

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2018

Findings Date: January 26, 2018

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: L-11394-17

Facility: FMC East Northampton County

FID #: 945259

County: Northampton

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

Project: Add two dialysis stations for a total of 21 stations upon completion of this project

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. d/b/a Fresenius Medical Care East Northampton County (FMC East Northampton County), proposes to add two dialysis stations to the existing facility for a total of 21 certified dialysis stations upon completion of this project.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of seven dialysis stations in Northampton County, thus the applicant cannot apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 FMC East Northampton County in the July 2017 SDR is 3.26 patients per station per week, or 81.58% (3.2632 / 4 patients per station = .8158). This utilization rate was calculated based on 62 in-center dialysis patients and 19 certified dialysis stations (62 patients / 19 stations = 3.263 patients per station per week).

Application of the facility need methodology indicates two additional stations are needed for this facility, as illustrated in the following table.

FMC East Northampton County OCTOBER 1 REVIEW- JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		81.6%
Certified Stations		19
Pending Stations		0
Total Existing and Pending Stations		19
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		62
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		60
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	2
	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0667
(ii)	Divide the result of Step (i) by 12	0.0056
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0667
(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	66.1333
(v)	Divide the result of Step (iv) by 3.2 patients per station	20.6667
	and subtract the number of certified and pending stations to determine the number of stations needed	1.6667

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. 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, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3, on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. 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 57-61, 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), pages 9-10, Section C.3, page 17, Section I.2(c), page 41, Section L, pages 50-54 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), pages 10-12, Section N, page 56, and referenced exhibits. 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. The application is consistent with Policy GEN-3.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant’s use of the facility need methodology in accordance with the July 2017 SDR.
- The applicant’s use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.

- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- Repealed effective July 1, 1987.
- 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 its existing facility for a total of 21 certified dialysis stations at the FMC East Northampton County facility upon completion of this project. In addition to in-center (IC) dialysis, FMC East Northampton County provides both home hemodialysis (HH) and peritoneal dialysis (PD). However, this application is for additional in-center dialysis stations only.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the 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 is Northampton County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 22, the applicant provides a table, as shown below with the historical patient origin for IC, HH and PD patients, served by FMC East Northampton County; although this proposal is to increase IC dialysis services only.

FMC EAST NORTHAMPTON COUNTY			
Patient Origin			
as of June 30, 2017			
County	# In-Center Dialysis Patients	Home Hemo Dialysis Patients	Peritoneal Dialysis Patients
Northampton	48	0	5
Bertie	1	0	0
Halifax	2	0	0
Hertford	12	1	0
Total	63	1	5

In Section C.1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion. For the purposes of this proposal for IC stations only, the IC patient projections are illustrated below:

FMC EAST NORTHAMPTON COUNTY Projected Patient Origin				
	OY1 CY2019	OY2 CY2020	County Patients as % of Total OY1 CY2019	County Patients as % of Total OY2 CY2020
County	IC Patients	IC Patients		
Northampton	53	55	76.8%	76.4%
Bertie	1	1	1.4%	1.4%
Halifax	2	2	2.8%	2.8%
Hertford	13	14	19.0%	19.4%
Total	69	72	100.0%	100.0%

OY = Operating Year. CY = Calendar Year.

The applicant provides the assumptions and methodology for the above projections on pages 13-15. As shown in the above two tables, the applicant projects a six to nine patient increase from OY1-OY2 for Northampton County IC patients once this project is complete. The applicant currently serves 48 IC patients from Northampton County, 12 IC patients from Hertford County, two IC patients from Halifax County and one IC patient from Bertie County. The applicant assumes that these 63 IC patients will continue their care at FMC East Northampton County. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add two dialysis stations to the existing FMC East Northampton County facility for a total of 21 certified dialysis upon project completion. In Section B.2, page 6, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR. In Section C.1, pages 13-15, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s in-center patients who reside in Northampton County have increased at a rate of 7.73% over six years ending December 31, 2016 (43 to 62 patients). The applicant projects a lower rate of increase of 4.0% in the Northampton County IC patients which is greater than the Northampton County Five Year AACR of 2.4%, but less than the 7.7% growth over the past six years. Although there are Bertie, Halifax and Hertford county patients dialyzing at FMC East Northampton County, the applicant does not project an increase in its patient population for Bertie and Halifax counties, but does project an increase by one patient from Hertford County. Bertie, Halifax and Hertford counties represent 23.8% (as reported in the June 2017 Dialysis Report) of the IC patient population of FMC East Northampton County.

OY1 = CY2019
 OY2 = CY2020

Projected Utilization

In Section C.1, pages 14-15, the applicant provides the methodology used to project in-center utilization, as illustrated in the following table. The applicant also provides the methodologies for projecting home hemodialysis and peritoneal dialysis on pages 15-16.

FMC EAST NORTHAMPTON COUNTY In-Center Dialysis Projections	
Begin with 63 total in-center patients dialyzing at FMC East Northampton County as of June 30, 2017.	63
Project patient population forward 6 months to December 31, 2017; while using one half the 4% change rate.	$63 \times 1.02 = 64.26$
Project the patient population forward one year to December 31, 2018.	$*64.26 \times 1.04 = 66.83$
Project the patient population forward one year to December 31, 2019. This is the ending census for OY1 (Calendar Year 2019).	$66.83 \times 1.04 = 69.50$
Project the patient population forward one year to December 31, 2019. This is the ending census for OY2 (Calendar Year 2020).	$69.50 \times 1.04 = 72.28$

*Applicant stated incorrect number of patients on page 14; but arrived at the correct patients in this step of the formula.

The applicant projects that FMC East Northampton County will serve a total of 69 in-center patients at the end of Operating Year One for a utilization rate of 82% or 3.2 patients per station (69 patients / 21 stations = 3.28 / 4 = .8214 or 82%). The projected utilization of 3.2 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). [Note: In Section C.1, page 13, the applicant states, “BMA is proposing to add two dialysis stations for a total of 21 stations. In order to meet the Review Criteria for Need and the Rules at 10A NCAC 14C .2203(b), BMA must demonstrate that the facility will serve 3.2 patients per station at the end of the first operating year. This is 67.2 rounded up to 68 patients (rounding down would not meet performance standards). This is the applicant’s only reference to 68 patients in OY1. Other references in the application states 69 patients for OY1. Therefore, the Project Analyst thinks that it is reasonable to assume that the reference to 68 patients in OY1 is a typographical error.]

Projected utilization is based on reasonable and adequately supported assumptions regarding continued IC patient growth at FMC East Northampton County.

Access

In Section L, pages 50-51, the applicant states that each of BMA’s 109 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons. The applicant projects over 92% of its total patient revenue will be from Medicare and Medicaid in Project Year 2, and states on page 51 that the projection is based on recent facility performance. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

BMA does not propose the reduction or elimination of a service in the proposed application, but rather the addition of two dialysis stations pursuant to the facility need methodology in the 2017 SMFP, 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

In Section E.1, page 26, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because the failure to add more dialysis stations will result in a lack of capacity at the facility; since projections at the end of Operating Year 1 is greater than 80.0%. Failure to develop additional stations could result in restricting patient admissions. Therefore, this alternative was rejected.
- Apply for Fewer Stations – The applicant states it considered applying for less than two stations but rejected the alternative because utilization is projected to exceed 3.2 patients per station.

The applicant states that adding two dialysis stations at FMC East Northampton County, as proposed in this application and with no capital expenditure required, is the cost-effective alternative to meet the identified need.

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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton County shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton County shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton County shall develop no more than two additional dialysis stations for a total of no more than 21 certified stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton County 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 station for a total of 21 certified dialysis stations at the FMC East Northampton County facility upon completion of this project.

Capital and Working Capital Costs

In Section F.1, page 28, the applicant projects that there are no capital costs for the proposed project. In Section F.10, page 31, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

Availability of Funds

Exhibit F.2 contains the Subsidiaries Consolidated Financial Statements for FMCH which indicates that it had \$357.9 million in cash and cash equivalents as of December 31, 2016, \$20.1 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, should there be a need.

Financial Feasibility

The applicant provides pro forma financial statements for the first two 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 below in the table.

FMC EAST NORTHAMPTON COUNTY		
	Operating Year 1	Operating Year 2
Total Treatments (adjusted for missed treatments)	10,078	10,374
Total Gross Revenues (Charges)	\$41,961,736	\$47,736,396
Total Net Revenue	\$2,760,080	2,867,735
Total Operating Expenses (Costs)	\$2,525,202	\$2,608,459
Net Income	\$234,878	\$259,276

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. 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.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

The applicant proposes to add two dialysis stations for a total of 21 certified dialysis stations upon completion of this project at FMC East Northampton County.

On page 373, the 2017 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Northampton County. Facilities may also serve residents of counties not included in their service area.

As shown in the following table, the July 2017 SDR indicates there is one dialysis facility in Northampton County, and that is the applicant’s facility – FMC East Northampton County.

NORTHAMPTON COUNTY DIALYSIS FACILITIES					
as of December 31, 2016					
Dialysis Facilities	Owner	# Patients	Location	# Certified Stations	% Utilization
FMC East Northampton County	FMC	62	Conway	19	81.58%

Source: July 2017 SDR, Table B.

As shown in the table above, the applicant, FMC owns the current dialysis facility in Northampton County. Currently, there are no other providers of dialysis services in Northampton County. Based on the most recent SDR, the FMC East Northampton County was operating above 80% (3.2 patients per station).

In Section C, pages 13-15, the applicant projects that FMC East Northampton County will serve a total of 69 IC patients at the end of Operating Year One for a utilization rate of 82.1% or 3.2 patients per station (69 patients / 21 stations = 3.28 / 4 = .821 or 82.1%). According to the July

2017 SDR, there is a deficit of seven dialysis stations in Northampton County. The applicant is applying to add two additional stations based on the facility need methodology.

The applicant states that the projected utilization rates are based on historical utilization at FMC East Northampton County. The applicant adequately demonstrates the need to add two additional stations at FMC East Northampton County based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section H.1, page 37, the applicant provides the current and projected staffing for the FMC East Northampton County, which is 13.90 full-time equivalent (FTE) employees. The applicant projects that the projected staffing will not change from current staffing following completion of the project as shown below in the table.

FMC EAST NORTHAMPTON COUNTY Facility Staffing	
Position	Current & Projected
Registered Nurse	2.50
Technician (PCT)	6.00
Clinical Manager	1.00
Administrator	0.15
Dietician	0.50
Social Worker	0.50
Home Training RN	1.00
Chief Tech	0.50
Equipment Tech	0.60
In-Service	0.15
Clerical	1.00
Total	13.90

In Section H.3, page 37, the applicant describes its experience and process for recruiting and retaining staff, and states that it does not anticipate difficulties in hiring the required staff for this project. In Section H.7, page 39, the applicant provides the projected direct care staff for FMC East Northampton County in OY2. Exhibit I-5 contains a copy of an August 18, 2017 letter from Lorenzo Santarina, M.D., expressing his interest in continuing to serve as the Medical Director for the facility.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of FMC East Northampton County.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section I, page 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 41-43. Exhibits I-2 through I-4, respectively, contain copies of agreements that the facility has with Spectra Laboratories, Halifax Regional Medical Center and transplant services at East Carolina University Medical School and Pitt County Memorial Hospital.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.

- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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.

- (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 has not historically served members of HMOs as evidenced by the historical payor mix provided in Section L.7 of the application. Additionally, the projected payor mix, shown in Section L.1 of the application, does not include HMOs. 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 proposes to add two stations to the existing facility. The applicant does not propose any new construction or renovation of any existing space at the FMC East Northampton County dialysis facility. As indicated in a revised line drawing received from the applicant in response to a request for clarifying information on January 18, 2018, plumbing and wiring already exists in the spaces designated as station #14 and station #21, for the proposed two new dialysis stations.

- (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 54, the applicant reports that over 92% of the total patient revenue received for treatments at FMC East Northampton County was from Medicare and Medicaid recipients in CY 2016. The table below shows the facility's historical payor sources.

FMC EAST NORTHAMPTON COUNTY CY 2016	
Payor Source	Percent of Total Revenue
Self-Pay/ Indigent/ Charity*	0.05%
Medicare	81.16%
Medicaid	3.45%
Commercial Insurance	5.83%
Medicare / Commercial	7.87%
Misc. (VA)	1.65%
Total	100.00%

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 Northampton County, 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
Northampton	24%	52%	62%	27%	17%	13%
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) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore, the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant’s historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant’s historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant’s existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3(e), page 52, 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 applicant will treat all patients the same regardless of race or handicap status.”

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.

In Section L.6, page 53, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the last five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 51, the applicant projects that 95.07% of the revenue for IC treatments at FMC East Northampton County in the second operating year (CY2020) will be paid by Medicare and Medicaid. The table below shows the projected PY2 payment sources for the facility for in-center patients:

FMC EAST NORTHAMPTON COUNTY	
Projected Payor Source PY2	In-Center Revenue by Percent of Total
Self-Pay/ Indigent/ Charity	0.55%
Medicare	83.01%
Medicaid	3.40%
Medicare / Commercial	8.66%
Commercial Insurance	1.66%
Misc. (VA)	2.71%
Total	100.00%

In Section L.1, page 51, the applicant states that projections are based on recent facility experience. The applicant's projected payment sources are similar to the facility's historical (CY2016) payment sources as reported by the applicant in Section L.7, page 54 and in Section R, Form C, pages 72-73. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at FMC East Northampton County.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 53, the applicant describes the range of means by which a person has access to the dialysis services at FMC East Northampton County, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility offers a range of means by which patients have access to dialysis services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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

Exhibit M.1 contains a copy of correspondence to Halifax Community College expressing an interest on the part of the applicant to offer the facility as clinical training site for student nurses. The information provided is reasonable and adequately supported.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

The applicant proposes to add two dialysis stations for a total of 21 certified dialysis stations upon completion of this project.

On page 373, the 2017 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus,

the service area for this facility consists of Northampton County. Facilities may also serve residents of counties not included in their service area.

The July 2017 SDR indicates there is one dialysis facility in Northampton County, and that is the applicant's facility – FMC East Northampton County, as follows:

NORTHAMPTON COUNTY DIALYSIS FACILITIES					
as of December 31, 2016					
Dialysis Facilities	Owner	# Patients	Location	# Certified Stations	% Utilization
FMC East Northampton County	FMC	62	Conway	19	81.58%

Source: July 2017 SDR, Table B.

As shown in the table above, the applicant, FMC owns the only dialysis facility in Northampton County. Currently, there are no other providers of dialysis services in Northampton County. Based on the most recent SDR, the FMC East Northampton County was operating above 80% (3.2 patients per station).

In Section N.1, page 56, the applicant discusses how this project is not expected to have any impact on competition because it is the only end stage renal disease treatment facility in the county. The applicant states the following as the project relates to cost-effectiveness, quality and access,

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. ... The facility must capitalize upon every opportunity for efficiency.

... This proposal will certainly not adversely affect quality, but rather, enhance the quality of ESRD patients' lives ...”

See also Sections B, C, F, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality and access to the proposed services in Section N, page 56. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative.
- The applicant adequately demonstrates that FMC East Northampton County will continue to provide quality dialysis services.
- The applicant demonstrates that FMC East Northampton County will continue to provide adequate access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

BMA owns and operates 108 facilities in North Carolina. In Section O and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18-month look-back period. Two facilities, BMA East Rocky Mount and RAI West College (shown below in the table) are in compliance now. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Rocky Mount	1/25/2017	Yes	3/2/2017
RAI West College	3/15/2016	Yes	4/13/2016

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation of its current policies with regard to providing quality care.
- The applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

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

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- FMC East Northampton County is an existing 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, pages 13-15, the applicant demonstrates that FMC East Northampton County will serve a total of 69 in-center patients at the end of Operating Year One for a utilization rate of 82% or 3.2 patients per station (69 patients / 21 stations = 3.28 / 4 = .8214 or 82%). The projected utilization of 3.2 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project in-center utilization of FMC East Northampton County. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.