

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 21, 2017

Findings Date: December 21, 2017

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: J-11407-17

Facility: Johnston Dialysis Center

FID #: 944566

County: Johnston

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

Project: Add one dialysis station for a total of 28 stations upon completion of this project, Project I.D. # J-11230-16 (Add six stations), and Project I.D. #J-11372-17 (Relocate four stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center [**BMA Johnston**] proposes to add one dialysis station for a total of 28 certified dialysis stations upon completion of this project, Project I.D. # J-11230-16 (Add six stations) and Project I.D. #J-11372-17 (Relocate four stations).

Subsequent to submission of this application, the Agency issued a Certificate of Need, effective December 12, 2017, for the applicant's project (Project I.D. # J-11372-17) to develop a new 10-station facility in Selma (Johnston County) by relocating four dialysis stations from BMA Johnston, four dialysis stations from FMC New Hope (Wake County), and two dialysis stations from FMC Four Oaks (Johnston County). In Project I.D. # J-11372-

17, the applicant projected that 21 patients currently served at BMA Johnston would transfer to Fresenius Kidney Care Selma (FKC Selma) upon completion of that project. Therefore, BMA Johnston will have 28 dialysis stations upon completion of this project and Project I.D. # J-11372-17 ($31 - 4 + 1 = 28$).

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 no county need determination for Johnson County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for BMA Johnston in the July 2017 SDR is 3.8 patients per station per week. This utilization rate was calculated based on 94 in-center dialysis patients and 25 certified dialysis stations as of December 31, 2016 ($94 \text{ patients} / 25 \text{ stations} = 3.8 \text{ patients per station per week}$). Application of the facility need methodology indicates one additional station is needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		94.0%
Certified Stations		25
Pending Stations		6
Total Existing and Pending Stations		31
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		94
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		90
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0889
(ii)	Divide the result of Step (i) by 12	0.0074
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0889
(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	102.3556
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.9861
	and subtract the number of certified and pending stations to determine the number of stations needed	1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. 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 only one new station and, therefore, 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 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 54-58, 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 L, pages 46-50, 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 9-10, and Section N, pages 52-53. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. 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.

- (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, BMA Johnston, proposes to add one dialysis station for a total of 28 certified dialysis stations upon completion of this project, Project I.D. # J-11230-16 (Add six stations) and Project I.D. #J-11372-17 (Relocate four stations).

Patient Origin

On page 373 the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may 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 Johnston patients as of June 30, 2017, which is summarized in the following table:

BMA Johnston Historical Patient Origin

County	In-Center
Johnston	91
Wake	1
Wayne	3
TOTAL	95

Source: Table on page 17 of the application.

In Section C.1, page 13, the applicant provides the projected patient origin for BMA Johnston for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

County	Operating Year 1 CY2019			Operating Year 2 CY2020			Percent of Total	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Johnston	100.02	0	0	113.02	0	0	96.2%	96.6%
Wake	1.00	0	0	1.00	0	0	1.0%	0.9%
Wayne	3.00	0	0	3.00	0	0	2.9%	2.6%
Total*	104.02	0	0	117.02	0	0	100.0%	100.0%

*Rounded to the whole patient

The applicant states that Johnston Dialysis does not offer home dialysis services. The applicant provides the assumptions and methodology used to project patient origin on pages 13-15. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B.2, pages 5-6, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR, and it proposes to add one dialysis station to BMA Johnston for a total of 32 stations at that facility. The applicant used the following assumptions:

1. The applicant projects the first two full operating years of the project will be January 1, 2019 – December 31, 2019 (CY2019) and January 1, 2020 – December 31, 2020 (CY2020).
2. On June 30, 2017, BMA Johnston was providing dialysis treatment for 95 in-center patients, including 91 patients who reside in Johnston County, three patients who reside in Wayne County, and one patient who resides in Wake County.
3. BMA Johnston assumes the in-center patient population utilizing the facility who reside in Johnston County will increase at the rate of 13 percent per year. On page 13, the applicant states,

“BMA assumes that the dialysis patient population of Johnston Dialysis will increase at a rate of 13%. The facility historical growth through the end of 2016 has been consistently greater than the Johnston County Five Year Average Annual Change Rate as published within the SDR. The facility census has increased by 32 patients since December 31, 2014. The following table of information is extracted from the July SDR for the years indicated.

SDR	July 2015	July 2016	July 2017
<i>Census Date</i>	<i>12/31/2014</i>	<i>12/31/2015</i>	<i>12/31/2016</i>
<i>Census</i>	<i>62</i>	<i>85</i>	<i>94</i>
<i>Change</i>		<i>23</i>	<i>9</i>
<i>Percent of Change</i>		<i>0.371</i>	<i>0.1063</i>

The average for these most recent years is 23.8%. BMA does not believe this rate would be sustained. BMA also does not believe that the Johnston County Five Year Average Annual Change Rate of 6.3% is appropriate for forecasting future population at the center. Rather, BMA will use a rate of 13.0%, which is significantly less than the average for the most recent two years.”

Projected Utilization

The applicant’s methodology is illustrated in the following table.

	In-Center
The applicant begins with the facility census of Johnston County in-center residents as of June 30, 2017.	91
The census of Wake County in-center patients is increased by 6.5% to project the census forward six months to December 31, 2017.	$[91 \times 0.065] + 91 = 96.9$
The census of Johnston County in-center patients is increased by 13% to project the census forward one year to December 31, 2018.	$[96.9 \times 0.13] + 96 = 109.5$
The applicant subtracts 21 patients from the projected in-center census who are projected to transfer to FMC Selma.	$109.5 - 21 = 88.5$
The applicant adds four patients who reside in other counties.	$88.5 + 4 = 92.5$
The census of Johnston County in-center patients is increased by 13% to project the census forward one year to December 31, 2019.	$[88.5 \times 0.13] + 88.5 = 100.02$
The applicant adds four patients who reside in other counties. This is the projected ending census for Operating Year 1.	$100.02 + 4 = 104.02$
The census of Johnston County in-center patients is increased by 13% to project the census forward one year to December 31, 2020.	$(100.02 \times 0.13) + 100.02 = 113.02$
The applicant adds four patients who reside in other counties. This is the projected ending census for Operating Year 2.	$113.02 + 4 = 117.02$

The applicant projects to serve 104 in-center patients or 3.3 patients per station per week ($104/32 = 3.3$) by the end of Operating Year 1 and 117 in-center patients or 3.7 patients per station per week ($117/32 = 3.7$) by the end of Operating Year 2 for the proposed 32-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the

first operating year as required by 10A NCAC 14C .2203(b). The July 2017 SDR indicates that BMA Johnston operated at a utilization rate of 94 percent (3.8 patients per station) as of December 31, 2016. Based on data reported in the SDR, during the period from December 31, 2014 to December 31, 2016, the in-center census at BMA Johnston increased from 62 to 94 patients, which equivalent to an average annual rate of growth of 23 percent. In this application, the applicant assumes a projected annual rate of growth of 13 percent for the in-center patient census (Johnston County residents only) at BMA Johnston. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Subsequent to submission of this application, the Agency issued a Certificate of Need, effective December 12, 2017, for the applicant's project (Project I.D. # J-11372-17) to develop a new 10-station facility in Selma (Johnston County) by relocating four dialysis stations from BMA Johnston, four dialysis stations from FMC New Hope (Wake County), and two dialysis stations from FMC Four Oaks (Johnston County). In Project I.D. # J-11372-17, the applicant projected that 21 patients currently served at BMA Johnston would transfer to Fresenius Kidney Care Selma (FKC Selma) upon completion of that project. Therefore, BMA Johnston will have 28 dialysis stations upon completion of this project and Project I.D. # J-11372-17 ($31 - 4 + 1 = 28$). In this application, the applicant projects an in-center patient census of 117 at the end of the second operating year (CY2020). Therefore, upon completion of this project and Project I.D. # J-11372-17, the applicant's projected in-center patient census for BMA Johnston would be 96 following the transfer of the 21 in-center patients to FKC Selma ($117 - 21 = 96$). As such, BMA Johnston's projected utilization following completion of both project would be projected to be 3.4 patients per station per week ($96/28 = 3.4$).

Access

In Section L.1(a), pages 46-47, 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, and other underserved persons. In Section R, page 69, the applicant reports that 80% of the in-center patients who received treatments at BMA Johnston had some or all of their services paid for by Medicare or Medicaid in CY2016. In Section R, page 70, the applicant projects 80% of its patients will be Medicare or Medicaid recipients in the second operating year of the project. 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.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose the reduction or elimination of a service, or the relocation of a facility or service.

- (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 21, the applicant states that maintaining the status quo was the only other possible alternative. The applicant states that maintaining the status quo is not an effective alternative due to the fact that BMA Johnston is already highly utilized and has a growing patient population.

After considering that alternative, the applicant states the alternative represented in the application is the most 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 Johnston Dialysis Center shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center shall develop and operate no more than one additional dialysis station for a total of no more than 28 certified stations upon completion of this project, Project I.D. # J-11230-16 (Add 6 stations), and Project I.D. #J-11372-17 (Relocate four stations to FKC Selma), which shall include any isolation or home hemodialysis stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Johnston Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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, BMA Johnston, proposes to add one dialysis station for a total of 28 certified dialysis stations upon completion of this project, Project I.D. # J-11230-16 (Add six stations) and Project I.D. #J-11372-17 (Relocate four stations).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant projects \$3,750 in capital costs for dialysis machines and other equipment. In Section F.10, page 27, 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

In Section F.2, page 24, the applicant states it will finance the capital costs with accumulated reserves. Exhibit F-1 contains a letter dated September 15, 2017, from the Senior Vice

President and Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), authorizing and committing \$3,750 in capital costs for the project.

Exhibit F-2 contains the Consolidated Financial Statements for FMCH for the year ending December 31, 2016. These statements indicate that as of December 31, 2016, it had \$358 million in cash and cash equivalents, \$20 billion in total assets and \$9.3 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided 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 in the table below.

	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	14,968	15,709
Total Gross Revenues (Charges)	\$59,692,384	\$62,647,492
Total Net Revenue	\$4,233,781	\$4,443,376
Total Operating Expenses (Costs)	\$3,970,607	\$4,139,796
Net Income	\$263,174	\$303,580

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, BMA Johnston, proposes to add one dialysis station for a total of 28 certified dialysis stations upon completion of this project, Project I.D. # J-11230-16 (Add six stations) and Project I.D. #J-11372-17 (Relocate four stations).

On page 373 the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

The applicant operates three dialysis centers in Johnston County. The existing and approved Johnston County dialysis facilities are shown below:

Johnston County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/16	CON Issued Not Certified	% Utilization	Patients Per Station
FMC Four Oaks	22	0	65.91%	2.6
FMC Stallings Station	24	0	81.25%	3.3
BMA Johnston	25	6	94.00%	3.8

Source: July 2017 SDR, Table B.

As shown in the table above, two of the three operational Johnston County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2016.

In this project, BMA Johnston proposes to add one in-center dialysis station for a total of 32 dialysis stations upon project completion. BMA Johnston was serving 94 patients weekly on 25 stations, which is 3.8 patients per station or 94% of capacity, as of December 31, 2016. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13-15 of the application. The growth projections are based on a projected 13% average annual growth rate in the number of in-center dialysis patients (Johnston County residents only) at the BMA Johnston facility. At the end of Operating Year Two, BMA Johnston projects utilization will be 3.7 in-center patients per station (117 patients / 32 dialysis stations = 3.7), which is 93% of capacity. The applicant adequately

demonstrates the need to develop one additional dialysis station at the existing facility based on the number of in-center patients it proposes to serve.

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 33, the applicant provides the current staffing for the facility, which includes 23 full-time equivalent (FTE) employees. The applicant states that no additional staffing is projected to be added to the facility following completion of the project. In Section H.3, page 33, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-5 contains a copy of a letter from William L. Fan, 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 BMA Johnston.
- 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.1, page 36, 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 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 is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 50, the applicant reports that 80% of the patients who received treatments at BMA Johnston had some or all of their services paid for by Medicare or Medicaid in CY2016. The table below shows the historical (CY2016) payment source for the facility:

Payment Source	Total Patients by Percent of Total
Self Pay/Indigent/Charity	10.74%
Medicare	61.26%
Medicaid	8.72%
Commercial Insurance	6.18%
Medicare/Commercial Insurance	9.76%
Miscellaneous (including VA)	3.34%
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 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
Johnston	13%	51%	31%	13%	10%	14%
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

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

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.

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, page 48, 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.”

In Section L.6, page 49, the applicant states there have been no civil rights access complaints filed within the last five years.

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.
 - The applicant states it has not had any civil rights access complaints filed against it 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 R, page 70, the applicant projects that 80% of the patients who will receive treatments at BMA Johnston in the second operating year (CY2020) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected Year 2 payment source for the facility for patients:

Payment Source	Total Patients by Percent of Total
Self Pay/Indigent/Charity	10.74%
Medicare	61.26%
Medicaid	8.72%
Commercial Insurance	6.18%
Medicare/Commercial Insurance	9.76%
Miscellaneous (including VA)	3.34%
Total	100.00%

In Section L.1, pages 46-47, the applicant provides the assumptions used to project payer mix. The applicant's projected payment sources are consistent with the facility's historical (CY2016) payment sources as reported by the applicant in Section R, page 69. The applicant adequately demonstrated that medically underserved groups will have access to the services offered at BMA Johnston.

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.

Therefore, 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 49, the applicant describes the range of means by which a person will have access to the dialysis services at BMA Johnston, including referrals from nephrologists, other physicians, or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will 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.

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In Section M.1, page 51, the applicant states that BMA Johnston has established relationships with local community training programs, and the applicant will continue to offer the same opportunities to local health professional training programs. Exhibit M-1 contains a copy of correspondence to an area health professional training program expressing an interest on the part of the applicant to offer the facility as clinical training site.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

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, BMA Johnston, proposes to add one dialysis station for a total of 28 certified dialysis stations upon completion of this project, Project I.D. # J-11230-16 (Add six stations) and Project I.D. #J-11372-17 (Relocate four stations).

On page 373 the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Johnston County. Facilities may serve residents of counties not included in their service area.

The applicant operates three dialysis centers in Johnston County. The existing and approved Johnston County dialysis facilities are shown below:

Johnston County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/16	CON Issued Not Certified	% Utilization	Patients Per Station
FMC Four Oaks	22	0	65.91%	2.6
FMC Stallings Station	24	0	81.25%	3.3
BMA Johnston	25	6	94.00%	3.8

Source: July 2017 SDR, Table B.

As shown in the table above, two of the three operational Johnston County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2016.

In Section N.1, page 52, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 88% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.

BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

See also Sections B, C, E, F, G, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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 BMA Johnston will continue to provide quality dialysis services.
- The applicant demonstrates that BMA Johnston 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.

In Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Section O.3, pages 67-68, the applicant identifies two of its North Carolina facilities, BMA East Rocky Mount and RAI West College-Warsaw, as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that the facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. 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.

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 application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria 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- BMA Johnston 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, page 14, the applicant projects to serve 104 in-center patients by the end of Operating Year 1, which is 3.3 patients per station ($104 / 32 = 3.3$). The discussion regarding projected utilization 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 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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.