

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 29, 2019

Findings Date: March 29, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Gloria Hale

Project ID #: M-11650-19

Facility: Fresenius Kidney Care Rockfish

FID #: 170017

County: Cumberland

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

Project: Relocate one dialysis station from FMC Services of West Fayetteville to FKC Rockfish for a total of 21 stations at FKC Rockfish.

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 one dialysis station from FMC Services of West Fayetteville (FMC West Fayetteville) to Fresenius Kidney Care Rockfish (FKC Rockfish) for a total of 21 dialysis stations at FKC Rockfish and 39 dialysis stations at FMC West Fayetteville upon project completion.

Need Determination

The 2019 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 Table D in the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for additional dialysis stations in 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. FKC Rockfish is an approved but not yet developed facility and has no utilization to report. Therefore, neither of the two need determination methodologies in the 2019 SMFP apply to this proposal.

Policies

There is one policy in the 2019 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2, on page 25 of the 2019 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	Cumberland
(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	605
(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	NA
(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	NA

On page 7, the applicant states the number of Cumberland County patients dialyzing at BMA facilities in Cumberland County reported in the table above is taken from the ESRD Data Collection Forms submitted to the Agency in February 2019.

The applicant states the application is consistent with *Policy ESRD-2* because both dialysis facilities are in Cumberland County; thus, the application proposes a relocation of one dialysis station within 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 because the relocation of one dialysis station within Cumberland County will have no effect on the number of dialysis stations within the county.

- (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 one dialysis station from FMC West Fayetteville to FKC Rockfish for a total of 21 dialysis stations at FKC Rockfish and 39 dialysis stations at FMC West Fayetteville upon project completion. It is important to know the history of the FKC Rockfish facility. See the following projects:

- Project ID #M-11286-17 – the applicant was awarded a certificate of need on May 23, 2017 to develop a new 10-station dialysis facility named Fresenius Kidney Care Rockfish in Fayetteville, in Cumberland County.
- Project ID #M-11344-17 – the applicant was awarded a certificate of need on August 22, 2017 to develop a new 10-station dialysis facility named Fresenius Kidney Care Hope Mills in Hope Mills, also in Cumberland County.
- Project ID #M-11502-18 – the applicant was awarded a certificate of need on August 14, 2018 to combine Project ID#s M-11286-17 and M-11344-17 into one 20-station dialysis facility named Fresenius Kidney Care Rockfish in Fayetteville at the same location as the previously approved FKC Rockfish.

In this application, the applicant proposes to relocate one existing dialysis station from FMC West Fayetteville to the approved but not yet developed FKC Rockfish.

Patient Origin

On page 369, the 2019 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.

Since FKC Rockfish is not an existing facility, there is no current or historical patient origin to report. In Section C.1, page 13, the applicant provides the following table to illustrate projected patient origin for FKC Rockfish in the first Operating Year (OY):

COUNTY	FIRST FULL FY OF OPERATION (CY 2020)		SECOND FULL FY OF OPERATION (CY 2021)	
	IN-CTR. PTS.	% OF TOTAL	IN-CTR. PTS.	% OF TOTAL
Cumberland	54.3	75.1%	56.1	75.7%
Hoke	13.0	18.0%	13.0	17.5%
Robeson	5.0	6.9%	5.0	6.7%
Total	72.3	100.0%	74.1	100.0%

Note: numbers may not sum due to rounding

In Section C, pages 13 - 14, 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 13 - 15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

1. The applicant states FKC Rockfish is not yet certified, but is still eligible for a station increase, pursuant to the language of 10A NCAC 14C .2203(b), which provides for an increase in dialysis stations in an existing facility, or in a facility that is *“not operational prior to the beginning of the review period but which had been issued a certificate of need”*. FKC Rockfish has been issued a CON but is not operational.
2. The applicant states that, pursuant to Project ID#M-11286-17, the original application for FKC Rockfish, the applicant projected to serve patients from Cumberland and Hoke counties as follows:

Projected Patient Census, Project ID #M-11286-17

COUNTY	FIRST FULL FY OF OPERATION		SECOND FULL FY OF OPERATION	
	IN-CTR. PTS.	% OF TOTAL	IN-CTR. PTS.	% OF TOTAL
Cumberland	26.3	79.0%	27.7	79.8%
Hoke	7.0	21.0%	7.0	20.2%
Total	33.0	100.0%	34.0	100.0%

Note: numbers may not sum due to rounding

3. The applicant states that, pursuant to Project ID#M-11344-17, the original application for FKC Hope Mills, the applicant projected to serve patients from Cumberland, Hoke and Robeson counties as follows:

Projected Patient Census, Project ID #M-11344-17

COUNTY	FIRST FULL FY OF OPERATION		SECOND FULL FY OF OPERATION	
	IN-CTR. PTS.	% OF TOTAL	IN-CTR. PTS.	% OF TOTAL
Cumberland	26.3	79.0%	27.7	79.8%
Hoke	2.0	6.0%	2.0	5.8%
Robeson	5.0	15.0%	5.0	14.4%
Total	33.0	100.0%	34.0	100.0%

Note: numbers may not sum due to rounding

4. The applicant states that in Project ID#M-11502-18, it proposed to consolidate the two projects above into one 20-station dialysis facility with the following patient census projected to transfer their care to the new facility:

**FKC Rockfish Patients to Transfer
 by County of Residence**

COUNTY	NUMBER OF IN-CENTER PATIENTS TO TRANSFER
Cumberland	52.6
Hoke	9
Robeson	5
Total	66.0

5. The applicant provides four patient letters in Exhibit C-1, each of which is signed by a resident of Hoke County. Each of the letters states that the patient began dialysis after the previously approved applications were submitted, and that the proposed FKC Rockfish facility would be closer to the patient’s residence. Each letter indicates the patient would consider transferring dialysis care to FKC Rockfish. The applicant states on page 15 that each of these patients would have to drive past the FKC Rockfish facility to reach the FMC West Fayetteville facility, where each is currently dialyzing.
6. The applicant states the beginning patient census for FKC Rockfish is thus 70 patients (66 from the previously approved projects and four from the new patient letters submitted with this application).
7. The applicant projects growth of the Cumberland County in-center dialysis patient population by applying the Five Year Average Annual Change Rate (AACR) of 3.3% found in Table D on page 60 of the January 2019 SDR.

8. The applicant does not project growth for patients residing outside of Cumberland County; rather, those patients are added in at the end of the growth calculations for Cumberland County residents.
9. The applicant projects the project to be complete by December 31, 2019.
10. 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 bases projected patient census on the projected patient census within the three previously approved but not yet developed projects (Project ID #M-11286-17, #M-11344-17 and #M-11502-18).
- The applicant projects growth only of the Cumberland County patients and adds to that growth the patients from outside Cumberland County.
- The applicant utilizes the 3.3% Cumberland County Five Year AACR to project future patient growth.

Projected Utilization

In Section C.1, page 15, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table:

Begin with Cumberland County patients projected from Project ID #s M-11286-17 and M-11344-17, as of December 31, 2019, projected date of completion.	52
Project this patient population forward to December 31, 2020, using 3.3% Cumberland County AACR.	$52 \times 1.033 = 53.7$
Add Hoke and Robeson county patients. This is the end of OY 1.	$53.7 + 18 = 71.7$
Project Cumberland County patient population forward to December 31, 2021, using 3.3% Cumberland County AACR.	$53.7 \times 1.033 = 55.5$
Add Hoke and Robeson county patients. This is the end of OY 2.	$55.5 + 18 = 73.5$

The applicant projects to serve 72 in-center dialysis patients on 21 stations at the end of OY 1, and 74 in-center dialysis patients on 21 stations at the end of OY 2, which is 3.4 patients per station per week at the end of OY 1, or 85.7% of capacity [$72 / 21 = 3.43$; $3.43 / 4 = 0.8571$]; and 3.5 patients per station per week at the end of OY 2, or 88.1% of capacity [$74 / 21 = 3.52$; $3.52 / 4 = 0.8809$].

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 January 2019 SDR to project in-center patient utilization.
- The applicant projects growth of only the Cumberland County patient population rather than the entire in-center patient population, because the majority of the projected patients will come from Cumberland County.
- 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 16, 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 FKC Rockfish, 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 52, 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:

CY 2021

PAYOR	% OF TOTAL
Self-Pay / Indigent / Charity	0.32%
Medicare	74.45%
Medicaid	5.27%
Commercial Insurance	3.82%
Medicare / Commercial	13.29%
Miscellaneous (includes VA)	2.85%
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.
- The applicant reasonably projects that the utilization rate of the new facility will be 3.4 patients per station per week at the end of OY 1, 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 January 2019 Semiannual Dialysis Report (SDR).
- 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 one dialysis station from FMC West Fayetteville to the approved but not yet developed FKC Rockfish, for a total of 39 certified dialysis stations at FMC West Fayetteville and 21 certified dialysis stations at FKC Rockfish upon project completion. Both facilities are in Cumberland County.

In Section D, pages 23 - 25, the applicant explains why it believes the needs of the population presently dialyzing at FMC West Fayetteville will be adequately met following the relocation of one in-center station to FKC Rockfish. See the following table from page 23 that illustrates the total patient census at FMC West Fayetteville as of December 31, 2018:

**FMC West Fayetteville Patient Census
December 31, 2018**

COUNTY	IN-CENTER PATIENTS
Cumberland	150
Bladen	1
Hoke	16
Johnston	1
Mecklenburg	1
Robeson	3
South Carolina	1
Virginia	1
Other States	3
Total	177

FMC West Fayetteville is currently certified for 40 dialysis stations. Based on the facility census as shown above, the facility was operating at 111% of capacity as of December 31, 2018 [177 patients / 40 stations = 4.425; 4.425 / 4 = 1.106].

On page 23, the applicant states it will use the 3.3% Cumberland County Five Year AACR from the January 2019 SDR to project utilization of the stations that will remain at FMC West Fayetteville following the relocation of one station to FKC Rockfish. On page 24, the applicant states it will not project growth of the patients who dialyze at FMC West Fayetteville and reside in Bladen, Hoke and Robeson counties. In addition, the applicant states on page 24 that the patients from Johnston and Mecklenburg counties, South Carolina, Virginia and other states are transient patients and therefore are not included in the projected utilization for FMC West Fayetteville. The following table, from page 24, illustrates projected utilization at FMC West Fayetteville:

Begin with Cumberland County patient census as of December 31, 2018.	150
Project census forward 12 months to December 31, 2019, using the Cumberland County Five Year AACR in the January 2019 SDR.	$150 \times 1.033 = 155.0$
Subtract Cumberland County patients projected to transfer to FKC Rockfish.	$155.0 - 30 = 125.0$
Add patients from Bladen County (1), Hoke County (6, after 10 transfer to FKC Rockfish) and Robeson (1, after 2 transfer to FKC Rockfish). This is the projected completion date for FKC Rockfish.	$125.0 + 8 = 133.0$
Project Cumberland County patient census forward 12 months to December 31, 2020, using the Cumberland County Five Year AACR in the January 2019 SDR.	$125.0 \times 1.033 = 129.1$
Add patients from Bladen, Hoke and Robeson counties. This is the projected census one year after completion, December 31, 2020.	$129.1 + 8 = 137.1$
Project Cumberland County patient census forward 12 months to December 31, 2021, using the Cumberland County Five Year AACR in the January 2019 SDR.	$129.1 \times 1.033 = 133.3$
Add patients from Bladen, Hoke and Robeson counties. This is the projected census two years after completion, December 31, 2021.	$133.3 + 8 = 141.3$

Thus, on December 31, 2020, the applicant projects that FKC Rockfish will dialyze 138 patients on 39 in-center stations, which is a utilization rate of 88.46%, or 3.5 patients per station per week [$138 / 39 = 3.5385$; $3.5385 / 4 = 0.8846$].

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

- The applicant utilizes the 3.3% Cumberland County Five Year AACR as published in the January 2019 SDR to project in-center patient utilization at FMC West Fayetteville following the relocation of one station to FKC Rockfish.
- The applicant subtracts the Hoke and Robeson county patients who will transfer their care to FKC Rockfish.
- The applicant projects growth only of the Cumberland County patient population dialyzing at FMC West Fayetteville, and adds patients who reside in other counties but choose to dialyze at that facility at the end of the growth projections.
- The applicant does not include transient patients.

In Section D, page 25, the applicant states FMC West Fayetteville was operating above 80% utilization as of June 30, 2018 and will submit a later application for the addition of one station at FMC West Fayetteville.

In Section D.2, on page 25, the applicant states the relocation of stations as proposed in this application will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped, elderly and other groups to obtain needed dialysis treatments.

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 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 one dialysis station from West Fayetteville to FKC Rockfish for a total of 21 dialysis stations at FKC Rockfish and 39 dialysis stations at FMC West Fayetteville upon project completion.

In Section E.1, page 26, 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 would benefit from additional dialysis stations closer to their residence.
- Relocate dialysis stations from a Cumberland County facility – The applicant states each of the facilities operated by the applicant in Cumberland County are well utilized, and that patient census has increased from 616 to 648 in-center patients from June 30, 2018 to December 31, 2018.
- Relocate dialysis stations to a different BMA – The applicant states the patient growth in the area in which the FCK Rockfish facility will be located warrants additional stations at that facility.

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 and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**

2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate three dialysis stations from FMC Services of West Fayetteville to Fresenius Kidney Care Rockfish.
 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station which shall include any isolation stations, for a total of no more than 21 stations at Fresenius Kidney Care Rockfish.
 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify one dialysis station at FMC Services of West Fayetteville for a total of no more than 39 dialysis stations at FMC Services of West Fayetteville 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 one dialysis station from FMC West Fayetteville to FKC Rockfish for a total of 21 dialysis stations at FKC Rockfish and 39 dialysis stations at FMC West Fayetteville upon project completion.

Capital and Working Capital Costs

In Section F.1, page 28, the applicant projects the total capital cost of the project as shown in the table below:

ITEM	AMOUNT
Construction Costs	\$0
RO Water Treatment Equipment	\$750
Miscellaneous Costs	\$3,000
Total	\$3,750

In Sections F.10 - F.12, page 31, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since those expenses were accounted for in the previously approved Project ID #M-11502-18. The relocation of one station as proposed in this application will take place after the FKC Rockfish facility is operational.

Availability of Funds

In Section F, page 29, the applicant states that the capital cost will be funded as shown in the table below.

TYPE	SOURCE
Loans	0
Accumulated Reserves or OE*	\$3,750
Other (Specify)	0
Total	\$3,750

*OE = Owner's Equity

Exhibit F-1 contains a letter dated January 15, 2019 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 \$3,750 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 Section R, forms A, B and C, pages 78 and 81 – 83 respectively, 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 In-Center Treatments	10,522	10,670
Total Gross Revenues (Charges)	\$41,961,736	\$42,551,960
Total Net Revenue	\$2,879,109	\$2,919,606
Average Net Revenue per Treatment	\$273.63	\$273.63
Total Operating Expenses (Costs) (From Form A)	\$2,623,789	\$2,668,549
Average Operating Expense per Treatment	\$249.36	\$250.10
Net Income	\$255,320	\$251,057

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
- Supplemental information requested 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 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.
 - The applicant adequately demonstrates sufficient funds for the capital needs of the proposal
- (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 one dialysis station from FMC West Fayetteville to FKC Rockfish for a total of 21 dialysis stations at FKC Rockfish and 39 dialysis stations at FMC West Fayetteville upon project completion.

On page 369, the 2019 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 January 2019 SDR, there are five 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 January 2019 SDR, is provided below:

**Cumberland County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2018**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Fayetteville Kidney Center	Fayetteville	50	172	86.00%
FMC Dialysis Services North Ramsey	Fayetteville	40	122	76.25%
FMC Dialysis Services South Ramsey	Fayetteville	51	166	81.37%
FMC Services of West Fayetteville	Fayetteville	40	156	97.50%
Fresenius Kidney Care Rockfish	Fayetteville	20*	0	0

*Stations are approved but not yet certified.

According to Table D in the January 2019 SDR, there is a deficit of 11 dialysis stations in Cumberland County. The applicant proposes to relocate one dialysis station within Cumberland County. In addition, in Section G, page 36, the applicant states that relocating an existing dialysis station within the county will not result in duplication. The applicant states it seeks to improve access to care and reduce patient travel time for patients.

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 relocates one existing dialysis station from one BMA facility to another in Cumberland County, and therefore would not result in an increase in the number of dialysis stations in Cumberland County.
- The applicant adequately demonstrates that the proposed relocation of one dialysis station is needed.

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 37, the applicant projects full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

POSITION	TOTAL FTE POSITIONS
Medical Director	NA*
Registered Nurse	3.00
Patient Care Technician	6.00
Dietician	0.80
Social Worker	0.80
Clinical Manager	1.00
Admin (FMC Dir. Ops)	0.20
In-Service	0.20
Clerical	1.00
Chief Technician	0.15
Equipment Technician	0.85
Total	14.00

*The applicant states the medical director is a contract position and not an employee

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 38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 41, the applicant identifies the proposed medical director. In Exhibit I-5, the applicant provides a letter from the proposed medical director indicating his interest in serving in that capacity.

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 40, 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	Cumberland County Mental Health
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	Cape Fear Valley 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
Vocational rehabilitation & counseling	Vocational Rehabilitation Services of Fayetteville
Transportation	Cumberland County Department of Social Services; Fayetteville Area System Transit

In Section I.2, page 41, 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 42, 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
- 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 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 associated with the relocation of one station as proposed in this application. The proposed construction for the FKC Rockfish facility was accounted for in Project ID#M-11502-18. 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

FKC Rockfish is not yet developed. In Section L.7, page 55, the applicant provides the historical payor mix during CY 2018 at FMC West Fayetteville, the facility from which one station is proposed to be relocated, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	0.32%
Medicare	74.45%
Medicaid	5.27%
Commercial Insurance	3.82%
Medicare/Commercial	13.29%
Miscellaneous (Incl. VA)	2.85%
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	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Cumberland	12%	50%	57%	19%	12%	11%
Statewide	16%	51%	37%	16%	10%	13%

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

*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., 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 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 53, 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 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.

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.

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

- (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, 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.

CY 2021

PAYOR CATEGORY	% OF TOTAL
Self Pay/Indigent/Charity	0.32%
Medicare	74.45%
Medicaid	5.27%
Commercial Insurance	3.82%
Medicare/Commercial	13.29%
Miscellaneous (Incl. VA)	2.85%
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 0.32% of total services will be provided to self-pay/charity patients, 87.74% to Medicare patients (including Medicare/commercial) and 5.27% 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 the projected payor mix is based on the historical experience of FMC West Fayetteville's recent patient census from which a majority of patients will be transferring to obtain dialysis services at FKC Rockfish.

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 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 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 one dialysis station from FMC West Fayetteville to FKC Rockfish for a total of 21 dialysis stations at FKC Rockfish and 39 dialysis stations at FMC West Fayetteville upon project completion.

On page 369, the 2019 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 January 2019 SDR, there are five 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 January 2019 SDR, is provided below:

**Cumberland County Dialysis Facilities
Certified Stations and Utilization as of June 30, 2018**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Fayetteville Kidney Center	Fayetteville	50	172	86.00%
FMC Dialysis Services North Ramsey	Fayetteville	40	122	76.25%
FMC Dialysis Services South Ramsey	Fayetteville	51	166	81.37%
FMC Services of West Fayetteville	Fayetteville	40	156	97.50%
Fresenius Kidney Care Rockfish	Fayetteville	20*	0	0

*Stations are approved but not yet certified.

According to Table D in the January 2019 SDR, there is a deficit of 11 dialysis stations in Cumberland County. The applicant proposes to relocate one dialysis station within Cumberland County.

In Section N, page 57, the applicant states the proposed project will not have any effect on competition in the service area, and discusses how the proposal will promote the cost-effectiveness, quality and access to the proposed services. 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
- Information publicly available 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.

- (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 61, the applicant states there are more than 100 Fresenius related dialysis facilities located in North Carolina.

In Section O.3, page 61, 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. 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 13, the applicant projects to serve 72 in-center patients on 21 in-center stations by the end of OY 1, which is 3.43 patients per station per week [$72 / 21 = 3.428$]. 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 13 - 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.