Project ID #
30	Total existing certified stations as of the January 2018 SDR	
+4	Stations to be added at BMA East Rocky Mount as part of this project	
-10	Stations previously approved to be relocated to FMC Boice-Willis	L-11374-17
24	Total stations upon completion of proposed project	

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.”* BMA East Rocky Mount is located in Edgecombe County; thus, the service area for this facility consists of Edgecombe County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 17, the applicant provides the historical patient origin for BMA East Rocky Mount in-center (IC) patients as summarized in the following table. There are no home hemodialysis (HH) or peritoneal dialysis (PD) patients served at the facility.

BMA EAST ROCKY MOUNT Historical Patient Origin 12/31/17	
County	IC
Edgecombe	72
Halifax	3
Nash	39
Pitt	1
Wilson	1
TOTAL	116

Source: ESRD Data Collection Forms 12/31/ 2017

In Section C.1, page 13, the applicant provides the projected patient origin for BMA East Rocky Mount patients for the first two operating years following completion of the project, as summarized below.

BMA EAST ROCKY MOUNT Projected Patient Origin*								
County	OY1 CY2019			OY2 CY2020			Percent of Total Patients**	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Edgecombe	48.6	0	0	48.8	0	0	52.5%	52.6%
Halifax	3	0	0	3	0	0	3.2%	3.2%
Nash	39	0	0	39	0	0	42.1%	45.4%
Pitt	1	0	0	1	0	0	1.1%	1.1%
Wilson	1	0	0	1	0	0	1.1%	1.1%
TOTAL	92.6	0	0	92.8	0	0	100.0%	100.0%

*Fractions rounded up to the whole patient, as stated on page 13. **Totals may not foot due to rounding.

In Section C, pages 13-14, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C2., page 15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 15, applicant states:

“The need of this population for the proposed services is a function of the individual patient need for dialysis care and treatment.”

Section B.2, page 6, includes the ESRD facility need methodology table which shows a need for up to four additional dialysis stations at BMA East Rocky Mount.

The information is reasonable and adequately supported for the following reasons:

- as stated in Section C.1. page 14, the applicant begins its projection of the patient population to be served with the existing patient census of BMA East Rocky Mount on December 31, 2017, consistent with the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in February 2018,
- as stated in Section C.1, page 13, the applicant grows the Edgecombe County patient population by the January 2018 SDR Edgecombe County five-year average annual change rate (AACR) of .005% and holds the utilization constant for current patients from outside Edgecombe County, and
- as calculated from Section C.1. page 14, the utilization rate of the in-center patients projected to be dialyzing at BMA East Rocky Mount by the end of the first year is above 3.2 patients per station [92 patients/24 stations = 3.83 patients per station per week].

Projected Utilization

In Section C.1, page 14, the applicant provides the methodology used to project in-center patient utilization, as summarized below:

BMA EAST ROCKY MOUNT	In-Center
Begin with the BMA East Rocky Mount in-center Edgecombe County dialysis patients as of December 31, 2017.	72
The applicant projects the Edgecombe County patient population forward one year to December 31, 2018, using the AACR of 0.005%	$72 \times 1.005 = 72.4$
Subtract 24 Edgecombe County patients who expressed desire to transfer to FMC Boice-Willis. This is the Edgecombe County patient census.	$72.4 - 24 = 48.4$
Add the patients from other counties. This is the starting census for the project at January 1, 2019.	$48.4 + 44 = 92.4$
The applicant projects the Edgecombe County patient population forward one year to December 31, 2019.	$48.4 \times 1.005 = 48.6$
Add the patients from other counties. This is the ending census for OY1.	$48.6 + 44 = 92.6$
The applicant projects the Edgecombe County patient population forward one year to December 31, 2020.	$48.6 \times 1.005 = 48.8$
Add the patients from other counties. This is the end of OY2 census.	$48.8 + 44 = 92.8$

Totals may not sum due to rounding

The applicant provides the assumptions for the projected in-center utilization on pages 13-14, as summarized below:

- Beginning census, December 31, 2017, is as listed in the ESRD Data Collection Forms submitted to DHSR Healthcare Planning in February 2018.
- OY1 is the period from January 1 through December 31, 2019.
- OY2 is the period from January 1 through December 31, 2020.
- The 48 in-center patients from Edgecombe County and the 44 patient from Halifax, Nash, Pitt and Wilson counties will continue to dialyze at BMA East Rocky Mount.
- The Edgecombe County patient census will grow at the Edgecombe County AACR of .005%, as reported in the January 2018 SDR, and the census of the other counties will be held constant.

- 24 Edgecombe County patients will transfer to FMC Boice-Willis (Project ID #L-11374-17), as of December 31, 2018.

Therefore, based on the methodology and assumptions above, the applicant projects that at the end of OY1, 92 in-center patients will be dialyzing on 24 stations for a projected utilization rate of 3.83 patients per station per week (92 in-center patients / 24 stations = 3.833) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

In Section C.2, page 15, the applicant states:

“In this application, BMA has projected a patient population of 92.6 rounded down to 92 in-center patients, to be dialyzing at the BMA East Rocky Mount facility at the end of the first year. ... Utilization by 92 patients on 24 dialysis stations is calculated to be 3.83 patients per station, or 95.83% utilization.”

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

- the applicant begins its utilization projection with the existing patients of BMA East Rocky Mount,
- the applicant grows the Edgecombe County patient population by the January 2018 SDR Edgecombe County AACR and holds the patient population from outside Edgecombe County constant, and
- the resulting utilization rate at BMA East Rocky Mount by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Access

In Section C.3, pages 15, the applicant states:

“BMA has a history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to BMA, currently operates 112 facilities in 48 North Carolina Counties (includes our affiliations with RRI facilities); in addition, BMA has several facilities under development or pending CON approval. 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.”

The applicant projects the payor mix during the second full fiscal year of operation following completion of the project in Section L.1(b), page 46, as summarized below.

BMA EAST ROCKY MOUNT Projected Payor Mix OY2/CY2020 As a Percent of Total Patients	
Payor Source	Total Patients
Private Pay	0.60%
Medicare	75.88%
Medicaid	10.53%
Commercial Insurance	6.67%
Medicare / Commercial	4.82%
Medicare / Medicaid	0.00%
Misc. (including VA)	1.50%
Other	0.00%
Total	100.00%

The applicant states, on page 46, that the projected payor mix is based on facility experience throughout 2017. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion 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 proposed project does not involve the reduction or elimination of a service or the relocation of a facility or a 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, Bio-Medical Applications of North Carolina, Inc., currently operates BMA East Rocky Mount, a 30-station dialysis facility located in Edgecombe County. The applicant proposes to add four dialysis stations to its existing facility for a total of 24 stations upon completion of this project and Project ID #L-11374-17 (relocate 10 stations to the new FMC Boice-Willis).

In Section E.1, page 21, 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. The alternatives considered prior to the submission of this application are summarized as follows:

1. Maintain the status quo,
2. Apply for fewer stations, and
3. Relocate stations from one of the existing BMA facilities in Edgecombe County.

Thus, after considering the above alternatives, the applicant concludes that its proposal to add four dialysis stations at BMA East Rocky Mount through the facility need methodology, as proposed, is the most effective alternative because it meets the identified need for additional stations at the facility while incurring no capital costs.

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

- 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 would result in higher utilization and potentially restrict patient admission,
- applying for fewer than four stations would result in higher utilization than 3.6 patients per station, and
- relocation of stations from FMC Tarboro in Edgecombe County would not be feasible because doing so would result in fewer than 10 stations at that facility.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 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.**
 - 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a BMA East Rocky Mount shall develop no more than four additional dialysis stations for a total of no more than 24 certified stations at BMA East Rocky Mount upon completion of this project and Project ID #L-11374-17 (relocate 10 stations to the new FMC Boice-Willis facility), which shall include any isolation stations.**
 - 3. 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

The applicant proposes to add four dialysis stations to its existing facility for a total of 24 stations upon completion of this project and Project ID #L-11374-17 (relocate 10 stations to the new FMC Boice-Willis facility).

Capital and Working Capital Costs

In Section F.1, page 22, the applicant states that BMA is not projecting any capital costs for this project. The proposed additional stations are intended to replace four of 10 dialysis stations planned for relocation to the FMC Boice-Willis facility. The space already exists and the dialysis equipment will be leased.

In Sections F.10 and F.11, page 24, the applicant states that BMA East Rocky Mount is an existing facility, thus the project will not involve start-up or initial operating expenses.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below. [Please note: In Section R, Pro Formas, page 64, it appears that the applicant has mislabeled Column D as the interim period, and Column E as Operating Year 1, given that in several places in the application, the applicant refers to Calendar Year 2019 as Operating Year 1 and Calendar Year 2 as Operating Year 2. Therefore, Column D represents Operating Year 1 and Column E represents Operation Year 2.]

BMA EAST ROCKY MOUNT Revenues and Expenses		
	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Average Patients (IC)*	92.6	92.8
Total Treatments (IC) (adjusted for missed treatments)	13,634	13,634
Total Gross Revenues (Charges)	\$54,372,392	\$54,372,392
Total Net Revenue	\$4,116,434	\$4,116,434
Average Net Revenue per Treatment	\$302	\$302
Total Operating Expenses (Costs)	\$3,811,839	\$3,841,692
Average Operating Expense per Treatment	\$280	\$282
Net Income	\$304,595	\$274,742

*Assumptions on pages 68 state that pro forma calculations use the average of the number of patients at the beginning and end of year for the total average number of patients each year for IC (Example: OY1 average IC patients = 9268).

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, and
- 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 following reasons:

- the applicant adequately demonstrates sufficient funds for the needs of the proposal, and
- the applicant adequately demonstrates 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 four dialysis stations to the existing BMA East Rocky Mount facility, for a total of 24 stations upon completion of this project and Project ID #L-11374-17 (relocate 10 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.”* BMA East Rocky Mount is located in Edgecombe County; 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 January 2018 SDR, Table B, there are four dialysis facilities in Edgecombe County, as follows:

Edgecombe County Dialysis Facilities Existing and Approved			
Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA East Rocky Mount (FMC)	30	96.67%	3.8667
Fresenius Kidney Care Boice-Willis*	0	0%	0
FMC Tarboro	0	0%	0
FMS ENA Home, LLC**	0	0%	0
Dialysis Care of Edgecombe County (DaVita)	35	68.57%	2.7429

Source: January 2018 SDR, Table B. * Project ID #L-11374-17 has been approved. **Free standing Peritoneal Dialysis Facility; no dialysis stations.

Fresenius related entities own and operate four of the five existing and proposed dialysis facilities in Edgecombe County. Total Renal Care of North Carolina (DaVita) owns and operates one facility. BMA East Rocky Mount is well-utilized, operating above 3.2 patients per station. The DaVita facility is not well utilized, operating below the 3.2 patients per station.

According to Table D in the January 2018 SDR, there is a surplus of 11 dialysis stations in Edgecombe County. The county need methodology, as discussed on page 365 of the 2018 SMFP, requires a deficit of 10 stations or greater and the utilization of all facilities in the county to be 80% or greater to identify a county need for an additional facility. Therefore, there is no county need determination.

In Section G, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Edgecombe County. The applicant provides a map on page 31 and states on page 30:

“This application does not create a new dialysis facility in Edgecombe County. Approval of this application will result in four additional stations in the Service Area. ... The following map depicts the locations of the ESRD facilities in Edgecombe County. The BMA East Rocky Mount facility is situated on the western side of Edgecombe County, located approximately 13 road miles from the existing DC Edgecombe County 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 is proposing to add four stations based on facility need and demonstrates the facility was serving 116 patients weekly on 30 stations, which is 3.86 patients per station per week or 96.67% of capacity, as of June 30, 2017. The applicant adequately demonstrates that the facility will serve 92 in-center patients weekly on 24 stations, which is 3.83 patients per station per week or 95.75% of capacity by the end of OY1. The applicant does not propose to establish a new facility.

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 demonstrates the need for the stations based on the facility need methodology,
- the applicant demonstrates that its sole operational facility is operating at or above 80% utilization, and
- the applicant adequately demonstrates that the proposed stations are needed in addition to the existing or approved stations in Edgecombe County.

Conclusion

The Agency reviewed the:

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

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

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

In Section H.1, page 32, the applicant provides the current and projected OY2 staffing, which will remain the same as current staffing, for BMA East Rocky Mount by full-time equivalent (FTE) positions, as summarized below in the table:

BMA EAST ROCKY MOUNT		
FTE Positions		
Position	Current FTE Positions	Total OY2 FTE Positions
Medical Director	na	na
Registered Nurse	5.00	5.00
LPN	1.00	1.00
Patient Care Technician	12.00	12.00
Dietitian	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
Equipment Tech	.85	.85
Total FTEs	23.70	23.70

Note: The Medical Director is not a salaried employee.

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section I.3, page 36, the applicant states that Charles Jere, MD, is the Medical Director for the facility. Exhibit I.5 contains a letter from Dr. Jere, dated February 6, 2018, indicating support for the project and a willingness to continue to serve as Medical Director of the facility. Dr. Jere's curriculum vitae is included in Exhibit I-6. In Section H.3, pages 32-33, the applicant states it does not anticipate any difficulties in filling staff positions as it will use aggressive recruiting and advertising efforts, coupled with competitive salaries to attract qualified staff.

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

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

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

C

In Section I.1, page 35, the applicant identifies the necessary ancillary and support services and explains how they will be made available. Summarized below is the table the applicant provides on page 35.

BMA EAST ROCKY MOUNT Ancillary and Support Services	
Services	Provider
(a) In-center dialysis/maintenance	On Premises
(b) Self-care training (performed in-center)	Referred to FMC South Rocky Mount or BMA Rocky Mount
(c) Home training (1) Hemodialysis (2) Peritoneal dialysis (3) Accessible follow-up program	Referred to FMC South Rocky Mount or BMA Rocky Mount
(d) Psychological counseling	Referred to Eastpointe, Rocky Mount
(e) Isolation-hepatitis	On Premises
(f) Nutritional counseling	On Premises
(g) Social work services	On Premises
(h) Acute dialysis in an acute care setting	UNC Nash Healthcare System or Vidant Edgecombe
(i) Emergency care	UNC Nash Healthcare System or Vidant Edgecombe
(j) Blood bank services	UNC Nash Healthcare System
(k) Diagnostic and evaluation services	
(l) X-ray services	
(m) Laboratory services	Spectra
(n) Pediatric nephrology	Vidant Medical Center Greenville
(o) Vascular surgery	Access Centers: Eastern Nephrology, Raleigh or Triangle Vascular; Nash Day Hospital – Rocky Mount
(p) Transplantation services	Vidant Medical Center Greenville
(q) Vocational rehabilitation counseling & services	Division of Vocational Rehabilitation – Rocky Mount
(r) Transportation	Tar River Transit, K&L Transport, Bostic Transport, Eastern Medical Transportation, Edgecombe &/or Nash Rescue

In Section I.4, 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 through I-5.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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 proposed project does not involve construction of new space or renovation. The estimated square footage in the facility will not change pursuant to this project. 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 49, the applicant provides the historical payor mix during Calendar Year 2017 for the proposed services, as shown below in the table.

BMA EAST ROCKY MOUNT CY2017 Payor Mix As a Percent of Total Patients	
Payor Source	Total
Self-Pay/ Indigent / Charity	-0.18%
Medicare	76.85%
Medicaid	10.45%
Commercial Insurance	6.55%
Medicare / Commercial	4.80%
Medicare / Medicaid	0.00%
Misc. (including VA)	1.51%
Other	0.00%
Total	100.00%

Totals may not sum due to rounding

[Note: On page 49, the applicant states,

“The above table reflects a negative percentage in the Self Pay/Indigent/Charity Line. This 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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Edgecombe	18%	54%	64%	28%	13%	12%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). 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 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 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.

Conclusion

The Agency reviewed the:

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

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

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.3(e) [numbered incorrectly in the application, should have been L.3(d)], page 47, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status. In accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section L.6, page 48, the applicant states that no civil rights complaints have been lodged against any BMA North Carolina facilities in the past five years.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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.1(b), page 46, the applicant provides the projected payor mix for the BMA East Rocky Mount facility during the second full fiscal year following completion of the project, as summarized below in the table:

BMA EAST ROCKY MOUNT Projected Payor Mix Project Year 2	
Payor Source	Total
Self-pay/Indigent/Charity	0.60%
Medicare	75.88%
Medicaid	10.53%
Commercial Insurance	6.67%
Medicare / Commercial	4.82%
Medicare / Medicaid	0.00%
Misc. (including VA)	1.50%
Other	0.00%
Total	100.00%

Totals may not sum due to rounding

As shown in the table above, the applicant projects that 0.60% of total services will be provided to self-pay/indigent/charity patients, 91.23% to Medicare and Medicaid patients. The projected payor mix is comparable to the 2017 payor mix for BMA East Rocky Mount and the applicant states that the projected payor mix is based on the facility's experience throughout 2017. Based upon the above information, the projected payor mix is reasonable and adequately supported.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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.1, page 50, 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, and
- information publicly available during the review and used by the Agency.

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 four dialysis stations to the existing BMA East Rocky Mount facility, for a total of 24 stations upon completion of this project and Project ID #L-11374-17 (relocate 10 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.*” BMA East Rocky Mount is located in Edgecombe County; 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 January 2018 SDR, there are five existing or approved dialysis facilities in Edgecombe County (only four provide in-center dialysis; one provides peritoneal dialysis training and support only), as follows:

EDGECOMBE COUNTY DIALYSIS FACILITIES			
Existing and Approved			
Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA East Rocky Mount (FMC)	30	96.67%	3.8667
Fresenius Kidney Care Boice-Willis*	0	0%	0
FMC Tarboro	0	0%	0
FMS ENA Home, LLC**	0	0%	0
Dialysis Care of Edgecombe County (DaVita)	35	68.57%	2.7429

Source: January 2018 SDR, Table B. * Project ID #L-11374-17 has been approved. **Free standing Peritoneal Dialysis Facility; no dialysis stations.

Fresenius related entities own and operate four of the five existing and proposed dialysis facilities in Edgecombe County. Total Renal Care of North Carolina (DaVita) owns and operates one facility. BMA East Rocky Mount is well-utilized, operating above 3.2 patients per station. The DaVita facility is not well utilized, operating below the 3.2 patients per station.

According to Table D in the January 2018 SDR, there is a surplus of 11 dialysis stations in Edgecombe County. The county need methodology, as discussed on page 365 of the 2018 SMFP, requires a deficit of 10 stations or greater and the utilization of all facilities in the county to be 80% or greater to identify a county need for an additional facility. Therefore, there is no county need determination.

In Section N.1, pages 51, the applicant discusses the expected effects of the proposed project 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, stating:

“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 projected patient population for the BMA East Rocky Mount facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Edgecombe County five year average annual change rate of 0.5% as published within the January 2018 SDR.”

Furthermore, in Section G, page 30, the applicant discusses that the geographic locations of this facility and the one DaVita facility does not make it probable that they would serve the same patient population. Moreover, the applicant also states on page 51 that its application is based on facility need which should have no impact on competition.

In addition, the applicant states that BMA facilities are compelled to operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates. Moreover, the applicant states, on page 51, that its proposal will “*enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.*”

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), and
- 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, and
- information publicly available during the review and used by the Agency.

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

- (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 A.11, page 4, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. Exhibit A-4 includes a listing of more than 100 Fresenius facilities in North Carolina. In Section O, page 55, the applicant states:

“As of February 28, 2018, Fresenius related facilities were providing dialysis care and treatment for more than 9,800 dialysis patients receiving care in a North Carolina dialysis facility.”

Of the more than 100 applicant-related Fresenius facilities in North Carolina, the applicant identifies East Rocky Mount as the only BMA facility cited for an immediate jeopardy citation within the most recent 18-month period, prior to submission of the application. The applicant summarizes the deficiencies cited and the resolution in Section O.3 and provides documentation in Exhibit O-2. On page 56, the applicant states that BMA East Rocky Mount was back in full compliance with all CMS Guidelines upon the submittal of the application. 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 for the reasons stated above.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C.2200. The specific findings are discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant is not proposing to establish a new dialysis facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, page 14, the applicant projects to serve 92 in-center patients on 24 stations by the end of Operating Year 1, which is 3.83 patients per station per week ($92 / 24 = 3.8333$), which documents “*the need for the additional stations based on utilization of 3.2 patients per station per week*” as stated above.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 13-15.