

CORRECTED

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 20, 2019

Findings Date: March 20, 2019

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: M-11634-18

Facility: FMC Dialysis Services North Ramsey

FID #: 960411

County: Cumberland

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

Project: Relocate 3 dialysis stations from Dunn Kidney Center in Harnett County for a total of 43 stations at FMC Dialysis Services North Ramsey

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

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate three dialysis stations from Dunn Kidney Center (DKC) in Harnett County to FMC Dialysis Services North Ramsey (FMC North Ramsey) in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

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 January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows

there is no county need determination for Cumberland County. An applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology if the facility’s utilization rate as reported in the latest SDR is at least 3.2 patients per station per week. However, neither of the two need determination methodologies in the 2018 SMFP apply to this proposal.

Policies

There is one policy in the 2018 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2, on page 27 of the 2018 SMFP states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report; and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

In Section B.3, page 7, the applicant provides a table to illustrate the proposed relocation of stations, as shown below:

(a)	County from which stations will relocate	Harnett
(b)	County to which stations will relocate	Cumberland
(c)	Number of residents of county (row a) who are currently dialyzing in-center at a facility owned by the applicant and located in the county from which stations will be relocated	153
(d)	Projected station surplus in county that will lose stations (row a) as a result of the proposed project, as reflected in the most recent SDR	4 – 3 = 1
(e)	Projected station deficit in county that would gain stations (row b) as a result of the proposed project, as reflected in the most recent SDR	-9 + 3 = -6

The applicant addresses *Policy ESRD-2* as follows:

Facility Losing Stations: In Section D.1, page 21, the applicant provides a table to illustrate the current patient origin of Dunn Kidney Center in Harnett County, as shown below:

Dunn Kidney Center Patient Origin as of June 30, 2018

COUNTY	IN-CENTER PATIENTS	HOME HEMODIALYSIS PATIENTS	HOME PERITONEAL DIALYSIS PATIENTS
Harnett	72	1	9
Cumberland	5	0	0
Johnston	5	0	1
Sampson	16	2	0
Total	98	3	10

The applicant shows that Dunn Kidney Center currently serves patients who reside in Cumberland County, the county to which stations will relocate.

Proposal Will Not Result in Deficit or Increase in Deficit of Stations in County Losing Stations:

In Section B, page 7, the applicant states that Harnett County, the county that will lose stations, currently has a surplus of four dialysis stations, per the July 2018 SDR. The relocation of three dialysis stations from DKC in Harnett County will reduce that surplus by three stations, resulting in a surplus of one dialysis stations following project completion. Therefore, the relocation of stations as proposed in this application will not result in a deficit of dialysis stations or an increase in the existing deficit of dialysis stations in Harnett County.

Proposal Will Not Result in Surplus or Increase in Surplus of Stations in County Gaining Stations:

In Section B, page 7, the applicant states Cumberland County, the county to which the stations will relocate, currently has a deficit of nine dialysis stations per the July 2018 SDR. The relocation of three dialysis stations from DKC in Harnett County will reduce that deficit by three stations, resulting in a six-station deficit following project completion. In addition, on January 8, 2019, the applicant was awarded a CON to add six in-center dialysis stations to BMA Fayetteville, in Cumberland County (Project ID #M-11574-18). Therefore, the relocation of stations as proposed in this application will not result in a surplus of dialysis stations or an increase in an existing surplus of dialysis stations in Cumberland County.

The application is conforming to Policy ESRD-2.

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 reasons stated above.

- (2) Repealed effective January 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 relocate three dialysis stations from Dunn Kidney Center in Harnett County to FMC Dialysis Services North Ramsey in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

Patient Origin

On page 365, the 2018 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 for this application is Cumberland County. Facilities may serve residents of counties not included in their service area.

The following table, from pages 14 and 19, illustrates current and projected patient origin for FMC North Ramsey:

COUNTY	CURRENT (AS OF NOVEMBER 1, 2018)		SECOND FULL FY OF OPERATION (CY 2021)	
	IN-CTR. PTS.	% OF TOTAL	IN-CTR. PTS.	% OF TOTAL
Cumberland	132	95.7%	141	95.9%
Harnett	6	4.3%	6	4.1%
Total	138	100.0%	147	100.0%

In Section C, pages 14 - 16, 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 C.1, pages 14 - 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

1. The FMC North Ramsey facility has patient census at FMC North Ramsey was 138 in-center patients as of October 31, 2018, which is 3.45 patients per station per week, or 86.25% utilization [138 / 40 = 3.45; 3.45 / 4 = 0.8625].
2. The applicant states that, despite fluctuations in patient census at FMC North Ramsey over the last 10 months, the annualized growth during that time was 6.4%. The

applicant states that that type of growth is not sustainable and projects future Cumberland County patient census utilizing the Cumberland County Five Year Average Annual Change Rate (AACR) of 3.3% as published in the July 2018 SDR.

3. The applicant states it will not project growth of the Harnett County patient population that chooses to dialyze at FMC North Ramsey; instead, those patients will be added at appropriate times to project the patient census.
4. The applicant states that in Project ID #M-11502-18, a total of five in-center patients would transfer their care from FMC North Ramsey to a new facility when that project is complete in December 2019. The applicant states those five patients are still projected to transfer from FMC North Ramsey.
5. The applicant projects the project to be complete by December 31, 2019.
6. Operating Year (OY) one is calendar year (CY) 2020, and OY two is CY 2021.

The information is reasonable and adequately supported for the following reasons:

- The applicant projects, with this application, to eliminate the deficit of dialysis stations in Cumberland County.
- The applicant projects to reduce the surplus of dialysis stations in Harnett County.
- The applicant states it will utilize the Cumberland County Five Year AACR to project future growth, despite a higher historical growth rate.
- The applicant reasonably projects that the utilization rate of the new facility will be 3.45 patients per station per week at the end of OY one, which exceeds the required minimum operating standard promulgated in 10A NCAC 14C .2203(b), based on the growth of the patient population using the Cumberland County Five Year Average Annual Change Rate (AACR) of 3.3 percent as published in the July 2018 Semiannual Dialysis Report (SDR).

Projected Utilization of In-Center Patients

In Section C.1, page 16, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table:

Begin with census of Cumberland County patients as of October 31, 2018.	132
Project this patient population forward two months to December 31, 2018, using prorated Cumberland County AACR.*	$132 \times 1.0055 = 132.7$
Project Cumberland County population forward 12 months to December 31, 2019.	$132.7 \times 1.033 = 137.1$
Subtract five patients projected to transfer to FKC Rockfish (Project ID #M-11502-18).	$137.1 - 5 = 132.1$
Add six patients from Harnett County. This is the beginning census.	$132.1 + 6 = 138.1$
Project Cumberland County patient population forward 12 months to December 31, 2020.	$138.1 \times 1.033 = 142.5$
Add six patients from Harnett County. This is the ending census for OY 1.	$142.5 + 6 = 148.5$
Project Cumberland County patient population forward 12 months to December 31, 2021.	$148.5 \times 1.033 = 153.5$
Add six patients from Harnett County. This is the ending census for OY 2.	$153.5 + 6 = 159.5$

*The applicant states, on page 16, that it uses “an annual growth rate of 3.9%” for the first two months; however, it actually uses the Cumberland County Five Year AACR of 3.3% as stated above $[(0.033 / 12) \times 2 = 0.055]$

The applicant projects to serve 142 in-center dialysis patients on 43 stations at the end of OY 1, and 147 in-center dialysis patients on 43 stations at the end of OY 2, which is 3.3 patients per station per week at the end of OY 1, and 3.42 patients per station per week at the end of OY 2.

Therefore, the applicant’s projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The applicant uses the Five Year AACR for Cumberland County as published in the July 2018 SDR to project in-center patient utilization.
- The applicant projects growth in only the Cumberland County patient population rather than the entire in-center patient population dialyzing at FMC North Ramsey.
- The applicant’s projected in-center patient utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 17, the applicant states:

“BMA has a long history of providing dialysis services to the underserved populations of North Carolina. Fresenius Medical Care Holdings, Inc. parent company to FMC North Ramsey, currently operates 114 facilities in 48 North Carolina counties (includes our affiliation with RRI facilities). Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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, page 49, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table:

PAYOR	% OF TOTAL
Self-Pay / Indigent / Charity	0.33%
Medicare	70.10%
Medicaid	7.56%
Commercial Insurance	3.45%
Medicare / Commercial	15.59%
Miscellaneous (includes VA)	2.97%
Total	100.00%

Note: numbers may not sum due to rounding

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.

C

The applicant proposes to relocate three dialysis stations from Dunn Kidney Center in Harnett County to FMC Dialysis Services North Ramsey in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

In Section D, pages 21 - 22, the applicant explains why it believes the needs of the population presently dialyzing at Dunn Kidney Center in Harnett County will be adequately met following the relocation of three in-center stations to FMC North Ramsey in Cumberland County. See the following table from page 21 that illustrates the total patient census at Dunn Kidney Center as of June 30, 2018:

Dunn Kidney Center Patient Census, June 30, 2018

COUNTY	IN-CENTER PATIENTS	HOME HEMODIALYSIS PATIENTS	HOME PERITONEAL DIALYSIS PATIENTS
Harnett	72	1	9
Cumberland	5	0	0
Johnston	5	0	1
Sampson	16	2	0
Total	98	3	10

The table shows that Dunn Kidney Center was operating at 70% of capacity as of June 30, 2018 [98 patients / 35 stations = 2.8; 2.8 / 4 = 0.70].

On page 21, the applicant states that Dunn Kidney Center has a home training program; however, since the application involves only the proposed relocation of in-center dialysis stations, home training services and patients will not be affected by the project.

On page 21, the applicant states it will use the 8.2% Harnett County Five Year AACR from the July 2018 SDR to project utilization of the stations that will remain at Dunn Kidney Center following the relocation of three stations to FMC North Ramsey. The following table, from page 22, illustrates projected utilization at Dunn Kidney Center:

Begin with Harnett County patient census as of June 30, 2018.	72
Project census forward six months to December 31, 2018, using the Five Year AACR for Harnett County in the July 2018 SDR.	$72 \times 1.041 = 75.0$
Project census forward 12 months to December 31, 2019, using the Five Year AACR for Harnett County in the July 2018 SDR. This is the projected completion date for this project.	$75.0 \times 1.082 = 81.1$
Add 26 patients residing in other counties but dialyzing at DKC.	$81.1 + 26 = 107.1$
Projected census for DKC as of December 31, 2019.	107.1

Thus, on December 31, 2019, the applicant projects that Dunn Kidney Center will dialyze 107 patients on 32 in-center stations, which is a utilization rate of 83.6%, or 3.3 patients per station per week [$107 / 32 = 3.34$; $3.34 / 4 = 0.836$].

Projected utilization is reasonable and adequately supported based on the following:

- The applicant utilizes the 8.2% Harnett County Five Year AACR as published in the July 2018 SDR to project in-center patient utilization at Dunn Kidney Center following the relocation of three stations to FMC North Ramsey.
- The applicant projects growth in only the Harnett County patient population and adds patients who reside in other counties but choose to dialyze at Dunn Kidney Center at the end of the growth projections.

In Section D, page 22, the applicant states “*this application will not have any effect upon access to care – for any patient.*”

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 applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

The applicant proposes to relocate three dialysis stations from Dunn Kidney Center in Harnett County to FMC Dialysis Services North Ramsey in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

In Section E.1, page 23, 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 states that maintaining the status quo is not an effective alternative because it ignores the increasing numbers of patients who dialyze at FMC North Ramsey. The applicant states maintaining the status quo would necessitate a third shift because the facility would reach 100% utilization.
- Relocate dialysis stations from a Cumberland County facility – The applicant states each of the facilities operated by the applicant in Cumberland County are utilized in excess of 80%; therefore, relocating stations from one of those facilities would not be an effective alternative.
- Relocate dialysis stations to a facility other than FMC North Ramsey – The applicant states the patient growth at the FMC North Ramsey facility warrants additional stations at that facility.
- Relocate more than three dialysis stations – The applicant states that alternative would have increased utilization at Dunn Kidney Center and thus is not an effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

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. 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 Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate three dialysis stations from Dunn Kidney Center to FMC Dialysis Services North Ramsey.
 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations which shall include any isolation stations, for a total of no more than 43 stations at FMC Dialysis Services North Ramsey.
 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at Dunn Kidney Center for a total of no more than 32 dialysis stations at Dunn Kidney Center upon project completion.
 5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate three dialysis stations from Dunn Kidney Center in Harnett County to FMC Dialysis Services North Ramsey in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

Capital and Working Capital Costs

In Section F.1, page 26, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$725,001
RO Water Treatment Equipment	\$225,000
Miscellaneous Costs	\$243,138
Total	\$1,193,139

In Sections F.10 - F.12, page 29, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since FMC Dialysis Services North Ramsey is an existing facility.

Availability of Funds

In Section F, page 27, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SOURCE
Loans	0
Accumulated Reserves or OE*	\$1,193,139
Other (Specify)	0
Total	\$1,193,139

*OE = Owner's Equity

Exhibit F-1 contains a letter dated November 15, 2018 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company of BMA, authorizing and committing cash reserves in the amount of \$1,193,139 for the capital costs of the project. Exhibit F-2 contains a copy of the balance sheet for Fresenius Medical Care Holdings, Inc. and its subsidiaries for the year ending December 31, 2017. The report indicates that as of December 31, 2017, Fresenius Medical Care Holdings, Inc. had \$570 million in cash and cash equivalents, \$19.8 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities).

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 C, page 69, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	OY 1 (CY 2020)	OY 2 (CY 2021)
Total In-Center Treatments	20,748	21,340
Total Gross Revenues (Charges)	\$82,743,024	\$85,103,920
Total Net Revenue	\$5,563,610	\$5,722,356
Average Net Revenue per Treatment	\$268.15	\$268.15
Total Operating Expenses (Costs) (From Form A)	\$4,860,648	\$4,903,581
Average Operating Expense per Treatment	\$243.27	\$229.78
Net Income	\$702,962	\$818,775

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency
- Information requested by the Agency and received on March 13, 2019

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - 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.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate three dialysis stations from Dunn Kidney Center in Harnett County to FMC Dialysis Services North Ramsey in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

On page 365, the 2018 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 Cumberland County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are six existing or approved dialysis facilities in Cumberland County, all of which are or will be operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

**Cumberland County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2017**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Fayetteville Kidney Center	Fayetteville	50	161	80.50%
FMC Dialysis Services North Ramsey	Fayetteville	40	131	81.88%
FMC Dialysis Services South Ramsey	Fayetteville	51	160	78.43%
FMC Services of West Fayetteville	Fayetteville	40	165	103.13%
Fresenius Kidney Care Hope Mills*	Hope Mills	20	0	0
Fresenius Kidney Care Rockfish*	Fayetteville	0	0	0

*Fresenius Kidney Care Hope Mills and Fresenius Kidney Care Rockfish were merged into one 20-station dialysis facility, FKC Rockfish, in Project ID #M-11502-18.

According to Table D in the July 2018 SDR, there is a deficit of nine dialysis stations in Cumberland County, and a surplus of four dialysis stations in Harnett County. The applicant proposes to relocate three dialysis stations from Harnett County to Cumberland County, which will decrease the surplus in Harnett County and also decrease the deficit in Cumberland County. In addition, on page 34, the applicant states all of the existing facilities are currently located within the greater Fayetteville area, in response to patient demand and residence locations. The applicant does not propose in this application to establish a new facility. In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal decreases the surplus of dialysis stations in Harnett County and decreases the deficit of dialysis stations in Cumberland County.
- The applicant adequately demonstrates that the proposed relocation of dialysis stations is needed at FMC Dialysis Services North Ramsey.

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 current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

POSITION	TOTAL FTE POSITIONS
Medical Director	NA*
Registered Nurse	5.00
LPN	1.00
Patient Care Technician	13.00
Dietician	1.00
Social Worker	1.00
Clinical Manager	1.00
Admin (FMC Dir. Ops)	0.15
In-Service	0.15
Clerical	1.00
Chief Technician	0.15
Equipment Technician	0.85
Total	24.30

The applicant projects no new FTE positions at FMC Dialysis Services North Ramsey following the relocation of three stations from Dunn Kidney Center. The assumptions and methodology used to project staffing are provided in Section H. 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 Section H, page 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 40, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the facility.

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
- 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.

- (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 39, the applicant includes a list of providers of the necessary ancillary and support services.

FMC DIALYSIS SERVICES NORTH RAMSEY ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	BMA
Self-care training (in-center)	Refer to Fayetteville Kidney Center
Home training	
HH	--
PD	Refer to Fayetteville Kidney Center
Accessible follow-up program	--
Psychological counseling	Refer to Fayetteville Psychiatric Associates
Isolation – hepatitis	BMA – on site
Nutritional counseling	BMA – on site
Social Work services	BMA – on site
Acute dialysis in an acute care setting	Cape Fear Valley Hospital
Emergency care	BMA/911/Cape Fear Valley Hospital
Blood bank services	Cape Fear Valley Hospital
Diagnostic and evaluation services	Cape Fear Valley Hospital/Imaging Center/Valley Radiology
X-ray services	Central Harnett Hospital/Imaging Center/Valley Radiology
Laboratory services	Spectra Labs
Pediatric nephrology	Refer to UNC Pediatric Nephrology
Vascular surgery	Carolina Kidney Care Vascular Access Center/Village Surgical/Several physicians/patient choice
Transplantation services	UNC; Pitt County Memorial Hospital
Vocational rehabilitation & counseling	North Carolina Vocational Rehabilitation & Independent Living
Transportation	Cumberland County Department of Social Services; Fayetteville Area System Transit; FAMIK Transportation

In Section I.2, page 40, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1, I-2, I-3 and I-4. In addition, on page 41, the applicant provides a list of nephrologists who have agreed to provide medical coverage at the facility and who have expressed support for the project.

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

Conclusion

The Agency reviewed the application and supporting exhibits. 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 January 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. The applicant states in Section K, page 45 that it proposes to renovate 717 existing square feet of space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 52, the applicant provides the historical payor mix during CY 2017 at FMC North Ramsey, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL
Medicare	69.15%
Medicaid	9.42%
Commercial Insurance	5.63%
Medicare/Commercial	12.79%
Miscellaneous (Incl. VA)	3.01%
Total	100.00%

Numbers 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
Cumberland	12%	50%	57%	19%	12%	11%
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) 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 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 50, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The 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, page 51, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

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.

- (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

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

C

In Section L, page 49, 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
Self Pay/Indigent/Charity	0.33%
Medicare	70.10%
Medicaid	7.56%
Commercial Insurance	3.45%
Medicare/Commercial	15.59%
Miscellaneous (Incl. VA)	2.97%
Total	100.00%

Note numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.33% of total services will be provided to self-pay/charity patients, 85.69% to Medicare patients and 7.56% to Medicaid patients.

On page 49, 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 the projected payor mix is based on the historical experience of FMC North Ramsey's recent patient census.

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, page 51, 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 53, 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 application is conforming to this criterion.

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

C

The applicant proposes to relocate three dialysis stations from Dunn Kidney Center in Harnett County to FMC Dialysis Services North Ramsey in Cumberland County, for a total of 32 certified dialysis stations at DKC and 43 certified dialysis stations at FMC North Ramsey upon project completion.

On page 365, the 2018 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 Cumberland County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are six existing or approved dialysis facilities in Cumberland County, all of which are or will be operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

**Cumberland County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2017**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Fayetteville Kidney Center	Fayetteville	50	161	80.50%
FMC Dialysis Services North Ramsey	Fayetteville	40	131	81.88%
FMC Dialysis Services South Ramsey	Fayetteville	51	160	78.43%
FMC Services of West Fayetteville	Fayetteville	40	165	103.13%
Fresenius Kidney Care Hope Mills*	Hope Mills	20	0	0
Fresenius Kidney Care Rockfish*	Fayetteville	0	0	0

*Fresenius Kidney Care Hope Mills and Fresenius Kidney Care Rockfish were merged into one 20-station dialysis facility, FKC Rockfish, in Project ID #M-11502-18.

In Section N, page 54, 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 54, the applicant describes the existing relationships with several Cumberland County nephrology practices. The applicant states it does not anticipate the project will have effect on competition in the service area, since the applicant is the only provider of dialysis services in Cumberland County.

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.

(19) Repealed effective January 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 58, the applicant states there are more than 100 Fresenius related dialysis facilities located in North Carolina.

In Section O.3, page 58, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no quality of care incidents that resulted in a finding of “*Immediate Jeopardy*” (IJ) in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there was one incident related to quality of care, not resulting in an IJ, in June 2018. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section 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 January 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 promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicant does not propose to establish a new End Stage Renal Disease facility. Therefore, this performance standard is not applicable to this review.

- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, page 14, the applicant projects to serve 142 in-center patients on 43 in-center stations by the end of OY 1, which is 3.30 patients per station per week [142 / 43 = 3.30]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 14 - 16, 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.