

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 20, 2017

Findings Date: July 20, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: L-11313-17

Facility: BMA of Roanoke Rapids

FID #: 956044

County: Halifax

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

Project: Add four dialysis stations for a total of 50 stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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 BMA of Roanoke Rapids, aka BMA Roanoke Rapids, proposes to add four dialysis stations for a total of 50 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 January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of eight dialysis stations in Halifax 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 BMA Roanoke Rapids in the January 2017 SDR is 3.28 patients per station per week, or 82.07% ($3.2826 / 4 \text{ patients per station} = .8207$). This utilization rate was calculated based on 151 in-center dialysis patients and 46 certified dialysis stations ($151 \text{ patients} / 46 \text{ stations} = 3.282 \text{ patients per station per week}$).

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

BMA ROANOKE RAPIDS ---APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		82.07%
Certified Stations		46
Pending Stations		0
Total Existing and Pending Stations		46
In-Center Patients as of 6/30/16 (SDR2)		151
In-Center Patients as of 12/31/15 (SDR1)		143
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.1119
(ii)	Divide the result of step (i) by 12	0.0093
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0559
(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	159.4476
(v)	Divide the result of step (iv) by 3.2 patients per station	49.8274
	and subtract the number of certified and pending stations to determine the number of stations needed	4
Pending Stations: INCLUDE all previously approved stations to be added to this facility, which includes any stations certified after the cutoff date. Do NOT subtract any stations to be transferred from this facility.		

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four 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 four 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, pages 12-15, and Section O, pages 59-61. 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, page 13, Section C, page 21, Section I, page 42, Section L, pages 51-55 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, pages 14-17, Section N, pages 57-58, 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

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 SDR and Policy GEN-3. Therefore, 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

BMA proposes to add four dialysis stations for a total of 50 certified dialysis stations at BMA Roanoke Rapids upon completion of this project. In addition to in-center (IC) dialysis, BMA Roanoke Rapids 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 Halifax County. Facilities may serve residents of counties not included in their service area.

In Section C-8, page 24, the applicant provides a table, as shown below with the historical patient origin for IC, HH and PD patients, served by BMA Roanoke Rapids; although this proposal is to increase IC dialysis services only.

BMA ROANOKE RAPIDS As of December 31, 2016			
County	# In-Center Dialysis Patients	Home Hemo Dialysis Patients	Peritoneal Dialysis Patients
Halifax	129	4	9
Northampton	27	1	3
Virginia	1	0	0
Total	157	5	12

In Section C-1, page 18, 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:

BMA ROANOKE RAPIDS Projected Patient Origin				
			County Patients as % of Total	
	OY1 CY2019	OY2 CY2020	OY1 CY2019	OY2 CY2020
County	IC Patients	IC Patients		
Halifax	134.1	135.8	82.7%	82.3%
Northampton	27.7	27.9	16.7%	16.6%
Virginia	1	1	0.6%	0.6%
Total	162	164	100.0%	100.0%

OY = Operating Year.

The applicant provides the assumptions and methodology for the above projections on pages 18-19. As shown in the above two tables, the applicant projects a seven patient increase in Halifax County IC patients once this project is complete. The applicant currently serves 129 IC patients from Halifax County, 27 IC patients from Northampton County and one IC patient from Virginia. The applicant assumes that these 28 IC patients will continue their care at BMA Roanoke Rapids. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add four dialysis stations to the existing BMA Roanoke Rapids facility for a total of 50 certified dialysis upon project completion. In Section B-2, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the January 2017 SDR. In Section C-1, pages 18-20, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s patients who reside in Halifax County have increased at a rate commensurate with the Five-Year Average Annual Change Rate (AACR) for Halifax County, which is 1.30%. The applicant projects a very slight increase (0.8%) in the Northampton County IC patients; which is commensurate with the Northampton County Five Year AACR. Although there is one Virginia patient dialyzing at BMA Roanoke Rapids, the applicant does not project an increase in its Virginia patient population which represents approximately one percent of the IC patient population of BMA Roanoke Rapids.

OY1 = CY2019

OY2 = CY2020

Projected Utilization

In Section C, page 19, 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 19-20.

BMA ROANOKE RAPIDS IN-CENTER DIALYSIS PROJECTIONS	
Begin with 129 Halifax County and 27 Northampton County patients dialyzing at BMA Roanoke Rapids as of December 31, 2016.	129 27
Project both patient populations forward one year to December 31, 2017.	$(129 \times .013) + 129 = 130.7$ $(27 \times .008) + 27 = 27.2$
Project both patient populations forward one year to December 31, 2018.	$(130 \times .013) + 130.7 = 132.4$ $(27.2 \times .008) + 27.2 = 27.4$
Project both patient populations forward one year to December 31, 2019.	$(132.4 \times .013) + 132.4 = 134.1$ $(27.4 \times .008) + 27.4 = 27.7$
OY1: Add one patient from Virginia. This is the ending census for OY1 (Calendar Year 2019).	$134.1 + 27.7 + 1 = \mathbf{162.7}$
Project growth of Halifax County and Northampton County patient populations forward one year to December 31, 2020.	$(134.1 \times .013) + 134.1 = 135.8$ $(27.7 \times .008) + 27.7 = 27.9$
OY2: Add one patient from Virginia. This is the ending census for OY2 (Calendar Year 2020).	$135.8 + 27.9 + 1 = \mathbf{164.7}$

The applicant projects that BMA Roanoke Rapids will serve a total of 162 in-center patients at the end of Operating Year One for a utilization rate of 81% or 3.2 patients per station (162 patients / 50 stations = 3.24 / 4 = .81 or 81%). 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).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued IC patient growth at BMA Roanoke Rapids.

Access

In Section L, pages 51-52, the applicant states that each of BMA’s 108 facilities in 42 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 92.3% of its revenue will be from Medicare or Medicaid in Project Year 2. 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

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed in-center dialysis stations and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, 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

- (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 27, 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 expand 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 four stations but rejected the alternative because utilization is projected to exceed 3.2 patients per station.
- Relocate Stations from FMC Halifax County in Scotland Neck – This alternative was rejected by the applicant because FMC Halifax County does not have excess stations because the facility is well utilized.

The applicant states that adding four dialysis stations at BMA Roanoke Rapids is a 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.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. 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 BMA of Roanoke Rapids shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Roanoke Rapids shall develop and operate no more than four additional dialysis station for a total of no more than 50 certified stations upon completion of this project, which shall include any isolation stations and home training stations.**
- 3. Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Roanoke Rapids 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

BMA proposes to add four dialysis station for a total of 50 certified dialysis stations at the BMA Roanoke Rapids facility upon completion of this project.

Capital and Working Capital Costs

In Section F-1, page 29, the applicant projects it will incur \$15,000 in capital costs to acquire water treatment equipment (\$3,000) and equipment/furniture (\$12,000) for the proposed project. In Section F-10 through 13, page 32, the applicant states that there are no working capital needs for the proposed project since BMA Roanoke Rapids is an existing facility.

Financial Feasibility

In the projected revenue and expense statement in Section R, Form B, page 72, the applicant projects revenues will exceed operating expenses in the first two operating years following completion of the proposed project, as shown below in the table.

BMA ROANOKE RAPIDS		
	OY1 / CY2019	OY2 / CY2020
Total Treatments*	23,860	24,157
Total Gross Revenues (Charges)	\$105,199,452	\$106,383,888
Total Net Revenue	\$7,092,428	\$7,171,857
Total Operating Expenses (Costs)	\$6,212,590	\$5,988,879
Net Income	\$879,838	\$1,182,978

*Form C, pages 74 and 75. Adjusted by the applicant for missed treatments.

The assumptions used by the applicant in preparation of the pro formas are reasonable including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. In Section, H-1, page 38, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussions regarding projected utilization found in Criterion (3) and staffing found in Criterion (7) are 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 on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, 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 four dialysis stations for a total of 50 certified dialysis stations upon completion of this project at BMA Roanoke Rapids.

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 Halifax County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are two dialysis facilities in Halifax County, as follows:

HALIFAX COUNTY DIALYSIS FACILITIES					
as of June 30, 2016					
Dialysis Facilities	Owner	# Patients	Location	# Certified Stations	% Utilization
BMA Roanoke Rapids	FMC	151	Roanoke Rapids	46	82.07%
FMC Dialysis Services of Halifax	FMC	61	Scotland Neck	19	80.26%

Source: January 2017 SDR, Table A.

As shown in the table above, the applicant, FMC owns both of the current dialysis facilities in Halifax County. Currently, there are no other providers of dialysis services in Halifax County. Based on the most recent SDR, the two existing dialysis facilities in Halifax County were operating above 80% (3.2 patients per station).

In Section C, pages 18-19, the applicant projects that BMA Roanoke Rapids will serve a total of 162 IC patients at the end of Operating Year One for a utilization rate of 81% or 3.2 patients per station ($162 \text{ patients} / 50 \text{ stations} = 3.24 / 4 = .81$ or 81%). According to the January 2017 SDR, there is a deficit of eight dialysis stations in Halifax County. The applicant is applying to add four additional stations based on the facility need methodology.

The applicant states that the projected utilization rates are based on patients currently dialyzing at BMA Roanoke Rapids. The applicant adequately demonstrates the need to add four additional stations at BMA Roanoke Rapids 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 applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Halifax County. Consequently, 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 38, the applicant provides the current and projected staffing for the BMA Roanoke Rapids, which is 36.95 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.

BMA ROANOKE RAPIDS Facility Staffing	
Position	Current & Projected FTEs
Registered Nurse	8.00
Technician (PCT)	19.00
Clinical Manager	1.00
Administrator	0.15
Dietician	1.25
Social Worker	1.25
Home Training RN	3.00
Chief Tech	0.15
Equipment Tech	1.00
In-Service	0.15
Clerical	2.00
Total	36.95

In Section H-3, page 39, 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 40, the applicant provides the projected direct care staff for BMA Roanoke Rapids in OY2. Exhibit I-5 contains a copy of a letter from Danilo Bernardo, M.D., expressing his interest in continuing to serve as the Medical Director for the facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, 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 41, 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 42-43. Exhibits I-2 through I-4, respectively, contain copies of agreements, including Spectra Laboratories, Halifax Regional Medical Center and

transplant services at Virginia Commonwealth University Medical Center. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

- (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

- (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 55, the applicant reports that 93.45% of the revenue received for treatments at BMA Roanoke Rapids was from Medicare or Medicaid in CY 2016. The table below shows the historical payor sources of the facility:

BMA ROANOKE RAPIDS CY 2016	
Payor Source	Percent of Total Revenue
Self-Pay/ Indigent/ Charity*	0.0%
Medicare	82.79%
Medicaid	5.47%
Commercial Insurance	5.13%
Medicare / Commercial	5.19%
Misc. (VA)	1.43%
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**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Halifax	18%	52%	61%	24%	17%	17%
Northampton	23%	52%	62%	26%	18%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*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., V2015) refers to the final year of the series (2010 thru 2015). 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.

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

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 applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L-3(e), page 54, 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 55, the applicant states there have been no civil rights access complaints filed against any BMA North Carolina facilities within the last five years. Therefore, 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 52, the applicant projects that 93.27% of the revenue for IC treatments at BMA Roanoke Rapids in the second operating year (CY2020) will be paid by Medicare or Medicaid. The table below shows the projected Year 2 payment sources for the facility for in-center patients:

²http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf

BMA ROANOKE RAPIDS	
Projected Payor Source PY2	In-Center Revenue by Percent of Total
Self-Pay/ Indigent/ Charity	.06%
Medicare	81.77%
Medicaid	6.28%
Medicare / Commercial	5.22%
Commercial Insurance	5.48%
Misc. (VA)	1.19%
Total	100.00%

In Section L-1, pages 51-52, the applicant states that projections are based on facility historical 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 55 and in Section R, Form C. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at BMA Roanoke Rapids. 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 54, the applicant describes the range of means by which a person will have access to the dialysis services at BMA Roanoke Rapids, 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. Therefore, 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 the health professional training program at Halifax Community College expressing an interest on the part of the applicant to offer the facility as clinical training site. The information provided is reasonable and adequately supports a determination 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 four dialysis stations for a total of 50 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 Halifax County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are two dialysis facilities in Halifax County, as follows:

HALIFAX COUNTY DIALYSIS FACILITIES					
as of June 30, 2016					
Dialysis Facilities	Owner	# Patients	Location	# Certified Stations	% Utilization
BMA Roanoke Rapids	FMC	151	Roanoke Rapids	46	82.07%
FMC Dialysis Services of Halifax	FMC	61	Scotland Neck	19	80.26%

Source: January 2017 SDR, Table A.

As shown in the table above, the applicant, FMC operates both of the operating dialysis facilities in Halifax County. Currently, there are no other providers of dialysis services in Halifax County. Based on the most recent SDR, the two existing dialysis facilities in Halifax County were operating above 80% (3.2 patients per station).

In Section N-1, pages 57-58, the applicant discusses how this project is not expected to have any impact on competition.

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

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that BMA Roanoke Rapids will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that BMA Roanoke Rapids will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, 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

In Section B-4(a), pages 12-13, Section O, pages 59-63, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, page 62, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two facilities listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Rocky Mount	1/25/2017	Yes	3/1/2017
RAI West College	3/15/2016	Yes	4/11/2016

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 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- BMA Roanoke Rapids 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 18-20, the applicant demonstrates that BMA Roanoke Rapids will serve a total of 162 in-center patients at the end of Operating Year One for a utilization rate of 81% or 3.2 patients per station ($162 \text{ patients} / 50 \text{ stations} = 3.2 / 4 = .81$ or 81%). 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 18-21, the applicant provides the assumptions and methodology used to project utilization of BMA Roanoke Rapids. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.