

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 21, 2018

Findings Date: December 21, 2018

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: M-11573-18

Facility: Lumberton Dialysis Unit

FID #: 955445

County: Robeson

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

Project: Add two stations for a total of 24 stations upon completion of this project, Project ID # N-11447-18 (relocate 20 stations to develop FKC East Lumberton) and Project ID #N-11479-18 (add 7 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. (BMA and/or the applicant), d/b/a Lumberton Dialysis Unit (LDU and/or the facility) proposes to add two dialysis stations to the existing facility for a total of 24 dialysis stations upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations). LDU currently offers a home hemodialysis and peritoneal program; however, in Project ID #N-11447-18 the applicant proposes to relocate the entire home training program to the new FKC East Lumberton once that facility becomes operational in January, 2020.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), there is a deficit of eight dialysis stations in Robeson County. Therefore, there is no county need for additional dialysis stations in 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 LDU in the July 2018 SDR is 3.7143 patients per station per week. This utilization rate was calculated based on 130 in-center dialysis patients and 35 certified dialysis stations as of December 31, 2017 (130 patients / 35 stations = 3.7143 patients per station per week). The facility need methodology requires a facility's utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need. Application of the facility need methodology indicates that two additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		92.9%
Certified Stations		35
Pending Stations		7
Total Existing and Pending Stations		42
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		130
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		125
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 6/30/17	0.0800
(ii)	Divide the result of Step (i) by 12	0.0067
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	0.0800
(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	140.400
(v)	Divide the result of Step (iv) by 3.2 patients per station	43.875
	and subtract the number of certified and pending stations to determine the number of stations needed	1.875

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is two stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2018 SDR. Step (C) of the facility need methodology states, "*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*" The applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles* on page 233 of the 2018 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.”

The applicant addresses *Policy GEN-3* as follows:

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 K.1(g), page 47, Section N, page 57, Section O, pages 59 - 62, and Exhibits O-1 and O-2. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 9, Section C.3, pages 17 - 18, Section L, pages 51 – 55 and Section N, page 57. 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 Sections B.4(c) and (d), pages 10 - 11, Section C.3, pages 16 - 18, Section K, pages 45 - 49 and Section N.1, page 57. 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 Agency reviewed the:

- Application

- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- (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 two dialysis stations to Lumberton Dialysis Unit for a total of 24 dialysis stations upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations). LDU currently offers a home hemodialysis and peritoneal program; however, in Project ID #N-11447-18 the applicant proposes to relocate the entire home training program to the new FKC East Lumberton once that facility becomes operational in January 2020.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Robeson County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 20 and Section C.1, page 14, the applicant provides historical and projected patient origin for in-center (IC) patients, home hemodialysis (HH) patients and peritoneal (PD) patients, as summarized in the following tables:

LUMBERTON DIALYSIS UNIT DIALYSIS PATIENTS AS OF 6/30/18

COUNTY	IC	HH	PD
Robeson	121	5	8
Bladen	7	1	0
Cumberland	2	0	0
Hoke	0	1	0
Mecklenburg	0	0	1
Scotland	0	0	1
Totals	130	7	10

Source: Application page 20.

LUMBERTON DIALYSIS UNIT PROJECTED PATIENT ORIGIN

COUNTY	OY 1	OY 2	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Robeson	71.4	75.5	91.0%	91.4%
Bladen	7	7	6.4%	6.1%
Cumberland	2	2	2.6%	2.5%
Totals	80	84	100.0	100.0%

Source: Application page 14.

In Section C, pages 14 - 15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.2, pages 6 – 7, the applicant states the application is filed pursuant to the facility need methodology in the 2018 SMFP utilizing data from the January 2018 and July 2018 SDR. The facility need methodology shows a need for two dialysis stations and the proposed project is for two dialysis stations.

In Section C, pages 14 - 18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant uses the 5.7% Five Year Average Annual Change Rate (AACR) for Robeson County as published in the July 2018 SDR.
- In Project ID #N-11447-18, the applicant projects that 64 Robeson County ESRD patients will transfer their care from LDU to the new FKC East Lumberton facility; thus, the applicant subtracts 64 Robeson County patients as of January 1, 2020 (projected completion date for Project ID# N-11447-18).
- The applicant assumes the Bladen and Cumberland county patient populations will continue to dialyze at LDU following the addition of the two stations proposed in this application. The applicant adds these patients at appropriate times following projected growth of Robeson County patients.
- The home patient population will relocate to the new facility proposed in Project ID #N-11447-18 as of December 31, 2019; therefore, the applicant subtracts these patients at the appropriate point in time, but projects growth in that population until that time.
- The first two full operating years (OYs) of the project will be

OY 1: January 1, 2020 – December 31, 2020 (CY 2020), and
 OY 2: January 1, 2021 – December 31, 2021 (CY 2021).

- 121 patients were receiving in-center dialysis treatments at Lumberton Dialysis Unit as of June 30, 2018. The facility was at 86.43% utilization with 35 in-center stations [121 patients / 35 stations = 3.457; $3.457 / 4 = 0.8643$].
- Assuming no growth in the patient population when the stations are relocated and the patients transferred, the utilization as of December 31, 2019 will be 95.0%, based on 57 patients [121 – 64 = 57] and 15 in-center stations [35 – 20 = 15]; [57 / 15 = 3.8; $3.8 / 4 = 0.95$].

The information is reasonable and adequately supported.

Projected Utilization

In Section C.1, pages 15 - 16, the applicant projects utilization using the assumptions noted above, summarized as follows:

- Operating Year 1 = Calendar Year 2020 (CY 2020)
- Operating Year 2 = Calendar Year 2021 (CY 2021)
- As of June 30, 2018, the applicant states Lumberton Dialysis Unit was dialyzing 121 Robeson County in-center patients and nine patients from Bladen and Cumberland counties, for a total of 130 in-center patients.
- The applicant projects utilization of Robeson County patients using the 5.7% AACR for Robeson County, as shown in Table D in the July 2018 Semi-Annual Dialysis Report (SDR).
- The applicant projects no growth for the Bladen and Cumberland county patients, adding them to the Robeson County patients at the end of each year's projections.
- Sixty-four Robeson County in-center patients will transfer their care from Lumberton Dialysis Unit as of June 30, 2019 to FKC East Lumberton (Project ID #N-11447-18).
- All of the home trained patients will transfer their care to FKC East Lumberton as of June 30, 2019, pursuant to Project ID #N-11447-18.

The following table illustrates application of these assumptions and the methodology used.

In-Center Utilization

Begin June 30, 2018 with the 121 Robeson County patients	121
Project the Robeson County in-center patients forward six months to December 31, 2018, using one-half of the Five Year AACR for Robeson County.	$121 \times 1.0285 = 124.4$
Project the Robeson County in-center patients forward to December 31, 2019, using the Five Year AACR for Robeson County.	$124.4 \times 1.057 = 131.5$
Subtract 64 Robeson County patients projected to transfer their care to the new FKC East Lumberton facility (Project ID# N-11447-18).	$131.5^* - 64 = 67.5$
Add the nine Cumberland County and Bladen County patients who are projected to continue to dialyze at LDU. This is the beginning census for Operating Year 1.	$67.5 + 9 = 76.5$
Project the Robeson County patient population forward one year to December 31, 2020 using the Five Year AACR for Robeson County.	$67.5 \times 1.057 = 71.4$
Add the nine Cumberland County and Bladen County patients who are projected to continue to dialyze at LDU. This is the ending census for Operating Year 1.	$71.4 + 9 = 80.4$
Project the Robeson County patient population forward one year to December 31, 2021 using the Five Year AACR for Robeson County.	$71.4 \times 1.057 = 75.5$
Add the nine Cumberland County and Bladen County patients who are projected to continue to dialyze at LDU. This is the ending census for Operating Year 2.	$75.5 + 9 = 84.5$

*In the application on page 15, the applicant has 161.5; however, the calculations used by the applicant are consistent with the use of 131.5. The applicant's use of 161.5 thus appears to be a typographical error.

Projected patients for OY 1 and OY 2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) and OY2 (CY 2021) the facility is projected to serve 80 and 84 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY 1: 3.33 patients per station per week, or 83.3% [$80 \text{ patients} / 24 \text{ stations} = 3.33$; $3.33 / 4 = 0.833$].
- OY 2: 3.5 patients per station per week, or 87.5% [$84 \text{ patients} / 24 \text{ stations} = 3.5$; $3.5 / 4 = 0.875$].

The projected utilization of 3.33 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 121 existing Robeson County patients.
- The Robeson County patients are projected to increase based on growth of 5.7% per year, consistent with the Five Year AACR for Robeson County as reported in Table D of the July 2018 SDR.

- The applicant holds the existing non-Robeson County patients constant.
- The resulting utilization rate at Lumberton Dialysis Unit by the end of the first year of operation exceeds the minimum standard of 3.2 patients per station per week required by 10A NCAC 14C .2203.

PD Patient Utilization

The following table illustrates application of these assumptions and the methodology used to project PD patient utilization, until the home population is relocated to FKC East Lumberton.

Begin June 30, 2018 with the five Robeson County PD patients.	5
Project the Robeson County PD patients forward to December 31, 2018, using one-half of the Five Year AACR for Robeson County.	$5 \times 1.0285 = 5.2$
Add two patients from Bladen and Hoke Counties.	$5.2 + 2 = 7.2$
Project the Robeson County patient population forward one year to December 31, 2019 using the Five Year AACR for Robeson County.	$5.2 \times 1.057 = 5.5$
Add two patients from Bladen and Hoke Counties.	$5.5 + 2 = 7.5$
The home program is projected to relocate to FKC East Lumberton as of January 1, 2020.	0

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

- The applicant starts with the five existing Robeson County PD patients currently dialyzing at LDU.
- The applicant uses the Robeson County AACR to project growth in the patient population until that population is relocated.
- The applicant accounts for the relocation of the entire home therapy program once FKC East Lumberton is licensed.

HH Patient Utilization

The following table illustrates application of the assumptions and the methodology used to project HH patient utilization:

Begin June 30, 2018 with the eight Robeson County HH patients.	8
Project the Robeson County HH patients forward to December 31, 2018, using one-half of the Five Year AACR for Robeson County.	$8 \times 1.0285 = 8.4$
Add two patients from Scotland County and South Carolina.	$8.4 + 2 = 10.4$
Project the Robeson County patient population forward one year to December 31, 2019 using the Five Year AACR for Robeson County.	$8.4 \times 1.057 = 8.8$
Add two patients from Scotland County and South Carolina.	$8.8 + 2 = 10.8$
The home program is projected to relocate to FKC East Lumberton as of January 1, 2020.	0

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

- The applicant starts with the eight existing Robeson County HH patients.
- The applicant uses the Robeson County AACR to project growth in the patient population until that population is relocated.
- The applicant accounts for the relocation of the entire home therapy program once FKC East Lumberton is licensed.

Access

In Section C.3, page 17, the applicant states “*It is corporate 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, page 52, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/ Indigent/Charity	1.67%
Medicare	72.97%
Medicaid	9.84%
Commercial Insurance	5.42%
Medicare/Commercial	5.52%
Miscellaneous (incl. VA)	4.59%
Total	100.00%

On page 52, the applicant states the projected payor mix is based on the historical payor mix for a twelve-month period ending June 30, 2018. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

The applicant does not propose to reduce or eliminate a service, nor does the applicant propose to relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

BMA proposes to add two dialysis stations to Lumberton Dialysis Unit for a total of 24 dialysis stations upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations).

In Section E, pages 24 - 25, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – the applicant considered not applying for additional stations at Lumberton Dialysis Unit; however, the applicant states to do so is to ignore the reality of an increasing patient population in the service area and at the facility. It would necessitate a third shift, which would not effectively serve the patients.
- Apply for Fewer Stations – the applicant states this is not an effective alternative, because with the two stations as proposed, the utilization rate is projected to be over 80% by the end of the first operating year.
- Relocate Existing Stations from Another BMA Facility – the applicant considered relocating stations from its other facilities in Robeson County, but states those

facilities' utilization will again increase and relocating stations would not serve the patients currently dialyzing at those facilities.

On page 23, the applicant states that its proposal is the most effective alternative because the proposed project will address both the issues of growth and access to the facility for no capital expenditure.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a Lumberton Dialysis Unit shall develop no more than two additional dialysis stations for a total of no more than 24 certified stations at Lumberton Dialysis Unit upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

BMA proposes to add two dialysis stations to Lumberton Dialysis Unit for a total of 24 dialysis stations upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations).

Capital and Working Capital Costs

In Section F.2, page 26, F.10, page 28 and F.11, page 29 the applicant states that the proposed project does not involve any capital expenditures or initial operating expenses, because the facility is currently operational.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In 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.

	OY 1 (CY 2020)	OY 2 (CY 2021)
Total Treatments*	12,168	12,792
Total Gross Revenues (Charges)	\$46,097,292	\$48,462,176
Total Net Revenue	\$3,114,090	\$3,273,849
Average Net Revenue per Treatment	\$256	\$256
Total Operating Expenses (Costs)	\$2,962,540	\$3,064,167
Average Operating Expense per Treatment	\$244	\$240
Net Income	\$151,550	\$209,862

*Source: Application Form C assumptions.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal.
- The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

BMA proposes to add two dialysis stations to Lumberton Dialysis Unit for a total of 24 dialysis stations upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Robeson County. Facilities may also serve residents of counties not included in their service area.

Currently, there are seven existing and approved dialysis facilities in Robeson County, six of which are operated by BMA. DaVita operates one dialysis facility in Robeson County, as shown below:

ROBESON COUNTY DIALYSIS FACILITIES

FACILITY	OWNER	# CERTIFIED STATIONS AS OF 12/31/17	# PATIENTS	UTILIZATION AS OF 12/31/17
BMA of Red Springs	BMA	19	51	67.11%
FMC Dialysis Services of Robeson County	BMA	23	73	79.35%
FMC Pembroke	BMA	15	56	93.33%
FMC St. Pauls	BMA	20	56	70.00%
FKC East Lumberton*	BMA	0	0	0.00%
Lumberton Dialysis Unit	BMA	35	130	92.86%
Maxton Dialysis	DaVita	14	14	59.93%

Source: Table B, July 2018 SDR

*A certificate of need was issued on May 30, 2018 for Project ID# N-11447-18 to develop a new 20 station dialysis facility by relocating 20 existing certified dialysis stations and the home therapies program from BMA Lumberton to the new facility.

As shown in the table above, three of the five operational dialysis facilities operated by BMA were being utilized at 79.35% or higher. The other facilities, FMC St. Pauls and BMA of Red Springs, were being utilized at 70.0% and 67.11%, respectively.

In Section G.2, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Robeson County. The applicant states:

“...the BMA facilities in Robeson County are very well utilized. Even though the BMA of Red Springs and the FMC St. Pauls facilities are reported with less than 70% utilization, BMA suggests this is but a temporary issue.

The ESRD patient population of Robeson County is the 7th largest in North Carolina, and is increasing at a rate of 5.7%. BMA is serving the majority of the patient population residing in Robeson County. The July 2018 SDR, Table A reports that BMA was serving

a total of 343 in-center patients at its facilities in Robeson County. This equates to 78.3% of the patients dialyzing with BMA.”

In Section E.1, page 24, the applicant states:

“As an additional consideration, St. Pauls is conveniently located between Fayetteville and Lumberton. When patients who would normally be admitted to BMA Lumberton [Lumberton Dialysis Unit] and or BMA Fayetteville have scheduling conflicts, the patients are diverted to FMC St. Pauls. FMC St. Pauls has more open slots in the Monday-Wednesday-Friday schedule.”

The applicant states on page 24 that BMA experience shows that more patients prefer the Monday-Wednesday-Friday schedule.

The applicant is proposing to add two dialysis stations based on facility need, and demonstrates that the facility was serving 130 patients weekly on 35 dialysis stations, which is 3.7143 patients per station, or 92.86% of capacity as of June 30, 2018 [$130 / 35 = 3.7143$; $3.7143 / 4 = 0.9286$]. The applicant does not propose the development of a new dialysis facility; rather, this application seeks to address the needs of this facility by adding needed stations.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services because the applicant adequately demonstrates that the proposed addition of two dialysis stations at Lumberton Dialysis Unit is needed in addition to the existing stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

- (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 36, the applicant provides the current staffing for the facility, and states that Lumberton Dialysis Unit is not projected to add any full time equivalent (FTE) positions as a result of this proposal. In fact, pursuant to Project ID #N-11447-18 and the relocation of stations to develop FKC East Lumberton, the applicant projects to decrease staff at Lumberton Dialysis Unit by 13.0 FTEs, as shown in the following table:

POSITION	CURRENT FTE POSITIONS	ADJUSTMENTS	TOTAL FTE POSITIONS
Registered Nurse	7.00	-3.00	4.00
Home Training Nurse	2.00	-2.00	0.00
Patient Care Technician	16.00	-8.00	8.00
Dietician	1.00		1.00
Social Worker	1.00		1.00
Clinical Manager	1.00		1.00
Administration	0.20		0.20
In-Service	0.15		0.15
Clerical	2.00		2.00
Chief Technician	0.15		0.15
Equipment Technician	1.00		1.00
Total	31.50	-13.00	18.50

The applicant provides projected direct care staff in OY 2 in Section H.7, page 39.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, page 37, the applicant describes the methods used to recruit personnel or fill new positions and its existing training and continuing education programs. In Exhibits H-1 and H-2, the applicant provides supporting documentation. In Section I.3, page 42, the applicant identifies the medical director. In Exhibit I-5, the applicant provides a letter from the current medical director indicating an interest in continuing to serve in that capacity following the addition of two stations.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 40, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

LUMBERTON DIALYSIS UNIT ANCILLARY AND SUPPORT SERVICES	
Services	Provider
In-center dialysis/maintenance	BMA
Self-care training (in-center)	BMA
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Currently on site; to be relocated to FKC East Lumberton when those stations are certified (Project ID #N-11479-18)
Psychological counseling	Robeson County DSS
Isolation – hepatitis	BMA
Nutritional counseling	BMA
Social Work services	BMA
Acute dialysis in an acute care setting	Southeastern Regional Medical Center
Emergency care	BMA
Blood bank services	Southeastern Regional Medical Center
Diagnostic and evaluation services	Southeastern Regional Medical Center
X-ray services	Southeastern Regional Medical Center
Laboratory services	Spectra Labs
Pediatric nephrology	UNC Pediatric Nephrology referral
Vascular surgery	Dr. Clinton Atkinson, Dr. Terry Lowery, Dr. Charles Anene, Dr. John Ross
Transplantation services	UNC
Vocational rehabilitation & counseling	Robeson County DSS
Transportation	Southeast Area Transit System, Robeson County DSS

The applicant provides supporting documentation in Exhibit I.

In Section I, pages 40 - 43, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

NA

The applicant does not propose to construct any new space nor renovate any existing space, since the facility currently has space for the additional stations proposed in this application. 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, page 55, the applicant provides the historical payor mix during CY 2017 for the proposed services, as shown in the table below.

Lumberton Dialysis Unit CY 2017 Payor Mix

PAYOR CATEGORY	SERVICES AS PERCENT OF TOTAL
Self-Pay / Indigent / Charity	0.76%
Medicare	75.57%
Medicaid	8.03%
Commercial	6.65%
Medicare Commercial	4.31%
Miscellaneous (Includes VA)	4.67%
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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Robeson	15%	52%	75%	28%	12%	18%
Bladen	21%	52%	46%	26%	17%	17%
Cumberland	12%	50%	57%	19%	12%	11%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(e), page 54, the applicant states:

“Fresenius related facilities in North Carolina do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”

In Section L.6, page 54, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1(b), page 52, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Lumberton Dialysis Unit
Projected Payor Mix, Project Year Two**

PAYOR CATEGORY	SERVICES AS PERCENT OF TOTAL
Self-Pay / Indigent / Charity	1.67%
Medicare	72.97%
Medicaid	9.84%
Commercial	5.42%
Medicare Commercial	5.52%
Miscellaneous (Includes VA)	4.59%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.67% of total services will be provided to self-pay/indigent/charity patients, 72.97% to Medicare patients and 9.84% to Medicaid patients.

On page 52, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for Lumberton Dialysis Unit from July 1, 2017 to June 30, 2018.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.4, page 54, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 56, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive

impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

BMA proposes to add two dialysis stations to Lumberton Dialysis Unit for a total of 24 dialysis stations upon completion of this project, Project I.D. # N-11447-18 (relocate 20 stations to develop the new FKC East Lumberton) and Project # N-11479-18 (add seven stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area for this facility consists of Robeson County. Facilities may also serve residents of counties not included in their service area.

Currently, there are seven existing and approved dialysis facilities in Robeson County, six of which are operated by BMA. DaVita operates one dialysis facility in Robeson County, as shown below:

ROBESON COUNTY DIALYSIS FACILITIES

FACILITY	OWNER	# CERTIFIED STATIONS AS OF 12/31/17	# PATIENTS	UTILIZATION AS OF 12/31/17
BMA of Red Springs	BMA	19	51	67.11%
FMC Dialysis Services of Robeson County	BMA	23	73	79.35%
FMC Pembroke	BMA	15	56	93.33%
FMC St. Pauls	BMA	20	56	70.00%
FKC East Lumberton*	BMA	0	0	0.00%
Lumberton Dialysis Unit	BMA	35	130	92.86%
Maxton Dialysis	DaVita	14	14	59.93%

Source: Table B, July 2018 SDR

*A certificate of need was issued on May 30, 2018 for Project ID# N-11447-18 to develop a new 20 station dialysis facility by relocating 20 existing certified dialysis stations and the home therapies program from BMA Lumberton to the new facility.

As shown in the table above, three of the five operational dialysis facilities operated by BMA were being utilized at 79.35% or higher. The other facilities, FMC St. Pauls and BMA of Red Springs, were being utilized at 70.0% and 67.11%, respectively.

In Section N, pages 57 - 58, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 57, the applicant states:

“The applicant does not expect this proposal to have effect on the competitive climate in Robeson County. ... The projected patient population for the ... facility begins with patients currently served by BMA at [Lumberton Dialysis Unit], and a growth of that patient population consistent with the Robeson County five year annual change rate of 5.7% as published within the July 2018 SDR.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section O.3, page 62, the applicant states there are more than 100 Fresenius related dialysis facilities and more than 9,900 dialysis patients located in North Carolina. The applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that resulted in an Immediate Jeopardy that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (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

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

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 is not proposing to establish 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 14 - 15, the applicant projects to serve 80 in-center patients by the end of OY 1 (CY 2020) for a utilization rate of 83.33% or 3.33 patients per station per week (80 patients / 24 stations = 3.33; $3.33 / 4 = 0.833$ or 83.33%). 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 14 - 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.