

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 11, 2017

Findings Date: December 11, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: N-11399-17

Facility: BMA of Red Springs

FID #: 980754

County: Robeson

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

Project: Add one dialysis station for a total of 20 stations upon completion of this project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of Red Springs [**BMA Red Springs**] proposes to add one dialysis station to the existing facility for a total of 20 certified dialysis stations upon project completion.

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 Robeson 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 of Red Springs in the July 2017 SDR is 3.46 patients per station per week. This utilization rate was calculated based on 52 in-center dialysis

patients and 15 certified dialysis stations as of December 31, 2016 (52 patients / 15 stations = 3.46 patients per station per week). Application of the facility need methodology indicates up to 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		88.1%
Certified Stations		15
Pending Stations*		4
Total Existing and Pending Stations		19
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		52
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		47
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.2128
(ii)	Divide the result of Step (i) by 12	0.0177
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.2128
(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	63.0638
(v)	Divide the result of Step (iv) by 3.2 patients per station	19.7074
	and subtract the number of certified and pending stations to determine the number of stations needed	0.7074

*These four pending stations were certified on June 30, 2017, according to correspondence from the Acute and Home Care Licensure and Certification Section, DHSR.

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 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 the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 52 - 54, 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 the proposed project would promote equitable access in Section B.4(b), page 9, Section L, pages 45 - 49, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 9 - 11, and Section N, page 51. However, the applicant does not adequately demonstrate that the proposed project is the least costly or most effective alternative or that the project will not result in the unnecessary duplication of existing health service capabilities or facilities. See Criteria (4) and (6), which are incorporated herein by reference. Based on these facts, the applicant does not adequately demonstrate that the proposal will maximize healthcare value.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2017 SDR. However, the applicant does not adequately demonstrate that the proposal will incorporate the basic principles of GEN-3. Therefore, the application is not 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 proposes to add one dialysis stations for a total of 20 certified dialysis stations upon project completion.

Patient Origin

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

In Section C.8, page 16, the applicant provides the historical patient origin for BMA Red Springs patients as of June 30, 2017, which is summarized in the following table:

In-Center Patient Census as of June 30, 2017

COUNTY OF RESIDENCE	# IN-CENTER PATIENTS	% OF TOTAL PATIENTS
Robeson	57	100.0%
Total	57	100.0%

In Section C.1, page 13, the applicant identifies the in-center patient population it proposes to serve during the first two Operating Years (OY) following project completion, as illustrated in the table below:

Projected In-Center Patient Census OY 1 and 2

COUNTY	OY 1	OY 2	COUNTY PATIENTS AS % OF TOTAL	
	# IN-CTR. PTS.	# IN-CTR. PTS.	OY 1	OY 2
Robeson	64.9	68.4	100.0%	100.0%
Total	64	68	100.0%	100.0%

The applicant operates five of six existing dialysis facilities in Robeson County. Total Renal Care of North Carolina, Inc. operates one dialysis facility, Maxton Dialysis, also in Robeson County.¹ The applicant projects to serve only in-center patients at BMA Red Springs. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B.1, page 5, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP. The applicant proposes to add one dialysis station to BMA Red Springs, for a total of 20 stations at that facility upon project completion.

In Section C.1, pages 13 - 14, the applicant uses the following assumptions in its projections:

- The applicant states that since 2016 the patient population of BMA Red Springs increased at a faster rate than the Five Year Average Annual Change Rate (AACR) published in the July 2017 SDR, which is 4.5%. The applicant states this increased growth (21%) is shown in the facility need methodology.

¹ In Project ID #N-10321-14, Total Renal Care of North Carolina, LLC was approved to relocate St. Pauls Dialysis Center and rename it Maxton Dialysis. In Project ID# N-11077-15, Total Renal Care of North Carolina, LLC was approved to relocate four stations from a facility in Hoke County to Maxton Dialysis.

- The applicant states the 21% growth will likely not continue, and elects to project growth at one-quarter of that rate, or 5.32%.
- The applicant projects that all of the patients who receive dialysis care at BMA Red Springs will be residents of Robeson County, consistent with the facility's experience, though the facility will not limit or restrict patients who have a referral for treatment.
- The applicant projects this project to be complete on December 31, 2018.

Operating Year 1 is Calendar Year 2019, January 1 through December 31, 2019.
Operating Year 2 is Calendar Year 2020, January 1 through December 31, 2020.

Projected Utilization

The applicant's methodology is illustrated in the following table, form page 14:

Begin with Robeson County census as of June 30, 2017.	57
Project that census forward six months to 12/31/2017.	$57 \times 1.0266 = 58.5$
Project that census forward one year to 12/31/2018.	$58.5 \times 1.0532 = 61.6$
Project that census forward one year to 12/31/2019. This is the end of Operating Year One.	$61.6 \times 1.0532 = 64.9$
Project that census forward one year to 12/31/2019. This is the end of Operating Year Two.	$64.9 \times 1.0532 = 68.4$

The applicant rounds down for each year, and thus projects to serve 64 in-center patients or 3.2 patients per station per week ($64 / 20 = 3.20$) by the end of Operating Year 1 and 68 in-center patients or 3.4 patients per station per week ($68 / 20 = 3.40$) by the end of Operating Year 2 for the facility. This satisfies 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at BMA Red Springs.

Access

In Section L.1, pages 45 - 46, 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.

The applicant projects that 93.04% of its patients will be Medicare or Medicaid recipients in CY 2020, based on its current facility patient data. 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, demonstrates the need that population has for the services proposed 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

The applicant does not propose to reduce, eliminate or relocate a facility or a service. The applicant proposes to add one dialysis station to an existing facility pursuant to the facility need determination.

- (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.

NC

In Section E, page 20, the applicant describes the one alternative it considered prior to submitting this application for the proposed project, which was to maintain the status quo and not apply for a station increase. The applicant states that, considering the recent growth of the facility, it was obvious that the additional station is needed.

After considering that alternative, the applicant states that this project represents an effective alternative to meet the identified need of the patient population to be served at BMA Red Springs.

However, the applicant does not indicate that it considered relocating an existing dialysis station from one of its other Robeson County dialysis facilities as an alternative to this proposal. Currently, the applicant operates five dialysis facilities in Robeson County. Total Renal Care of North Carolina, LLC operates one dialysis facility². The existing and approved Robeson County dialysis facilities are shown below:

² In Project ID #N-10321-14, Total Renal Care of North Carolina, LLC was approved to relocate St. Pauls Dialysis Center and rename it Maxton Dialysis. In Project ID# N-11077-15, Total Renal Care of North Carolina, LLC was approved to relocate four stations from a facility in Hoke County to Maxton Dialysis.

Existing and Approved Cumberland County Dialysis Facilities per the July 2017 SDR

DIALYSIS FACILITY	# CERTIFIED STATIONS 12/31/2016	CON ISSUED NOT CERTIFIED	% UTILIZATION	# PATIENTS PER STATION
BMA of Red Springs	15	4	86.67%	3.46
FMC Dialysis Services of Robeson County	23	0	57.61%	2.30
FMC Pembroke	15	4	93.33%	3.73
FMC St. Pauls	15	0	96.67%	3.86
Lumberton Dialysis Unit	35	0	83.57%	3.34
St. Pauls Dialysis Center	10	-10	50.00%	2.00
Maxton Dialysis	0	+14	0.00%	0.00

As shown in the table above, four of the five Robeson County dialysis facilities operated by the applicant were operating above 80% utilization (3.2 patients per station) as of December 31, 2016. However, FMC Dialysis Services of Robeson County had 23 in-center stations and 57.61% utilization at the same time. In fact, the utilization of the 23 stations at FMC Dialysis Services of Robeson County has decreased consistently for the last three reporting cycles for the SDR, as shown in the following table:

FMC Dialysis Services of Robeson County Historical Utilization

SDR	# PATIENTS	# STATIONS	# PATIENTS / STATION	% UTILIZATION
January 2016	71	23	3.08	77.2%
July 2016	68	23	2.95	73.9%
January 2017	62	23	2.69	67.4%
July 2017	53	23	2.30	57.6%

Source: January 2016 through July 2017 SDRs

The most recent utilization reported for FMC Dialysis Services of Robeson County is 57.6%, down from 77.2% as of June 30, 2015 (the date of reporting for the January 2016 SDR). Moreover, that facility's utilization has not met the minimum of 3.2 patients per station per week set forth in the performance standards at 10A NCAC 14C .2203(b), which an applicant is required to meet before stations can be added to the facility, in over two years of reporting. The applicant could relocate one station from FMC Dialysis Services of Robeson County, leaving that facility with 22 in-center stations. Even with the relocation of one station, that facility would be able to adequately serve its dialysis patients. The applicant does not provide sufficient information to adequately document that the chosen alternative is the least costly or most effective alternative to meet the need for one additional station at BMA Red Springs.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (6) and (18a), which are incorporated herein by reference. An application that cannot be approved is not an effective alternative.

In summary, the applicant did not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Consequently, the application is not conforming to this criterion.

- (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

In Section F.1, page 21, the applicant states that it will not incur any capital costs to develop this project. In Sections F.10 - F.12, page 25, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project.

Financial Feasibility

In Section R, the applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Forms B and C), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	CY2019 OPERATING YEAR 1	CY2020 OPERATING YEAR 2
Total Treatments	9,336	9,781
Total Gross Revenues (Charges)	\$37,231,968	\$39,006,628
Total Net Revenue	\$ 2,595,052	\$ 2,718,745
Total Operating Expenses (Costs)	\$ 2,565,516	\$ 2,661,462
Net Income	\$ 29,536	\$ 57,283

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. 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.

NC

The applicant proposes to add one dialysis stations for a total of 20 certified dialysis stations upon project completion.

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

The applicant is eligible to apply for additional stations at BMA Red Springs based on application of the facility need methodology, because the utilization rate reported in the July 2017 SDR was 86.67%, or 3.46 patients per station.

The applicant currently operates five dialysis facilities in Robeson County. Total Renal Care of North Carolina, LLC operates one dialysis facility.³ The existing and approved Robeson County dialysis facilities are shown below:

Existing and Approved Cumberland County Dialysis Facilities per the July 2017 SDR

DIALYSIS FACILITY	# CERTIFIED STATIONS 12/31/2016	CON ISSUED NOT CERTIFIED	% UTILIZATION	# PATIENTS PER STATION
BMA of Red Springs	15	4	86.67%	3.46
FMC Dialysis Services of Robeson County	23	0	57.61%	2.30
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Lumberton Dialysis Unit	35	0	83.57%	3.34
St. Pauls Dialysis Center	10	-10	50.00%	2.00
Maxton Dialysis	0	+14	0.00%	0.00

As shown in the table above, four of the five Robeson County dialysis facilities operated by the applicant were operating above 80% utilization (3.2 patients per station) as of December 31, 2016.

FMC Services of Robeson County currently has 23 in-center stations, with a current utilization of 57.61% [53 patients / 23 stations = 2.3; 2.3 / 4 = 0.5761]. In fact, utilization at that facility has continued to decrease since at least June 30, 2015, the date of reporting for the January 2016 SDR. The applicant could relocate one station from FMC Services of Robeson County, leaving that facility with 22 in-center stations.

³ In Project ID #N-10321-14, Total Renal Care of North Carolina, LLC was approved to relocate St. Pauls Dialysis Center and rename it Maxton Dialysis. In Project ID# N-11077-15, Total Renal Care of North Carolina, LLC was approved to relocate four stations from a facility in Hoke County to Maxton Dialysis.

The applicant does not discuss why it chose not to relocate one station from that facility to BMA Red Springs. In Section G, page 31, the applicant states:

“BMA operates five of the six facilities [in Robeson County]. Four of the five BMA facilities are operating above the 80% utilization threshold. Only FMC Robeson County is operating below 80%. The FMC Robeson County facility is not proximate to the BMA Red Springs facility. The two facilities are on opposite sides of the county, and serve different patient populations.”

While it is true that the two facilities are on opposite sides of the county (FMC Services of Robeson County is in Fairmont, in the southeastern corner of the county and BMA Red Springs is in Red Springs, in the northwestern area of the county), the two facilities are less than 30 miles apart, according to MapQuest®. Furthermore, relocation of one station from FMC Dialysis Services of Robeson County will not adversely impact the patient utilization at that facility. The utilization at FMC Services of Robeson County is 57.61%. Relocation of one station will reduce the number of stations to 22, which would bring the last reported utilization to 2.4 patients per station per week, or 60.22% [$53 / 22 = 2.4$; $2.4 / 4 = 0.6022$]. In fact, applying the Five Year AACR for Robeson County as reported in the July 2017 SDR indicates that the facility would take until 2022 to reach the minimum of 3.2 patients per station per week with 22 stations, as shown in the following table:

# PTS. BEGIN	ROBESON COUNTY AACR	# PTS. END	YEAR	# PTS. PER STATION	% UTILIZATION
53	4.5%	55.385	12/31/2017	2.6	65.9%
55.385	4.5%	57.877	12/31/2018	2.7	68.9%
57.877	4.5%	60.482	12/31/2019	2.8	72.0%
60.482	4.5%	63.203	12/31/2020	3.0	75.2%
63.203	4.5%	66.047	12/31/2021	3.1	78.6%
66.047	4.5%	69.019	12/31/2022	3.3	82.1%

The July 2017 SDR reports a surplus of two dialysis stations in Robeson County. Approval of the applicant’s proposal would increase the dialysis station surplus in Robeson County to three. Relocating an existing dialysis station would not increase the surplus.

The applicant does not adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Robeson County. Therefore, the application is not 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 32, the applicant provides the current staffing for the facility, which includes 11.45 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 32, the applicant describes its experience and process for recruiting and retaining staff, and states it anticipates no difficulty with recruiting staff in the event it adds any staff. Exhibit I-5 contains a copy of a letter from Ezra Lee McConnell, III, M.D., expressing his interest in continuing to serve as the Medical Director for the facility.

In Section H.7, page 34, the applicant shows the existing and projected direct care staff at BMA Red Springs.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis 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.1, page 35, the applicant identifies the necessary ancillary and support services at BMA Red Springs, and explains how the services will be made available. The applicant discusses coordination with the existing health care system on page 37. Exhibit I-5 includes a letter from the medical director of the facility expressing his support for the proposed project. Exhibits I-1 through I-4 contain copies of agreements for home training, lab services, acute services and transplantation services. 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

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, and has not historically served members of HMOs as evidenced by the historical payor mix provided by the applicant in Sections L-G of the application. Additionally, the projected payor mix, shown in Section L.7, does not include HMOs. Therefore, this Criterion 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 any new construction or renovation of existing space as part of this project.

- (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.6, page 49, the applicant reports that 91.13% of the patients who received treatments at BMA Red Springs in CY 2016 had some or all of their services paid for by Medicare or Medicaid. The table below shows the historical (CY 2016) payment source for the facility:

BMA Lenoir

PAYMENT SOURCE	FMC WEST FAYETTEVILLE PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	5.63%
Medicare	76.97%
Medicaid	8.13%
Commercial Insurance	3.25%
Medicare / Commercial	6.03%
Total	100.00%

Totals may not sum due to rounding

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
Robeson	14%	51%	75%	31%	13%	20%
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*⁴ 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.

⁴<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 27-28⁵. 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 47 the applicant states, “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*”. In Section L.6, page 48, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” 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, page 45, the applicant states, “*It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved*”. In Section L.1(b), page 46, the applicant projects that 93.04% of all patients in CY 2020 (OY 2) will have all or part of their services paid for by Medicare and or Medicaid, as shown in the table below:

**Projected Payor Mix, FMC North Ramsey
OY 2 (CY 2020)**

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	2.98%
Medicare	72.42%
Medicaid	11.11%
Commercial Insurance	3.97%
Medicare / Commercial	9.51%
Total	100.00%

Totals may not sum due to rounding

⁵http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. 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 48, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. BMA Red Springs has an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”* The applicant adequately demonstrates that BMA Red Springs offers a range of means by which a person can access the 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

In Section M.1, page 50, the applicant states, *“the applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the BMA Red Springs facility to enhance the educational opportunities for the nursing student.”* In Exhibit M-1, the applicant provides a September 14, 2017 letter to Robeson Community College which invites the college to include BMA Red Springs in student clinical rotations. The information provided in Section M is reasonable and credible and supports a finding of conformity 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.

NC

The applicant proposes to add one dialysis stations for a total of 20 certified dialysis stations upon project completion.

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

The applicant is eligible to apply for additional stations at BMA Red Springs based on application of the facility need methodology, because the utilization rate reported in the July 2017 SDR was 86.67%, or 3.46 patients per station.

The existing and approved Robeson County dialysis facilities are shown below:

Existing and Approved Cumberland County Dialysis Facilities per the July 2017 SDR

DIALYSIS FACILITY	# CERTIFIED STATIONS 12/31/2016	CON ISSUED NOT CERTIFIED	% UTILIZATION	# PATIENTS PER STATION
BMA of Red Springs	15	4	86.67%	3.46
FMC Dialysis Services of Robeson County	23	0	57.61%	2.30
FMC Pembroke	15	4	93.33%	3.73
FMC St. Pauls	15	0	96.67%	3.86
Lumberton Dialysis Unit	35	0	83.57%	3.34
St. Pauls Dialysis Center	10	-10	50.00%	2.00
Maxton Dialysis	0	+14	0.00%	0.00

In Section N, page 51, the applicant states it does not anticipate this project will have any effect on competition in the service area, as it does not anticipate serving any patients currently being served by any other dialysis provider. The applicant states it projects to serve the patient population currently being served at the facility. However, the applicant does not discuss why it chose not to relocate one stations from FMC Dialysis Services of Robeson County to BMA Red Springs, since the utilization at FMC Dialysis Services of Robeson County is and has been below 3.2 patients per station per week for at least the past two years. Relocation of one station from FMC Dialysis Services of Robeson County to BMA Red Springs will reduce the number of stations at FMC Dialysis Services of Robeson County to 22, which would bring the last reported utilization to 2.4 patients per station per week, or 60.22% [$53 / 22 = 2.4$; $2.4 / 4 = 0.6022$]. The applicant could relocate one station from that facility and still leave that facility with room for additional patient growth.

The July 2017 SDR reports a surplus of two dialysis stations in Robeson County. Approval of the applicant’s proposal would increase the dialysis station surplus in Robeson County to three. Relocating an existing dialysis station would not increase the surplus.

The applicant did not adequately demonstrate that the proposed project is the least costly or most effective alternative to meet the identified need. The discussion regarding alternatives found in Criterion (4) is incorporated herein by reference. Moreover, the applicant did not adequately demonstrate that the proposal to develop one new certified dialysis stations in Robeson County would not result in an unnecessary duplication of dialysis stations in the county. The discussion regarding duplication found in Criterion (6) is incorporated herein by reference. Therefore, the application is not 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, pages 8 - 11, Section O, pages 52 - 56 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in all of its dialysis facilities.

In Exhibit A-4, the applicant provides a list of the Fresenius-related owned and operated ESRD facilities in North Carolina. In Section O.3, pages 54 - 56, and Exhibits O-3 and O-4, the applicant identifies two of over 100 kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. The applicant provides documentation in Exhibit O that demonstrates those facilities are now back in compliance. In addition, on page 56, the applicant states that both of these facilities were back in full compliance with all CMS Guidelines upon the submittal of the 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 application is conforming to this criterion.

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

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant does not propose to develop a new End Stage Renal Disease Facility.

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

-C- In Section C.1, pages 13 - 14, the applicant adequately demonstrates that BMA Red Springs projects to serve a total of 64 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 80% or 3.2 patients per station per week (64 patients / 20 stations = 3.2; $3.2 / 4 = 0.80$ or 80.0%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 13 - 15, 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.