

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 21, 2017

Findings Date: April 21, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: M-11286-17

Facility: Fresenius Kidney Care Rockfish

FID #: 170017

County: Cumberland

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

Project: Develop a new 10-station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey and five dialysis stations from FMC Services of West Fayetteville.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA), d/b/a Fresenius Kidney Care Rockfish (**FKC Rockfish**) proposes to develop a new 10-station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey and five dialysis stations from FMC Services of West Fayetteville. All of the existing facilities and the proposed facility will be located in Cumberland County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations in Cumberland County.

Below is a table that illustrates this proposal and other previously approved projects impacting these facilities, using data from the January 2017 SDR:

FACILITY	BEGIN # STATIONS	PROJECT ID#	#STATIONS ADDED (+)OR DELETED (-)	END # STATIONS
Fresenius Kidney Care Rockfish	0	M-11286-17	+10	10
FMC Dialysis Services South Ramsey	51	M-11286-17	-5	46
FMC Services of West Fayetteville	40	M-11219-16	-5	35
FMC Services of West Fayetteville	35	M-11225-15	+5	40
FMC Services of West Fayetteville	40	M-11286-17	-5	35

Need Determination

The applicant proposes to relocate existing dialysis stations within Cumberland County; therefore, there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) that are applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 33 of the 2017 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 27 of the 2017 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS 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 contiguous counties 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.”*

The applicant proposes to develop a new 10-station dialysis facility, FKC Rockfish, in Cumberland County, by relocating 10 existing Cumberland County dialysis stations: five from FMC Services South Ramsey and five from FMC Services West Fayetteville. Because all three facilities are or will be located in Cumberland County, there is no change in the total dialysis station inventory in Cumberland County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new 10-station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey (FMC South Ramsey) and five dialysis stations from FMC Services of West Fayetteville (FMC West Fayetteville). Upon completion of the project, FKC Rockfish will be certified for 10 dialysis stations, FMC Dialysis Services South Ramsey will be certified for 46 stations (51 - 5), and FMC Services of West Fayetteville will be certified for 35 stations [40 - 5 (M-11219-16) + 5 (M-11225-15) - 5 (M-11286-17)]. All three facilities are or will be located in Cumberland County. The applicant does not propose to provide home therapies.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Cumberland County. Facilities may also serve residents of counties not included in their service area.

Fresenius Kidney Care Rockfish will be a new facility and thus has no historical patient origin to report.

In Section C.1, page 19, the applicant identifies the in-center patient population it proposes to serve during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OY 1 CY 2019	OY 2 CY 2020	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Cumberland	26.3	27.7	79.0%	79.8%
Hoke	7	7	21.0%	20.2%
Total	33.3	34.67	100.0%	100.0%

Numbers may not foot due to rounding

The applicant states it bases the patient origin for its proposed facility on patients who are currently dialyzing in existing Cumberland County dialysis facilities and who have signed letters indicating that the proposed facility would be closer to their residence. The applicant projects to serve only in-center patients at the proposed FKC Rockfish facility, and states it will refer those patients in need of home training to FMC Kidney Center (see Section C.6, page 26). The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C.1, pages 19 – 21, the applicant discusses the need to develop FKC Rockfish in western Cumberland County and provides assumptions and methodology to support the need. The application is filed pursuant to *Policy ESRD-2, Relocation of Dialysis Stations* and proposes to relocate stations within Cumberland County.

The applicant is currently the only provider of dialysis services in Cumberland County and operates four existing facilities, as illustrated in the following table:

Utilization of BMA Cumberland County Facilities / January 2017 SDR

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	39	139	89.10%
FMC North Ramsey	40	140	87.50%
FMC South Ramsey	51	132	64.71%
FMC West Fayetteville	40	156	97.50%

Source: January 2017 SDR, Application page 53

In Section C.4, page 23, the applicant provides a map to illustrate the location of the existing and proposed Cumberland County dialysis facilities. The applicant states on page 24 that the majority of Cumberland County dialysis patients live in Fayetteville, and that very few Cumberland County dialysis patients live east of Interstate 95, a major North-South corridor. In Exhibit C-1, the applicant provides 35 letters signed by current BMA dialysis patients who receive their care at an existing Cumberland County BMA facility. Each of these letters states that the patient would consider transferring his or her care to the proposed FKC Rockfish facility because the proposed facility would be closer to that patient’s home. The applicant proposes to develop the facility in the western area of Fayetteville, closer to those patients’ residences.

On pages 19 -20, the applicant provides the assumptions it used to project utilization, as summarized below:

1. The applicant plotted the residence location of existing Cumberland County dialysis patients and determined that a significant number of dialysis patients live in the western areas of Fayetteville and Cumberland County.
2. The applicant received 35 letters signed by existing Cumberland County dialysis patients, each of whom indicated that a facility located in the western area of Fayetteville would be a more convenient dialysis location than the facility in which they are currently dialyzing.
3. Of these 35 patients who signed letters, the applicant projects that 32 will actually transfer their care to the proposed facility, as illustrated in the following table:

EXISTING FACILITY	CUMBERLAND COUNTY		HOKE COUNTY	TOTAL
	28314	28304	28376	
FMC West Fayetteville	19	3	6	28
Fayetteville Kidney Center	0	0	1	1
FMC North Ramsey	1	0	0	1
FMC South Ramsey	2	0	0	2
Totals	22	3	7	32

Source: Application page 20

4. The applicant projects the project to be complete by December 31, 2018.

 Operating Year 1 is Calendar Year 2019, January 1 through December 31, 2019.
 Operating Year 2 is Calendar Year 2020, January 1 through December 31, 2020.
5. The applicant states the ESRD patient population to transfer their care to the proposed facility will be a part of the Cumberland County dialysis patient population as a whole and will increase at a rate commensurate with the 5.2% Five Year Average Annual Change Rate (AACR) published in the January 2017 SDR.
6. The applicant does not project growth in the Hoke County patient population; rather, it adds those patients each year to the Cumberland County patients.

Projected Utilization

In Section C.1, page 21, the applicant projects the following utilization:

FKC ROCKFISH	IN-CENTER PATIENTS
Begin with 25 Cumberland County in-center dialysis patients projected to transfer their care to the new facility upon certification on December 31, 2018.	25
Project this population forward one year to December 31, 2019, using the Cumberland County Five Year AACR of 5.2%.	$25 \times 1.052 = 26.3$
Add the Hoke County patients. This is the end of OY 1	$26.3 + 7 = 33.3$
Project the Cumberland County patient population forward one year to December 31, 2020, using the Cumberland County Five Year AACR of 5.2%.	$26.3 \times 1.052 = 27.67$
Add the Hoke County patients. This is the end of OY 2	$27.67 + 7 = 34.67$

The applicant projects to serve 33 in-center patients or 3.3 patients per station per week ($33 / 10 = 3.3$) by the end of Operating Year 1 and 34 in-center patients or 3.4 patients per station per week ($34 / 10 = 3.4$) by the end of Operating Year 2 for the proposed 10-station facility. This satisfies the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FKC Rockfish.

Access

In Section L.1, pages 72 - 73, the applicant states that each of BMA’s 107 facilities in 46 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons.

The applicant projects that 89.51% of its patients will be Medicare or Medicaid recipients in CY 2020, based on its current Cumberland County patient data. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility, FKC Rockfish, by relocating five existing certified dialysis stations from FMC Services of West Fayetteville and five existing certified dialysis stations from FMC South Ramsey. All three facilities are located in Cumberland County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Upon completion of the project, FKC Rockfish will be certified for 10 dialysis stations, FMC Dialysis Services South Ramsey will be certified for 46 stations (51 - 5), and FMC Services of West Fayetteville will be certified for 35 stations [40 – 5 (M-11219-16) + 5 (M-11225-15) – 5 (M-11286-17)]. All three facilities are or will be located in Cumberland County.

In Section D.1, pages 33 - 38, the applicant discusses how the needs of existing dialysis patients at FMC Dialysis Services South Ramsey and FMC Services of West Fayetteville will continue to be met after the relocation of stations to the proposed FKC Rockfish dialysis facility.

FMC Dialysis Services South Ramsey

In Section D.1, pages 33 - 34, the applicant provides the assumptions used to project utilization for FMC Dialysis Services South Ramsey for December 31, 2018, the date when FKC Rockfish is projected to be operational. The assumptions are summarized as follows:

- FMC Dialysis Services South Ramsey is currently certified for 51 dialysis stations as reported in the January 2017 SDR. Five dialysis stations will be relocated to FKC Rockfish, leaving 46 dialysis stations at FMC Dialysis Services South Ramsey.
- As of December 31, 2016 there were 138 patients dialyzing at FMC Dialysis Services South Ramsey; 135 from Cumberland County, and one each from Hoke, Robeson and Sampson counties.
- The applicant projects that two Cumberland County patients who currently dialyze at FMC Dialysis Services South Ramsey and who submitted letters of support for this project will transfer their care to FKC Rockfish as of December 31, 2018, when FKC Rockfish is projected to become operational.
- The applicant projects the Cumberland County patient population will grow at an annual rate of 5.2%, which is the Five Year AACR published in the January 2017 SDR. No growth will be projected for patients living outside Cumberland County.
- The three remaining patients from Hoke, Robeson and Sampson counties are added at the end of the calculations for each year.

Based on the above assumptions, the applicant projects utilization at FMC Dialysis Services South Ramsey from December 31, 2016 through December 31, 2018 as follows:

FMC DIALYSIS SERVICES SOUTH RAMSEY	
Begin with the Cumberland County ESRD patient population of FMC Dialysis Services South Ramsey as of December 31, 2016.	135
Project this population forward 12 months to December 31, 2017, applying the Cumberland County Five Year AACR of 5.2%.	$135 \times 1.052 = 142.0$
Project this population forward 12 months to December 31, 2018, applying the Cumberland County Five Year AACR of 5.2%.	$142.0 \times 1.052 = 149.4$
Subtract two Cumberland County patients projected to transfer their care to FKC Rockfish.	$149.4 - 2 = 147.4$
Add three patients from Hoke, Robeson and Sampson counties	$147.4 + 3 = 150.4$

The applicant projects that as of December 31, 2018, the projected date of certification for FKC Rockfish, FMC Dialysis Services South Ramsey will have 150 in-center dialysis patients dialyzing on 46 stations for a utilization rate of 3.3 patients per station per week, or 81.5% of capacity [$150 / 46 = 3.26$; $6.23 / 4 = 0.815$ or 81.5%].

The applicant demonstrates that the needs of the population presently served at FMC Dialysis Services South Ramsey will continue to be adequately met following the proposed relocation of five dialysis stations from FMC Dialysis Services South Ramsey to FKC Rockfish.

FMC Services of West Fayetteville

In Section D.1, pages 34 - 38, the applicant provides the assumptions used to project utilization for FMC Services of West Fayetteville for December 31, 2018, the date which FKC Rockfish is projected to be operational. The assumptions are summarized as follows:

- FMC Services of West Fayetteville is currently certified for 40 dialysis stations as reported in the January 2017 SDR. Project I.D. #s M-11219-16 and M-11225-16 have been previously approved and call for a net of no change in the number of stations at FMC Services of West Fayetteville. The applicant assumes that this application will be approved, and that five dialysis stations will be relocated to FKC Rockfish, leaving 35 in-center dialysis stations at FMC Services of West Fayetteville. The applicant assumes that Project ID #s M-11219-16 and M-11225-16 will be certified prior to the approval of this application.
- As of December, 2016 there were 166 in-center patients dialyzing at FMC Services of West Fayetteville; 144 of those patients were from Cumberland County, ten were from Hoke County, seven were from Robeson County and five were from Mecklenburg County and other states. The applicant states it considers the patients from Mecklenburg County and other states to be transient patients and will not calculate their return to the facility for future projections.
- The applicant projects that 22 Cumberland County patients currently dialyzing at FMC Services of West Fayetteville will transfer their care to FKC Rockfish. These transfers are expected to take place December 31, 2018, when FKC Rockfish becomes operational.

- The applicant states that in Project ID # M-11219-16 two patients from FMC Services of West Fayetteville would transfer their care to the Fayetteville Kidney Center by March 31, 2017, and thus will not be in the patient census when this application is approved.
- The applicant states that, of the ten Hoke County patients dialyzing at FMC Services of West Fayetteville, 6 signed letters indicating their intent to transfer their care to FKC Rockfish upon project completion. The remaining four Hoke County patients will remain at FMC Services of West Fayetteville.
- The applicant states that, of the seven Robeson County patients at FMC Services of West Fayetteville, 4 will transfer their care pursuant to Project ID #M-11219-16 and three will remain at FMC Services of West Fayetteville.
- There is one remaining patient from Sampson County who is added at the end of the calculations.

Based on the above assumptions, in Section D.1, page 36, the applicant calculates the in-center patient census for FMC Services of West Fayetteville starting December 31, 2016 through December 31, 2018, as follows:

FMC SERVICES OF WEST FAYETTEVILLE	
The applicant begins with the Cumberland County ESRD patient population of FMC Services of West Fayetteville as of December 31, 2016.	144
Project the Cumberland County ESRD patient population forward 3 months to March 31, 2017, applying the Cumberland County Five Year AACR of 5.2%.	$[144 \times (.052 / 12 \times 3)] = 145.9$
Subtract 2 patients projected to transfer to Fayetteville Kidney Center pursuant to Project ID #M-11219-16.	$145.9 - 2 = 143.9$
Project the Cumberland County ESRD patient population forward 9 months to December 31, 2017, applying the Cumberland County Five Year AACR of 5.2%.	$[143.9 \times (.052 / 12 \times 9)] = 149.9$
Project the Cumberland County ESRD patient population forward 12 months to December 31, 2018, applying the Cumberland County Five Year AACR of 5.2%.	$143.9 \times 1.052 = 157.3$
Subtract 22 patients projected to transfer to FKC Rockfish.	$157.3 - 22 = 135.3$
Add 4 Hoke County patients, 3 Robeson County patients, and 1 Sampson County patient.	$135.3 + 8 = 143.3$

The applicant projects that as of December 31, 2018, FMC Services of West Fayetteville will have 143 in-center dialysis patients dialyzing on 35 stations for a utilization rate of 4.09 patients per station per week, or 102.1% of capacity [$143 / 25 = 4.09$; $4.09 / 4 = 1.021$ or 102.1%].

On page 36, the applicant states:

“... the FMC Services of West Fayetteville also operates a third, or evening dialysis shift and a nocturnal dialysis shift. As of December 31, 2016 there were 14 patients dialyzing on the third shift.”

The applicant assumes FMC Services of West Fayetteville will continue to operate the third shift. The applicant further assumes that the census on these shifts will remain constant. Thus, the effective utilization at FMC Services of West Fayetteville on December 31, 2018 would be a function of 129 patients dialyzing on 35 stations. Utilization is calculated to be 3.69 patients per station." [129 / 35 = 3.685; 3.685 / 4 = 0.921 or 92.1%].

The applicant states on page 38 that the proposed relocation of these stations will not create any undue hardship or impair admissions to either BMA facility. The applicant also states BMA will apply to add additional dialysis stations in response to a Facility Need Methodology.

The applicant demonstrates that the needs of the population presently served at FMC Services of West Fayetteville will continue to be adequately met following the proposed relocation of four dialysis stations to FKC Rockfish.

Conclusion

The applicant demonstrates that the needs of the population presently served at FMC Dialysis Services of South Ramsey and FMC Services of West Fayetteville will continue to be adequately met following the proposed relocation of five dialysis stations from FMC Dialysis Services of South Ramsey and five dialysis stations from FMC Services of West Fayetteville to FKC Rockfish, and that access for medically underserved groups will not be negatively impacted at either facility.

Therefore, the application is conforming to this criterion.

- (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.

C

In Section E, pages 39 - 40, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo – The applicant states that maintaining the status quo is not an effective alternative because there are a significant number of dialysis patients currently being served by BMA who reside close to the proposed location.
- Develop a facility in another area of Cumberland County - The applicant states this is not an effective alternative. The applicant evaluated existing patient populations currently served by Cumberland County BMA facilities and projected future patient populations in the western area of Cumberland County. The applicant determined that a facility in the western area might better serve that dialysis patient population.

- Propose a larger facility – The applicant states it rejected this alternative because the 10-station facility will meet the needs of the projected patients who will transfer their care to the proposed facility upon certification, and will also meet the performance standards at 10A NCAC 14C .2203.
- Expand at existing facilities – The applicant states that expansion at existing facilities is not an effective alternative because the existing facilities are at physical plant capacity; therefore, expansion is not physically possible.
- Relocate more stations from FMC South Ramsey – The applicant states this alternative was rejected because the dialysis patient population in Cumberland County is increasing at a rate of 5.2% annually, which will result in a need for additional stations within the County. Additionally, the FMC South Ramsey facility is not located close to the patient population that has signed letters to transfer to the proposed facility, and does not qualify for additional stations.

After considering the above alternatives, the applicant states that given the residence location of the existing patients projected to be served and the existing physical plant capacity issues, the proposed project represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and is approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Care Rockfish shall materially comply with all representations made in the certificate of need application.**
2. **Bio-Medical Applications of North Carolina, Inc. shall relocate no more than five dialysis stations from FMC South Ramsey and no more than five dialysis stations from FMC Services of West Fayetteville.**
3. **Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Care Rockfish shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
4. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify five dialysis stations at FMC South Ramsey for a total of no more than 46 dialysis stations at FMC South Ramsey upon project completion.**

5. **Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify five dialysis stations at FMC Services of West Fayetteville for a total of no more than 35 dialysis stations at FMC Services of West Fayetteville upon completion of this project, Project ID #M-11225-16 (add five stations) and Project ID #M-11219-16 (relocate five stations).**
 6. **Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Care Rockfish shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility by relocating five dialysis stations from FMC South Ramsey and five dialysis stations from FMC West Fayetteville.

Capital and Working Capital Costs

In Section F.1, page 43, the applicant projects \$1,569,013 in capital costs to develop the proposed project. In Sections F.10 - F.12, pages 46 - 48, the applicant states that start-up expenses and initial operating expenses incurred for this project will be \$136,579 and \$1,003,803, respectively, for a total estimated working capital of \$1,148,382.

Availability of Funds

In Section F.2, page 44, and Section F.13, page 48, the applicant states it will finance the capital costs and working capital costs with accumulated reserves of Fresenius Medical Care, Inc., as shown below.

Accumulated Reserves / Owner's Equity	
	TOTAL
Capital Costs	\$1,569,013
Working Capital	\$1,148,382

Exhibit F-1 contains a letter dated January 17, 2017, from the Senior Vice President & Treasurer for Fresenius Medical Care Holdings, Inc. (FMCH), as the parent company of BMA, which confirms authorization and commitment of the cash reserves for the full project capital costs as well as “any additional funds as may be necessary for start-up costs in the new location.” Exhibit F-2 contains the Consolidated Financial Statements for FMCH which indicates that it had \$249 million in cash and cash equivalents as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

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

PROJECTED REVENUES AND OPERATING EXPENSES		
FKC ROCKFISH	OPERATING YEAR 1 CY 2019	OPERATING YEAR 2 CY 2020
Total Treatments	4,742	4,860
Total Gross Revenues (Charges)	\$18,911,096	\$19,381,680
Total Net Revenue	\$ 1,511,176	\$ 1,548,780
Total Operating Expenses (Costs)	\$ 1,505,705	\$ 1,540,919
Net Income	\$5,470	\$7,861

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. 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. Therefore, the application is conforming to this criterion.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to develop a new 10-station dialysis facility by relocating five dialysis stations from FMC South Ramsey and five dialysis stations from FMC West Fayetteville. All three facilities are or will be located in Cumberland County.

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates four dialysis centers in Cumberland County, and is the only provider of dialysis services in the county. All of the facilities are located in Fayetteville. See the following table:

Utilization BMA Cumberland County Facilities / January 2017 SDR

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	39	139	89.10%
FMC North Ramsey	40	140	87.50%
FMC South Ramsey	51	132	64.71%
FMC West Fayetteville	40	156	97.50%

Source: January 2017 SDR, Application page 53

As shown in the table above, three of the four Cumberland County dialysis facilities are operating above 80% utilization (3.2 patients per station); in fact, those facilities are operating above 85% utilization. One facility, FMC South Ramsey, is operating below 70% utilization. It is from this underutilized facility that the applicant proposes to relocate five stations.

In Section C, pages 19 – 22, the applicant provides reasonable projections for the patient population it proposes to serve. The growth projections are based on a projected 5.2% average annual growth rate in the number of Cumberland County dialysis patients transferring their care to the proposed facility. At the end of the first operating year following project completion, FKC Rockfish projects the in-center utilization will be 3.2 in-center patients per station (32 patients / 10 dialysis stations = 3.2), which is 80% of capacity. The applicant does not propose to increase the number of certified stations in the service area. Rather, the applicant proposes to relocate existing dialysis stations according to information in 35 letters signed by existing patients which indicate the proposed location will be easier for those patients to travel to in order to receive necessary dialysis care. The applicant adequately demonstrates the need to develop a new 10-station dialysis center by relocating existing Cumberland County dialysis stations, five of which will come from a facility that is operating below 70% utilization.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H, page 41, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for FKC Rockfish. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

POSITION	# FTEs
Registered Nurse	1.50
Technician (PCT))	4.00
Clinical Manager	1.00
Administrator	0.15
Dietician	0.40
Social Worker	0.40
Chief Tech	0.15
Equipment Tech	0.60
In-Service	0.15
Clerical	0.75
Total	9.10

As illustrated in the table above, the applicant projects to begin the proposed facility with 9.10 FTEs.

In Section H.7, page 59, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2020), as shown in the table below:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	1.50	2,080	3,120	3,120	1.00
Technician (PCT)	4.00	2,080	8,320	3,120	2.67
Total	5.50	2,080	11,440	3,120	3.67

In Section H.6, page 58, the applicant states dialysis services will be available from 6:00 AM to 4:00 PM, Monday through Saturday, for a total of 10 hours per day / 60 hours per week.

In Section I.3, page 61, the applicant identifies Dr. Ken Melton as the Medical Director of the proposed facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Melton supporting the project and confirming his commitment to serve as Medical Director. In Section H.3, page 57, the applicant describes the methods used to recruit and fill the new positions.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 60, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 62 - 63. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, lab services, acute services and transplantation services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.

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

C

In Section K.2 – K.4, pages 67 - 68, the applicant states it proposes to lease and upfit 2,927 square feet of space in which to develop the proposed facility. In Section K, pages 66 - 67, the applicant states the facility will be constructed in compliance with all laws and regulations pertaining to staffing, fire and safety equipment, physical environment and other relevant health safety requirements. In Section B.4, pages 12 - 13, and Section K, pages 65 - 66, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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

The facility is not yet developed and has no patient payor mix to report. However, in Section L.7, page 76, the applicant provides two tables to illustrate historical payor mix for the two facilities that will relocate stations to the proposed FKC Rockfish (FMC South Ramsey and FMC West Fayetteville) for CY 2016. See the following table, which combines the two tables on page 76:

PAYMENT SOURCE	FMC SOUTH RAMSEY PERCENT OF TOTAL PATIENTS	FMC WEST FAYETTEVILLE PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	0.83%	1.06%
Medicare	67.36%	72.67%
Medicaid	6.57%	4.37%
Commercial Insurance	2.82%	6.24%
Medicare Commercial	14.62%	12.47%
Miscellaneous (Incl. VA)	7.81%	3.20%
Total	100.00%	100.00%

Totals may not sum due to rounding

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Cumberland	11%	51%	55%	18%	11%	16%
Statewide	15%	51%	36%	17%	10%	15%

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

*Excludes "White alone" who are "not Hispanic or Latino"

***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The *Southeastern Kidney Council Network 6 Inc. Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

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

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

C

In Section L.3€, page 74, the applicant states “*Fresenius related facilities in North Carolina do not have any obligation to provide uncompensated care or community service under any federal regulations*” In Section L.6, page 75, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” The application is conforming to this criterion.

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

C

In Section L.1, page 72, the applicant states: *“It is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”* In Section L.1(b), page 73, the applicant projects that 89.51% of all patients in CY 2020 (OY 2) will have all or part of their services paid for by Medicare and or Medicaid, as shown in the table below:

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	1.06%
Medicare	72.67%
Medicaid	4.37%
Commercial Insurance	6.24%
Medicare Commercial	12.47%
Miscellaneous (Incl. VA)	3.20%
Total	100.00%

The projected payor mix is based on the historical payor mix of the two existing facilities that will relocate stations to develop FKC Rockfish (FMC South Ramsey and FMC West Fayetteville). The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 75, the applicant states *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FKC Rockfish will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”* The applicant adequately demonstrates that FKC Rockfish will offer a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 77, the applicant states *“the applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the FKC*

Rockfish facility to enhance the educational opportunities for the nursing student.” In Exhibit M-1, the applicant provides a copy of a letter to Fayetteville Community College inviting the nursing students to include FKC Rockfish in their clinical rotations. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 10-station dialysis facility by relocating five dialysis stations from FMC South Ramsey and five dialysis stations from FMC West Fayetteville. All three facilities are or will be located in Cumberland County.

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant currently operates four dialysis centers in Cumberland County, and is the only provider of dialysis services in Cumberland County. All of the facilities are located in Fayetteville. See the following table:

Utilization BMA Cumberland County Facilities / January 2017 SDR

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	39	139	89.10%
FMC North Ramsey	40	140	87.50%
FMC South Ramsey	51	132	64.71%
FMC West Fayetteville	40	156	97.50%

Source: January 2017 SDR, Application page 53

As shown in the table above, three of the four Cumberland County dialysis facilities are operating above the statutory minimum 80% utilization (3.2 patients per station); in fact, those facilities are operating above 85% utilization. One facility, FMC South Ramsey, is operating below 70%

utilization. The average utilization rate for the 170 existing Cumberland County stations is 83.4% [567 patients / 170 stations = 3.33; $3.33 / 4 = 83.4\%$].

FKC Rockfish will be created by relocating five existing dialysis stations from FMC South Ramsey and five existing dialysis stations from FMC West Fayetteville.

In Section N.1, page 78, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services.

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

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

Therefore, the application is conforming to this criterion.

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

C

In Section B.1, pages 13-14, Section O, pages 79 - 81 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in its dialysis facilities.

In Section O.3, pages 82 - 83, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Charlotte	8/11/2015	Yes	9/24/2015
RAI West College-Warsaw	3/15/2016	Yes	4/13/2016

Source: Information provided in Application Exhibit O-3

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
- C- In Section C.1 – C.2, pages 19 - 22, the applicant adequately demonstrates that FKC Rockfish projects to serve a total of 32 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 80.00% or 3.2 patients per station per week (32 patients / 10 stations = 3.2; $3.2 / 4 = 0.80$ or 80.00%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (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.

-NA- FKC Rockfish is not an existing facility.

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

-C- In Section C, pages 19 -22, 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.