

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 21, 2017

Findings Date: July 21, 2017

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: M-11344-17

Facility: Fresenius Kidney Care Hope Mills

FID #: 170235

County: Cumberland

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

Project: Develop a new 10-station dialysis facility by relocating 5 stations from FMC Dialysis Services South Ramsey and 5 stations from FMC Dialysis Services North Ramsey. Upon completion of the project, FMC Dialysis Services South Ramsey will have 41 stations and FMC Dialysis Services North Ramsey will have 35 stations.

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 131E-183(a) The Department 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) d/b/a Fresenius Kidney Care Hope Mills (FKC Hope Mills), proposes to develop a new 10-station dialysis facility in Hope Mills by relocating five stations from FMC Dialysis Services South Ramsey (FMC South Ramsey) and five stations from FMC Dialysis Services North Ramsey (FMC North Ramsey). The proposed facility and the two existing facilities are 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 this project, FKC Hope Mills will be certified for 10 dialysis stations and FMC North Ramsey will be certified for 35 dialysis

stations; FMC South Ramsey will be certified for 41 dialysis stations following completion of this project and Project ID #M-11286-17 (relocate five stations from FMC South Ramsey to Fresenius Kidney Care Rockfish (FKC Rockfish)).

### **Need Determination**

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

### **Policies**

There is one policy in the 2017 SMFP that is applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27.

*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 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.”*

The applicant proposes to develop a new 10-station dialysis facility in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey. All three facility locations are in Cumberland County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with the applicable policy in the 2017 SMFP.

- (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 in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey. All three facility locations are in Cumberland County.

The following tables, summarized from pages 4-5 of the application, illustrate the proposed FKC Hope Mills stations, and the current projects under development which impact the number of dialysis stations at FMC South Ramsey and FMC North Ramsey, the two facilities from which the applicant plans to relocate stations to develop the proposed new facility.

FKC Hope Mills

Stations	Description	Project ID #
0	Total existing certified stations as of the January 2017 SDR	
+10	Stations to be added as part of this project	M-11344-17
10	Total stations upon completion of above projects	

FMC North Ramsey

Stations	Description	Project ID #
40	Total existing certified stations as of the January 2017 SDR	
-5	Stations to be deleted as part of this project	M-11344-17
35	Total stations upon completion of above projects	

FMC South Ramsey

Stations	Description	Project ID #
51	Total existing certified stations as of the January 2017 SDR	
-5	Stations to be deleted as part of this project	M-11344-17
-5	Stations previously approved to be deleted but not yet certified	M-11286-17
41	Total stations upon completion of above projects	

As the tables above illustrate, upon project completion, FKC Hope Mills will be certified for 10 dialysis stations and FMC North Ramsey will be certified for 35 stations; FMC South Ramsey will be certified for 41 dialysis stations following completion of this project and Project ID #M-11286-17 (relocate five stations to FKC Rockfish).

**Patient Origin**

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The proposed new facility, FKC Hope Mills, will be located in Cumberland County; thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

FKC Hope Mills will be a new facility in Cumberland County and therefore has no existing patient origin.

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

**Fresenius Kidney Care Hope Mills  
 Projected Patient Origin by County**

County	Operating Year 1 1/1/19 –12/31/19	Operating Year 2 1/1/20-12/31/20	County Patients as Percent of Total	
	In-Center Patients	In-Center Patients	OY1	OY2
Cumberland	26.3	27.7	79.0%	79.8%
Hoke	2.0	2.0	6.0%	5.8%
Robeson	5.0	5.0	15.0%	14.4%
<b>Total*</b>	<b>33.0</b>	<b>34.0</b>	<b>100.0%</b>	<b>100.0%</b>

\*Rounded down to the whole patient

The applicant does not propose to serve home hemodialysis or peritoneal dialysis patients. On page 19, the applicant states that patients who might be candidates for home dialysis will be referred to Fayetteville Kidney Center.

In Section C.1, pages 19-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant states that projected patient origin is based on the existing patients living in close proximity to the proposed facility who signed letters stating their willingness to transfer their care to the proposed facility. Exhibit C-1 contains copies of the 36 signed letters.

The applicant adequately identifies the population to be served.

**Analysis of Need**

The applicant proposes to develop a new 10-station dialysis facility in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey. All three facility locations are in Cumberland County.

In Section C.2, page 22, the applicant states:

*“The need methodology for dialysis stations is focused on four patient shifts per week and recognizes that patients will dialyze on a Monday-Wednesday-Friday, morning or afternoon shift schedule, or on a Tuesday-Thursday-Saturday, morning or afternoon shift schedule. Failure to receive dialysis care will ultimately lead to the patient’s demise.”*

The applicant has included 36 in-center patient letters of support (Exhibit C-1), which state the patient would consider transferring their care to the new facility. The applicant states that each of these patients resides in close proximity to the proposed facility location, is currently receiving dialysis care at a Fresenius-affiliated dialysis facility in Cumberland County, and has expressed a willingness to transfer to the proposed location because it is more convenient and closer to their homes. The applicant provides a table on page 20 of the application showing at which Fresenius-affiliated Cumberland County facility the patients who are expected to transfer are currently dialyzing, as summarized below.

<b>Facility</b>	<b>Number of Patients Projected to Transfer</b>
FMC North Ramsey	4
FMC South Ramsey	6
FMC West Fayetteville	10
Fayetteville Kidney Center	12
Total	32

In the applicant’s table on page 20 of the application, the applicant identifies two Hoke County residents and five Robeson County residents who are currently dialyzing in a Fresenius facility in Cumberland County and are willing to transfer their treatment. The applicant states that the need this population has for the proposed service is a function of the individual patient need for dialysis care, and the stated desire of the patients to have dialysis at the proposed facility.

*Projected Utilization*

In Section C.1, pages 19-21, the applicant provides the following assumptions used to project utilization:

- The applicant plotted the residence location of patients dialyzing at BMA facilities within Cumberland County. The applicant includes 36 letters (Exhibit C-1) from

patients who reside in close proximity to the proposed facility, who could be better served by the proposed location.

- The applicant projects, based on the patient letters, that 32 in-center dialysis patients will transfer their care to the new facility upon project certification. This is 89% of the patients who signed letters stating willingness to consider transferring their care to the proposed facility.
- The applicant states that the project will be completed on December 31, 2018. Operating Year 1 (OY1) is the period from January 1 through December 31, 2019. Operating Year 2 (OY2) is the period from January 1 through December 31, 2020.
- The applicant assumes that the Cumberland County dialysis patients transferring to the new facility are part of the Cumberland County ESRD patient population as a whole, and that this population will increase at a rate commensurate with the Cumberland County Five Year Average Annual Change Rate (AACR) of 5.2%, as published in the January 2017 Semiannual Dialysis Report (SDR).
- The applicant does not project any increase in the patient population from outside Cumberland County who are projected to transfer their care.

In Section C.1, page 21, the applicant provides the methodology used to project utilization, as summarized below:

<b>FKC Hope Mills</b>	<b>In-Center</b>
Begin with 25 in-center Cumberland County dialysis patients projected to transfer their care to the new facility upon certification of the project, December 31, 2018.	25
The applicant projects the patient population forward to December 31, 2019 (end of OY1), using the Cumberland County Five Year AACR of 5.2%.	$(25 \times 0.052) + 25 = 26.3$
Add the transferring patients from Hoke and Robeson counties. This is the end of OY1.	$26.3 + 7 = 33.3$
The applicant projects the patient population forward to December 31, 2020 (end of OY2), using the Cumberland County Five Year AACR of 5.2%.	$(26.3 \times 0.052) + 26.3 = 27.7$
Add the transferring patients from Hoke and Robeson counties. This is the end of OY2.	$27.7 + 7 = 34.7$

The applicant states on page 19, that it rounds down to the whole patient in this calculation. Therefore, the applicant projects that at the end of OY1, 33 patients will be dialyzing on 10 stations for a projected utilization rate of 3.3 patients per station per week (33 in-center patients / 10 stations = 3.3) which exceeds the minimum standard of 3.2 patients per station per week as required by 10A NCAC 14C.2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need that population has for the proposed facility.

## Access

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 87% of its in-center patients will be covered by some combination of Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

## Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed services based on reasonable and supported utilization projections and assumptions, 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 in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey. All three facility locations are 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 this project, FKC Hope Mills will be certified for 10 stations and FMC North Ramsey will have 35 certified stations ( $40 - 5 = 35$ ); FMC South Ramsey will have 41 certified stations upon completion of this project and Project ID # M-11286-17 ( $51 - 5 - 5 = 41$ ).

The following table shows the projected relocation of stations in the proposed FKC Hope Mills project and identifies the number of patients projected to transfer from Fresenius-affiliated Cumberland County facilities.

**Proposed FKC Hope Mills Project**

<b>Facility</b>	<b>Number of Stations to be Relocated</b>	<b>Number of Patients Transferring</b>
FMC South Ramsey	5	6
FMC North Ramsey	5	4
FMC West Fayetteville	0	10
Fayetteville Kidney Center	0	12
<b>Total Relocated and Transferred</b>	<b>10</b>	<b>32</b>

FMC South Ramsey

In Section D.1, pages 35-37, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 138 patients dialyzing at FMC South Ramsey on 51 dialysis stations, for a utilization rate of 67.7% ( $138 / 51 = 2.70 / 4 = 0.677$ ). In addition, the applicant states that 135 of the 138 in-center patients live in Cumberland County, with one patient from each of Hoke, Sampson and Robeson counties. Five Cumberland residents and one Robeson resident have indicated a desire to transfer to FKC Hope Mills.

The applicant assumes that the number of in-center patients at FMC South Ramsey who live in Cumberland County will increase at 5.2% per year based on the Five Year AACR for Cumberland County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the in-center patients from outside Cumberland County. In Section D.1, page 36, the applicant calculates the in-center patient census for FMC South Ramsey starting December 31, 2016 through OY1 (CY2019) and OY2 (CY2020), summarized as follows:

<b>FMC South Ramsey</b>	<b>In-Center Patients</b>
Begin with the ESRD patient population of Cumberland County, as of December 31, 2016.	135
Project this population forward for 12 months to December 31, 2017, using the Five Year AACR for Cumberland County.	$(135 \times 0.052) + 135 = 142.02$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Cumberland County	$(142.0 \times 0.052) + 142.0 = 149.4$
Subtract two Cumberland County patients projected to transfer their care to FKC Rockfish along with the relocation of five stations (M-11286-17).	$149.4 - 2 = 147.4$
Subtract five Cumberland County patients projected to transfer their care to FKC Hope Mills.	$147.4 - 5 = 142.4$
Add 2 patients from Hoke and Sampson counties. The patient from Robeson County has indicated a desire to transfer to FKC Hope Mills.	$142.4 + 2.0 = 144.4$

Thus, on December 31, 2018, FMC South Ramsey is projected to have 41 ( $51 - 5 - 5 = 41$ ) certified dialysis stations with a patient population of 145 (rounded up). Utilization is

calculated to be 3.54 patients per station ( $145 / 41 = 3.54$ ) or 88.4% utilization ( $3.54 / 4 = 0.884$ ).

Therefore, the applicant states that no FMC South Ramsey patients will be adversely impacted by this application to relocate five stations to FKC Hope Mills.

FMC North Ramsey

In Section D.1, pages 37-38, the applicant states that as of December 31, 2016, as reported to DHSR Healthcare Planning as part of the ESRD Data Collection reporting for the period ended December 31, 2016, there were 141 patients dialyzing at FMC North Ramsey on 40 dialysis stations, for a utilization rate of 88.1% ( $141 / 40 = 3.52 / 4 = 0.881$ ). In addition, the applicant states that four of the 141 in-center patients live in Harnett County.

In Project ID #M-11286-17, BMA projected that one patient from FMC North Ramsey would transfer to FMC Rockfish by December 31, 2018.

The applicant assumes that the number of in-center patients at FMC North Ramsey who live in Cumberland County will increase at 5.2% per year based on the Five Year AACR for Cumberland County, as reported in Table B of the January 2017 SDR. The applicant assumes that no growth will occur for the four in-center patients living outside of Cumberland County. In Section D.1, page 38, the applicant calculates the in-center patient census for FMC North Ramsey starting December 31, 2016 through OY1 and OY2, illustrated as follows:

<b>FMC North Ramsey</b>	<b>In-Center Patients</b>
Begin with the ESRD patient population of Cumberland County, as of December 31, 2016.	137
Project this population forward for 12 months to December 31, 2017, using the Five Year AACR for Cumberland County.	$(137 \times 0.052) + 137 = 144.1$
Project this population forward for 12 months to December 31, 2018, using the Five Year AACR for Cumberland County	$(144.1 \times 0.052) + 144.1 = 151.6$
Subtract one Cumberland County patients projected to transfer their care to FKC Rockfish (M-11286-17).	$151.6 - 1 = 150.6$
Subtract four Cumberland County patients projected to transfer their care to FKC Hope Mills.	$150.6 - 4 = 146.6$
Add 4 patients from Harnett County.	$146.6 + 4.0 = 150.6$

Thus, at December 31, 2018, FMC North Ramsey is projected to have 35 certified dialysis stations with a patient population of 151 (rounded up) in-center dialysis patients. Utilization is calculated to be 4.31 patients per station ( $151 / 35 = 4.31$ ) or 1.079% ( $4.3 / 4 = 1.079$ ).

The applicant states that FMC North Ramsey had a December 31, 2016 census of 141 patients. Thus, the facility will qualify for addition of stations based on the facility need

methodology in the July 2017 SDR. In the facility need methodology table provided by the applicant on page 39, the applicant demonstrates that FMC North Ramsey will qualify to apply for up to five stations. The applicant states that BMA will file an application for five additional stations at FMC North Ramsey in September 2017 for an October 2017 review. Assuming approval of the application to add five stations, the facility would have a census of 151 patients dialyzing on 40 stations, a utilization rate of 3.775 patients per station ( $151 / 40 = 3.775$ ) or 94.4% ( $3.775 / 4 = 0.944$ ).

Therefore, the applicant states that no FMC North Ramsey patients will be adversely impacted by this application to relocate five stations to FKC Hope Mills.

In Section L.1(b), page 73, the applicant states that the projected payor mix at the proposed facility is based on the payor mix of its Cumberland County facilities. Thus, the applicant states that the proposed relocation of stations and transfer of patients will not have an adverse impact 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.

Thus, the applicant adequately demonstrates that the needs of the populations presently served at FMC South Ramsey and FMC North Ramsey will continue to be met following the proposed relocation of dialysis stations and transfer of patients from each facility to FKC Hope Mills; and that access for medically underserved groups will not be negatively impacted.

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.

#### CA

In Section E.1, pages 41-42, the applicant discusses the alternatives considered prior to the submission of this application, summarized as follows:

1. Maintain the Status Quo – the applicant states that it dismissed this alternative because there is a significant number of patients dialyzing in Fresenius-affiliated facilities and residing in close proximity to the proposed FKC Hope Mills facility, who can be more conveniently served by the development of the proposed facility. Therefore, the applicant determined the status quo would not be the most effective alternative.
2. Develop Facility in Another Area in Cumberland County – the applicant states that based on its evaluation of existing patients served by Fresenius related facilities, coupled with projections of future patient populations, there is indication of the need for an additional facility in the area of Hope Mills and southwestern Cumberland County near the location

of the proposed facility. Thus, the applicant determined any other location would be less effective.

3. Develop a Larger Facility with More Stations – after evaluation of the patient letters and the patient population served, the applicant states that it determined that FKC Hope Mills should not apply for more than 10 stations. The applicant projects that 32 patients will transfer to the facility upon certification, sufficient to meet Performance Standard 10A NCAC 14C .2203. Thus, the applicant determined a larger facility would not be the more effective alternative.
4. Expand Existing Facilities - the applicant states that existing Fresenius related facilities have little opportunity for physical plant expansion. Three of the four facilities are at physical plant capacity and the fourth is not proximate to the proposed patient residence locations to be served by that facility. Thus, in order to serve patients of the proposed area in a convenient setting, the applicant states a new facility is required; therefore, this alternative was rejected.
5. Apply to Offer Home Therapies – the applicant states that it could have proposed to provide home therapies at this location, however Fresenius has a centralized home therapies program in Cumberland County at the Fayetteville Kidney Center. The applicant states that the cost of the home training area is not insignificant; therefore, by utilizing existing home therapies programs, Fresenius is able to reduce development costs for the proposed facility. Therefore, the applicant rejected this alternative as more costly.

Thus, after considering the above alternatives, the applicant concludes that its proposal to develop a new 10-station dialysis center in Hope Mills by relocating stations from FMC South Ramsey and FMC North Ramsey is the most effective alternative.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. An application 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 need. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Hope Mills shall materially comply with all representations made in the certificate of need application.**
- 2. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Hope Mills shall relocate no more than five dialysis stations from FMC Dialysis Services South Ramsey and no more than five dialysis stations from FMC Dialysis Services North Ramsey.**

3. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Hope Mills 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 from FMC Dialysis Services South Ramsey for a total of 41 certified dialysis stations upon completion of this project and Project ID #M-11286-17 (relocate five stations to FMC Rockfish) and five dialysis stations from FMC Dialysis Services North Ramsey for a total of 35 at project completion.**
  5. **Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Hope Mills shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey.

**Capital and Working Capital Costs**

In Section F.1, page 44, the applicant provides the capital cost of the project as summarized in the following table:

**FKC Hope Mills  
 Project Capital Costs**

		<b>Total Capital Costs</b>
<b>Construction Project Costs</b>		
Construction Contract	\$1,055,596	
<b>Sub-Total Construction Costs</b>		<b>\$1,055,596</b>
<b>Miscellaneous Project Costs</b>		
Water Treatment Equipment	\$225,000	
Equipment/Furniture	\$133,871	
Architect & Engineering Fees	\$95,004	
Other: Contingency/Generator	\$122,203	
<b>Sub-Total Miscellaneous Costs</b>		<b>\$576,078</b>
<b>Total Capital Cost</b>		<b>\$1,631,674</b>

Totals may not sum due to rounding

In Section F.10, pages 47-48, and Section F.11, page 48, the applicant estimates start-up expenses of \$120,872 and initial operating expenses of \$1,034,192, respectively, for a total working capital of \$1,155,064 (Section F.12, page 48).

**Availability of Funds**

In Exhibit F-1, the applicant provides a letter dated May 15, 2017 from the Senior Vice President & Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project and committing cash reserves for the capital expenditure in the amount of \$1,631,674. The letter also authorizes additional funds as necessary for start-up costs. Exhibit F-2 contains the FMC and Subsidiaries Consolidated Financial Statements, as of December 31, 2016, showing cash and cash equivalents of \$357,899,000, total assets of \$20,135,661,000 and net assets (total assets less total liabilities) of \$10,533,297,000. The applicant adequately demonstrates the availability of funds for the capital, working capital, and operating needs of the project.

**Financial Feasibility**

In Section R, Form C, page 92, the applicant provides the allowable charges per treatment for each payment source, as illustrated in the table below:

**Allowable Charges**

<b>Payor</b>	<b>In-Center Charge</b>
Self Pay/Indigent/ Charity	\$250.41
Medicare	\$239.01
Medicaid	\$209.27
Commercial Insurance	\$1,128.58
Medicare/Commercial	\$303.59
Miscellaneous, including VA	\$495.06

In Section R, page 93, the applicant states that it calculates an average number of in-center patients (number of patients at the beginning of the year + number of patients at the end of the year / 2), rounded down to the nearest whole number, to calculate its revenues for the first  $((32 + 33.3)/2 = 32.65)$  and second  $((33.3 + 34.7)/2 = 34.00)$  operating years of the project. Therefore, the number of in-center patients used in operating year one should be 32, and the number of in-center patients used in operating year two should be 34. The Form C - Revenue Assumptions table on page 92, shows the applicant erroneously used 33 patients to calculate total treatments of 5,148  $(33 \times 3 \times 52 = 5,148)$  in Column (a) for OY2, reducing it to 4,860 total treatments adjusted for missed treatments in Column (b). The applicant then applies the patient payment percentages in Column (c) to the correct number of total treatments of 5,039 (not shown in the table) to calculate the correct number (except for rounding differences) of total treatments adjusted for missed treatments in Column (d). The following table reflects the correct numbers and calculations for Form C - Revenue Assumptions, OY2, based on the applicant's assumptions in Section R.

**Form C OY2**

**As Calculated by Analyst Based on Applicant's Assumptions Compared to Application Form C**

	<b>Pts x 3 days/Wk x 52 Wks/Yr</b>	<b>Total Tx Adjusted for Missed Tx</b>	<b>Pt Payment % by Source of Revenue</b>	<b>Number of Tx by Source</b>	<b>Allowable Charge per Tx by Source</b>	<b>Revenue by Source</b>
	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>	<b>(b)x(c)=(d)</b>	<b>(e)</b>	<b>(d)x(e)=(f)</b>
Self Pay/Indigent/ Charity	5,304	5,039	1.12%	56	\$250.41	\$14,132
Medicare	5,304	5,039	69.75%	3,515	\$239.01	\$840,016
Medicaid	5,304	5,039	4.16%	210	\$209.27	\$43,866
Commercial Insurance	5,304	5,039	7.14%	360	\$1,128.58	\$406,030
Medicare/Commercial	5,304	5,039	13.54%	682	\$303.59	\$207,125
Miscellaneous, including VA	5,304	5,039	4.29%	216	\$495.06	\$107,014
<b>Calculated by Analyst</b>	<b>5,304</b>	<b>5,039</b>		<b>5,039</b>		<b>\$1,618,183</b>
<b>Form C-Revenue and Assumptions, OY2, page 92</b>	<b>5,148</b>	<b>4,860</b>		<b>5,038</b>		<b>\$1,617,870</b>
Revenue Difference				(rounding)		(\$313)

As the table above shows, when compared to Form C – Revenue Assumptions, OY2, as provided in Section R, page 92, the Analyst's calculations result in an insignificant increase of \$313 in revenue in Column (f), due to rounding differences, which confirms the Analyst's assumption that the applicant inadvertently placed the wrong treatment numbers in Columns (a) and (b), but used the correct treatment numbers in the calculations for Column (d).

In Section R, Form B, page 91, the applicant projects operating expenses and revenues, summarized as follows:

**FKC Hope Mills**

	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Average # of In-Center Patients	32	34
Projected Treatments ((156 / Pt) - 5%)	4,742	5039
Projected Average Charge (Gross Patient Revenue / Projected # Treatments)	\$ 3,988	\$ 3,988
Gross Patient Revenue	\$ 18,910,372	\$ 20,090,775
Deductions from Gross Patient Revenue	\$ 17,387,557	\$ 18,472,905
Net Patient Revenue	\$ 1,522,815	\$ 1,617,870
Total Expenses	\$ 1,551,289	\$ 1,604,897
Net Income	(\$28,474)	\$ 12,973

Totals may not sum due to rounding

The applicant projects that revenues will exceed operating expenses in the second operating year of the project. The calculated OY2 net income is conservative based on the Project Analyst's revenue calculations, as discussed above, using the applicant's revenue

assumptions on page 92, and the fact that the applicant used higher staffing salary totals in Form A OY2 than those projected in Section H, page 56. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference. The assumptions used in preparation of the pro forma financial statements are reasonable, including projected utilization, cost and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for operating needs and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

### **Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital, working capital, and operating 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 in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey. The proposed and existing facilities are 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 this project, FKC Hope Mills will be certified for 10 dialysis stations and FMC North Ramsey will be certified for 35 dialysis stations; FMC South Ramsey will be certified for 41 dialysis stations following completion of this project, and Project ID #M-11286-17 (relocate five stations to FKC Rockfish),

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The proposed new facility, FKC Hope Mills, will be located in Cumberland County; thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are four operational dialysis facilities in Cumberland County, as follows:

### Cumberland County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Fayetteville Kidney Center	39	89.10%	3.5641
FMC Dialysis Services North Ramsey	40	87.50%	3.5000
FMC Dialysis Services South Ramsey	51	64.71%	2.5882
FMC Services of West Fayetteville	40	97.50%	3.9000

Source: January 2017 SDR, Table A.

Fresenius related entities own and operate all the existing dialysis facilities in Cumberland County. In addition to the above facilities, BMA was approved to develop FKC Rockfish in Cumberland County (Project ID #M-11286-17). With the exception of FMC South Ramsey, from which five stations are being relocated to both FKC Rockfish and the proposed project, each of the existing FMC dialysis facilities is reasonably well-utilized, operating above 87% utilization and 3.5 patients per station.

According to Table B in the January 2017 SDR, there is a deficit of eight dialysis stations in Cumberland County. However, the methodology as discussed on page 376 of the 2017 SMFP requires a deficit of 10 stations to identify a county need for an additional facility. The applicant is not proposing to increase the number of dialysis stations in Cumberland County, rather it is proposing to relocate 10 existing Cumberland County stations to develop a new facility, pursuant to Policy ESRD-2, which the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather the applicant states that it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, page 21, the applicant demonstrates that FKC Hope Mills will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5% ( $33 / 10 = 3.3$ ;  $3.3 / 4 = 0.825$ ). The applicant provides documentation in Exhibit C-1 from 36 in-center patients dialyzing at Fresenius-affiliated Cumberland County facilities stating their willingness to consider transferring to FKC Hope Mills because its location would be more convenient. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate existing Cumberland County Fresenius-affiliated dialysis stations to develop a new Fresenius dialysis facility in Cumberland County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the need of the populations presently served at FMC South Ramsey and FMC North Ramsey, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Cumberland County. Consequently, 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.1, pages 56-57, the applicant provides the projected staffing for FKC Hope Mills in OY2 by full-time equivalent (FTE) positions, as shown in the table below:

<b>FKC Hope Mills Proposed FTE Positions and Salaries OY2</b>			
<b>Position</b>	<b>Total FTE Positions</b>	<b>OY2 Projected Annual Salary per FTE</b>	<b>OY2 Total Projected Salary</b>
Registered Nurse	1.50	\$ 65,913	\$ 98,870
Patient Care Technician	4.00	\$ 32,388	\$ 129,552
Clinical Manager	1.00	\$ 78,414	\$ 78,414
Administrator	0.15	\$ 102,279	\$ 15,342
Dietitian	0.40	\$ 61,368	\$ 24,547
Social Worker	0.40	\$ 55,685	\$ 22,274
Chief Tech	0.15	\$ 52,276	\$ 7,841
Equipment Tech	0.60	\$ 37,502	\$ 22,501
In-Service	0.15	\$ 68,186	\$ 10,228
Clerical	0.75	\$ 31,820	\$ 23,865
<b>Total FTEs</b>	<b>9.10</b>		

Notes:

- 1) The Medical Director is an independent contractor, not an employee.
- 2) The medical records position is combined with the clerical position.
- 3) The position salary totals for OY2 above were used as OY1 salaries on Form A, with higher salaries used in OY2, resulting in a conservative projection for salary expenses in Form A.

In Exhibit I.5, the applicant provides a letter from Moses Y. Aboagye-Kumi, MD, dated May 4, 2017, indicating support for the project and a willingness to serve as Medical Director of the facility. In Section H.3, page 57, the applicant states it does not anticipate any difficulties in filling staff positions as it will use aggressive recruiting and advertising efforts, coupled with a range of benefits and competitive salaries to attract qualified staff. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 lists the providers of the necessary ancillary and support services for the proposed project. The table states that acute dialysis in an acute care setting, blood bank services, diagnostic/evaluation, and X-ray will be referred to Cape Fear Valley Hospital. Exhibit I-3 includes a letter of support from Cape Fear Valley CEO confirming its willingness to provide those services to FKC Hope Mills patients. Exhibit I-4 contains a letter from UNC Hospitals agreeing to enter in to an agreement with FKC Hope Mills to provide its patients with transplant services. Exhibit I-1 contains an agreement for home training services at Fayetteville Kidney Center. Exhibit I-2 contains an agreement for lab services between Spectra and FMC. The applicant discusses coordination with the existing health care system in Sections I.3 and I.4, pages 61-63, stating that Fresenius has relationships with the medical community in the area, including area physicians and hospitals. 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 healthcare 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, page 67, the applicant states that the proposed facility will have 2,927 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts a facility, with 9 main floor dialysis stations and one isolation dialysis station, for a total of 10 stations. In Section F.1, page 43, the applicant states that it relies upon the Fresenius Facility Design and Maintenance Department to develop anticipated project development costs. On page 44, the applicant provides the proposed costs, including \$1,055,596 for construction, \$576,078 in miscellaneous costs, including water treatment equipment, furniture, architect/engineering fees, and contingency for a total project cost of \$1,631,674. In Section K.1, pages 65-67, the applicant describes its plans for energy-efficiency, including water conservation. The applicant states its plans for implementing applicable energy saving features and water conservation methods, include the following:

- The building plumbing systems will be designed to ensure conservation of water.
- The exterior roof, walls and glass systems will meet current requirements for energy conservation.
- HVAC system operating efficiency "will equal current industry standards for high seasonal efficiency." In addition, the system will be controlled via 7 day/24 hour set back time clock and maintained and serviced quarterly.
- Energy efficient exit signs, water flow restrictors at sink faucets, water conserving flush toilets, optical sensor water switches and external insulation wrap for hot water heaters will be used for energy and water conservation.
- Water treatment system will allow for a percentage of the concentrate water to be re-circulated into the supply feed water, thus lowering water discharge quantity; and will use three-phase electric motors which run cooler and use less amperage.

Costs and charges are described by the applicant in Section F, pages 43-52, and in Section R proforma financial statements. 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

FKC Hope Mills is not an existing facility, thus, it has no historical payor mix. However, in Section L.7, page 76, the applicant provides the payor mix for FMC South Ramsey and FMC North Ramsey for CY2016. These are the facilities that will be contributing 10 dialysis stations, in total, to develop the proposed facility. The historical payor mix is illustrated as follows:

Payor Source	Percentage of In-Center Patients	
	FMC South Ramsey	FMC North Ramsey
Private Pay/Indigent/ Charity	0.83%	0.61%
Medicare	67.36%	69.68%
Medicaid	6.57%	7.43%
Commercial Insurance	2.82%	5.66%
Medicare/Commercial	14.62%	11.90%
Miscellaneous, including VA	7.81%	4.72%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Totals may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
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 IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>1</sup> percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>2</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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

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

C

In Section L.3(e), pages 74-75, the applicant states,

*"Fresenius related facilities in North Carolina do not have any obligation to provide uncompensated care or community service under any federal*

<sup>1</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

<sup>2</sup>[http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015\\_NW-6\\_Annual-Report\\_Final-11-29-2016.pdf](http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf)

*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 accepting payments from Medicare, Title XVIII of the Social Security Act, and Medicaid, Title XIX, all BMA North Carolina Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”*

In Section L.6, page 75, the applicant states that no civil rights complaints have been 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(b), page 73, the applicant provides the projected payor mix for the proposed services at FKC Hope Mills as shown in the table below:

**Projected Payor Mix, OY2  
1/1/20-12/31/20**

<b>Payor Source</b>	<b>Percentage</b>
Private Pay/Indigent/Charity	1.12%
Medicare	69.75%
Medicaid	4.16%
Commercial Insurance	7.14%
Medicare/Commercial	13.54%
Miscellaneous, including VA	4.29%
<b>Total</b>	<b>100.00%</b>

Totals may not sum due to rounding

As shown in the table above, the applicant projects that over 87% of in-center patients will have some or all of their services paid for by Medicare or Medicaid. In Section L.1(b), page 73, the applicant states that the projected payor mix is calculated based upon the payor mix of BMA facilities in Cumberland County. The projected payor mix is comparable to the 2016 payor mix for FMC South Ramsey and FMC North Ramsey, as shown in Criterion (13)(a). The applicant adequately demonstrates that medically underserved populations would 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 Hope Mills 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 Hope Mills will provide a range of means by which a person can access its 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 that health related education programs will be welcomed at the facility. Exhibit M-1 includes a letter from the applicant to the Dean of Health Programs at Fayetteville Technical Community College, dated May 12, 2017, inviting the school to include FKC Hope Mills in its clinical rotations for its nursing students. The information provided in Section M.1 and Exhibit M-1 is reasonable 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 in Hope Mills by relocating five stations from FMC South Ramsey and five stations from FMC North Ramsey. The proposed and existing 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 this project, FKC Hope Mills will be certified for 10 stations and FMC North Ramsey will be certified for 35 dialysis stations; FMC South Ramsey will be certified for 41 dialysis stations following completion of this project and Project ID #M-11286-17 (relocate five stations to FKC Rockfish).

On page 373, the 2017 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* The proposed new facility, FKC Hope Mills, will be located in Cumberland County; thus, the service area for this facility consists of Cumberland County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are four existing operational dialysis facilities in Cumberland County, as follows:

**Cumberland County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
Fayetteville Kidney Center	39	89.10%	3.5641
FMC Dialysis Services North Ramsey	40	87.50%	3.5000
FMC Dialysis Services South Ramsey	51	64.71%	2.5882
FMC Services of West Fayetteville	40	97.50%	3.9000

Source: January 2017 SDR, Table A.

Fresenius related entities own and operate all the existing dialysis facilities in Cumberland County. In addition to the above facilities, BMA was approved to develop FKC Rockfish in Cumberland County (Project ID #M-11286-17). With the exception of FMC South Ramsey, from which the applicant is proposing to relocate five stations to FKC Rockfish and five stations to FKC Hope Mills, each of the existing FMC dialysis facilities is reasonably well-utilized, operating above 87% utilization and 3.5 patients per station.

According to Table B in the January 2017 SDR, there is a deficit of eight dialysis stations in Cumberland County, which according to the need methodology as discussed in the 2017 SMFP, does not reach the required deficit of 10 in order to create a county need determination. However, the applicant is not increasing the number of dialysis stations in Cumberland County, rather it is proposing to relocate 10 existing Cumberland County stations, pursuant to Policy ESRD-2, to develop a new facility which the applicant states is closer to patients living in the area where the new facility will be located. Therefore, it is not duplicating services, rather the applicant states that it is proposing to create a new facility to better serve existing patients using existing stations.

In Section N.1, page 78, the applicant discusses the expected effects of the proposed project on competition, including cost-effectiveness, quality and access, stating,

*“The applicant does not expect this proposal to have effect on the competitive climate in Cumberland County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FKC Hope Mills facility begins with patients currently served by BMA at other BMA locations within the county, and a growth of that patient population consistent with the Cumberland County five year average annual change rate of 5.2% as published within the January 2017 SDR.”*

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 87% of the patients at FKC Hope Mills will have their services covered by Medicare or Medicaid. Moreover, the applicant states, on page 78, that its proposal will *“enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”*

See also Sections B, C, E, F, H, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access to the proposed dialysis 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 a cost-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 it will continue to provide quality services. The discussion regarding quality found in Criterion (20), is incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a), and (13) 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 A.11, page 5, the applicant states that Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc., which owns and operates more than 100 existing kidney disease treatment centers in North Carolina. In Exhibit A-4, the applicant provides a listing of the FMC-affiliated ESRD facilities owned and operated in North Carolina. In Section O, pages 82-83, the applicant provides information on quality of care provided at its sister facilities, including citations received during the 18 months immediately preceding the submittal of the application, and their resolution. Two FMC-affiliated facilities had immediate jeopardy citations: RAI West College-Warsaw and BMA East Rocky Mount. The applicant summarizes the deficiencies cited, the resolutions, and provides documentation in Exhibits O-3 and O-4, including correspondence from Licensure and the Centers for Medicare and Medicaid Services. On page 83, the applicant states that both facilities were back in full compliance with all CMS Guidelines upon the submittal of the application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C.2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C.2200. The specific findings 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.*
- C- In Section C.1, pages 19-21, the applicant documents the need for the project and demonstrates that it will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5% (33 patients / 10 stations = 3.3;  $3.3 / 4 = 0.825$  ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- .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.*
- NA- The applicant is seeking to develop a new 10-station dialysis facility.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section C.1, pages 19-21. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.