

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2018

Findings Date: January 29, 2018

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: M-11397-17

Facility: FMC Dialysis Services North Ramsey

FID #: 960411

County: Cumberland

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

Project: Add five dialysis stations for a total of 40 stations upon completion of this project and Project ID #M-11344-17 (relocate five stations to FKC Hope Mills)

### 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. d/b/a FMC Dialysis Services North Ramsey [FMC North Ramsey] proposes to add five dialysis stations to its existing facility for a total of 40 certified dialysis stations upon completion of this project and Project I.D. # M-11344-17 (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).

#### Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of four dialysis stations in Cumberland County; thus, no additional stations are

needed pursuant to the county need methodology. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC North Ramsey in the July 2017 SDR is 3.525 patients per station per week. This utilization rate was calculated based on 141 in-center dialysis patients and 40 certified dialysis stations as of December 31, 2016 (141 patients / 40 stations = 3.525 patients per station per week). Application of the facility need methodology indicates up to five additional stations are needed for this facility, as illustrated in the following table.

<b>OCTOBER 1 REVIEW-JULY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		88.1%
Certified Stations		40
Pending Stations		
<b>Total Existing and Pending Stations</b>		<b>40</b>
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		141
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		140
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	1
	Multiply the difference by 2 for the projected net in-center change	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.0143
(ii)	Divide the result of Step (i) by 12	0.0012
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.0143
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	143.0143
(v)	Divide the result of Step (iv) by 3.2 patients per station	44.6920
	and subtract the number of certified and pending stations to determine the number of stations needed	4.6920

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add five new stations and, therefore, is consistent with the facility need determination for dialysis stations.

**Policies**

There is one policy in the 2017 SMFP which is applicable to this review: Policy GEN-3: Basic Principles. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing*

*healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9 - 10, Section O, pages 56 - 60, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), pages 10 - 11, Section C.3, page 16, Section L, pages 48 - 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), pages 11 - 12, and Section N, page 54. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

### **Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant’s use of the facility need methodology in accordance with the July 2017 SDR, and
- the applicant’s use of existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 add five dialysis stations to its existing facility for a total of 40 certified dialysis stations upon completion of this project and Project I.D. # M-11344-17 (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). On page 14 the applicant states the facility is not certified to provide home therapies at this facility.

**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.

In Section C.8, page 18, the applicant provides the historical patient origin for FMC North Ramsey patients as of June 30, 2017, which is summarized in the following table:

**In-Center Patient Census as of June 30, 2017**

COUNTY OF RESIDENCE	# IN-CENTER PATIENTS	% OF TOTAL PATIENTS
Cumberland	128	93.4%
Harnett	9	6.6%
<b>Total</b>	<b>137</b>	<b>100.0%</b>

In Section C.1, page 14, the applicant identifies the in-center patient population it proposes to serve during the first two Operating Years (OY) following project completion, as illustrated in the table below:

**Projected In-Center Patient Census OY 1 and 2**

COUNTY	OY 1 CY 2019	OY 2 (CY 2020)	COUNTY PATIENTS AS % OF TOTAL	
	# IN-CTR. PTS.	# IN-CTR. PTS.	OY 1	OY 2
Cumberland	133.7	138.1	93.5%	93.7%
Harnett	9	9	6.5%	6.3%
<b>Total</b>	<b>142.7</b>	<b>147.1</b>	<b>100.0%</b>	<b>100.0%</b>

On page 16, the applicant states it rounded down to the nearest whole number for OYs 1 and 2.

The applicant is the only provider of dialysis services in Cumberland County. The applicant projects to serve only in-center patients at FMC North Ramsey. In Section C.2, page 20, the applicant states it bases projected patient origin on the existing patient population of the facility. The applicant adequately identifies the population it proposes to serve.

### **Analysis of Need**

In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR, and it proposes to add five dialysis stations to FMC North Ramsey, for a total of 40 stations at that facility following completion of this project and Project I.D. # M-11344-17 (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).

In Section C.1, pages 14 – 15, the applicant used the following assumptions in its projections:

- The applicant assumes projected patient growth will be consistent with the Cumberland County Five Year Average Annual Change Rate (AACR) of 3.3%, as published in the July 2017 SDR.
- Pursuant to Project ID# M-11344-17 (FKC Hope Mills), the applicant projected that four dialysis patients who reside in Cumberland County would transfer their care from FMC North Ramsey to the proposed new facility. The applicant continues in this application with that assumption. FKC Hope Mills is projected to open on December 31, 2018.
- Pursuant to Project ID #M-11286-17 (FKC Rockfish), the applicant projected that one patient from FMC North Ramsey would transfer to FKC Rockfish upon completion of that project. The applicant continues in this application with that assumption. FKC Hope Mills is projected to open on December 31, 2018.
- The patient census at FMC North Ramsey as of June 30, 2017 was 137 in-center patients. The applicant states nine of these patients reside in Harnett County, and the remainder reside in Cumberland County. The applicant assumes the Harnett County residents who dialyze at FMC North Ramsey do so by choice. The applicant will not project growth in that patient population, but will add the nine Harnett County patients to the projected patient census at the appropriate step in the methodology.
- The applicant projects this project to be complete on 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.

In Exhibit C.1, the applicant provides four petition-form letters signed by 64 FMC North Ramsey dialysis patients indicating support for the relocation of dialysis stations.

Projected Utilization

The applicant’s methodology is illustrated in the following table, form page 15:

Begin with the Cumberland County patient facility census as of June 30, 2017.	128
Project that census forward six months to 12/31/2017.	$128 \times 1.065 = 130.1$
Project that census forward one year to 12/31/2018.	$130.1 \times 1.033 = 134.4$
Subtract five patients projected to transfer to FKC Rockfish (1 patient) and FKC Hope Mills (4 patients)	$134.4 - 5 = 129.4$
Add nine patients from Harnett County who dialyze at FMC North Ramsey. This is beginning census for the facility.	$129.4 + 9 = 138.4$
Project Cumberland County patient population forward one year to 12/31/2019.	$129.4 \times 1.033 = 133.7$
Add nine patients from Harnett County who dialyze at FMC North Ramsey. This is the ending census for Operating Year 1.	$133.7 + 9 = 142.7$
Project Cumberland County patient population forward one year to 12/31/2020.	$133.7 \times 1.033 = 138.1$
Add nine patients from Harnett County who dialyze at FMC North Ramsey. This is the ending census for Operating Year 2.	$138.1 + 9 = 147.1$

The applicant projects to serve 142 in-center patients or 3.55 patients per station per week ( $142 / 40 = 3.55$ ) by the end of Operating Year 1 and 147 in-center patients or 3.67 patients per station per week ( $147 / 40 = 3.67$ ) by the end of Operating Year 2 for the proposed 40-station project. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FMC North Ramsey.

Access

In Section L.1, pages 48 - 50, the applicant states that each of BMA’s 109 facilities in 48 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 89.6% of its patients will be Medicare or Medicaid recipients in CY 2020, based on its current facility payor mix. 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

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- clearly cited, facility-specific historical data from which the applicant identifies the projected patient population and demonstrates the need the projected patient population has for the proposed dialysis services,
- use of established methodologies and assumptions which reasonably demonstrate the need the projected patient population has for the proposed services,
- documentation from existing dialysis patients who indicate support for the project,
- projected utilization supported by a facility growth rate consistent with the Cumberland county Five Year Average Annual Growth Rate published in the July 2017 SDR, and
- use of historical facility-specific data to project future access to dialysis services for all residents, including underserved groups.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

NA

The applicant does not propose to reduce, eliminate or relocate a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

In Section E, page 22, 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 it ignores the patients who reside in the county and who choose to dialyze at FMC North Ramsey. In addition, the applicant states that Cumberland County has the fourth largest dialysis patient population in the state; and the July 2017 SDR indicates a deficit of four stations in the county. The addition of five stations will alleviate the current deficit and address the growing dialysis patient population in the county.

- Apply for Fewer Stations - The applicant states this is not an effective alternative, because the projected patient census is expected to exceed 80% utilization by the first operating year of this project; therefore, the applicant states that more stations, not fewer, are needed at this facility.
- Relocate Stations from FMC South Ramsey – The applicant states utilization at FMC South Ramsey was 67.7% in the July 2017 SDR; however, the applicant proposes to relocate a total of ten existing stations from that facility (five to FKC Rockfish and five to FKC Hope Mills). FMC South Ramsey will then have 41 in-center stations after the proposed station relocations, which the applicant states will increase utilization at that facility.

After considering the above alternatives, the applicant states that this project represents the most effective alternative to meet the identified need of the patient population to be served at FMC North Ramsey.

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.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant used reasonable and adequately supported assumptions to project utilization, and
- the data cited by the applicant is reasonable to support the assumptions made with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 FMC Dialysis Services North Ramsey shall materially comply with all representations made in the certificate of need application.**
2. **Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than five additional dialysis stations for a total of no more than 40 certified stations at FMC Dialysis Services North Ramsey upon completion of this project and Project ID #M-11344-17, which shall include any home hemodialysis training or isolation stations.**



3. **Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add five dialysis stations to its existing facility for a total of 40 certified dialysis stations upon completion of this project and Project I.D. # M-11344-17 (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).

**Capital and Working Capital Costs**

In Section F.1, page 24, the applicant states that it will not incur any capital costs to develop this project. In Sections F.10 - F.12, pages 27 - 28, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project, because FMC Ramsey is an existing facility.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Forms B and C), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	<b>CY2019 OPERATING YEAR 1</b>	<b>CY2020 OPERATING YEAR 2</b>
Total Treatments	20,748	21,340
Total Gross Revenues (Charges)	\$82,743,024	\$85,103,920
Total Net Revenue	\$ 5,931,508	\$ 6,100,751
Total Operating Expenses (Costs)	\$ 5,301,441	\$ 5,441,094
Net Income	\$ 630,067	\$ 659,656

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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.

## **Conclusion**

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant uses reasonable and adequately supported assumptions to project utilization,
- historical data is used to project future costs and charges and demonstrate the project's financial feasibility, and
- since there is no capital cost associated with this project, no funding is needed by the applicant.
- the applicant projects that revenues will exceed operating expenses in the first two Operating Years of the project.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 add five dialysis stations to its existing facility for a total of 40 certified dialysis stations upon completion of this project and Project I.D. # M-11344-17 (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).

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 facilities in Cumberland County, and has been approved to develop three additional dialysis facilities in the county. The applicant is the only provider of dialysis services in the county. The existing and approved Cumberland County dialysis facilities are shown below:

**Existing and Approved Cumberland County Dialysis Facilities per the July 2017 SDR, Table B**

DIALYSIS FACILITY	# CERTIFIED STATIONS 12/31/2016	# IN-CTR. PATIENTS AS OF 12/31/16	CON ISSUED NOT CERTIFIED	% UTILIZATION	# PATIENTS PER STATION
BMA of Fayetteville*	0	0	50	0.00%	0
Fayetteville Kidney Center	39	137	-39	87.82%	3.5
FMC Dialysis Services North Ramsey	40	141	0	88.13%	3.5
FMC Dialysis Services South Ramsey	51	138	-5	67.65%	2.7
FMC Services of West Fayetteville	40	166	-5	103.75%	4.2
Fresenius Kidney Care Hope Mills*	0	0	10	0.00%	0
FKC Rockfish	0	0	10	0.00%	0

\*These stations were not certified when that data for the July 2017 SDR was collected

\*\*a Certificate of Need was issued to develop a new 10-station facility on August 22, 2017.

As shown in the table above, three of the four operational Cumberland County dialysis facilities were operating above 80% utilization (3.2 patients per station per week) as of December 31, 2016.

The table above also shows that utilization at FMC South Ramsey was 67.7% in the July 2017 SDR; however, the applicant was previously approved to relocate a total of ten existing stations from that facility (five to FKC Rockfish and five to FKC Hope Mills). Following those station relocations, FMC South Ramsey will have 41 in-center stations, which the applicant states will increase utilization at that facility. Indeed, if no growth in patient census occurs at FMS South Ramsey, then the utilization following the relocation of stations to FMC North Ramsey would be 3.36 patients per station per week, or 84% [ $138 / 41 = 3.365$ ;  $3.365 / 4 = 0.841$ ].

FMC North Ramsey proposes to add five in-center dialysis stations pursuant to the facility need methodology, for a total of 40 dialysis stations upon project completion. FMC North Ramsey was serving 141 patients weekly on 40 stations, which is 3.5 patients per station or 88% of capacity, as of December 31, 2016. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility in this application. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 14 - 15 of the application. The growth projections are based on a projected 3.3% average annual growth rate in the number of in-center dialysis patients (Cumberland County residents only) at the FMC North Ramsey facility. At the end of Operating Year One, FMC North Ramsey projects utilization will be 3.55 in-center patients per station ( $142 \text{ patients} / 40 \text{ dialysis stations} = 3.55$ ), which is 88.75% of capacity [ $3.55 / 4 = 0.8875$ ]. The applicant adequately demonstrates the need to develop five additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant is not proposing to develop a new dialysis facility, rather it is proposing to add dialysis stations to the existing facility based on the facility need methodology.
- All other operational BMA dialysis facilities in Cumberland County, with the exception of FMC Dialysis Services South Ramsey are operating at over 80% of capacity.

- The applicant demonstrates that the relocation of stations from the FMC South Ramsey facility will result in utilization at that facility of over 80%.
- The applicant expects to serve more than 3.2 patients per station per week at FMC North Ramsey at the end of the first operating year as required by 10A NCAC 14C .2203(b).

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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, page 35, the applicant provides the current staffing for the facility, which includes 28.45 full-time equivalent (FTE) employees. The applicant states that no additional staffing is projected to be added to the facility following completion of the project. In Section H.3, page 35, the applicant describes its experience and process for recruiting and retaining staff, and states it anticipates no difficulty with recruiting staff if, in the future, it becomes necessary to add staff. Exhibit I-5 contains a copy of a letter from Sanjay Mittal, M.D., expressing his support for the project and his willingness to continue serving as the Medical Director for the facility.

In Section H.7, page 37, the applicant projects the following direct care staff at FMC North Ramsey:

POSITION	# FTES	HRS./FTE/YEAR	TOTAL FTE HRS.	TOTAL ANNUAL HRS. OF OPERATION	FTE HRS. / HRS. OF OPERATION
Registered Nurse	7.00	2,080	14,560	3,744	3.89
Patient Care Tech	16.00	2,080	33,280	3,744	8.89
<b>Total</b>	<b>23.00</b>	<b>2,080</b>	<b>47,840</b>	<b>3,744</b>	<b>12.78</b>

In Section H.6, page 37, the applicant states that dialysis services will be available from 6:00 AM to 6:00 PM six days per week.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services,

- the applicant provides appropriate and credible documentation of support from the current and continuing Medical Director at FMC North Ramsey, and
- the applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 38, the applicant identifies the necessary ancillary and support services at FMC North Ramsey. The applicant discusses coordination with the existing health care system on pages 38 - 41. Exhibit I-5 includes a letter from the medical director of the facility expressing his support for the proposed project. 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 healthcare system.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant provides copies of agreements for the provision of any necessary ancillary services, including referral and patient transfer services as required for the provision of dialysis services, and
- the applicant identifies relationships with the medical community, including physicians and hospitals.
- the applicant provides a letter of support from the facility's medical director.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space, renovate existing space, or make more than minor renovations to existing space. The estimated square footage in the facility will not change pursuant to his project. Therefore Criterion (12) is not applicable to this review.

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

C

In Section L.7, page 52, the applicant reports that 90.06% of the patients who received treatments at FMC North Ramsey in CY 2016 had some or all of their services paid for by Medicare or Medicaid. The table below shows the historical (CY 2016) payment source for the facility:

<b>PAYMENT SOURCE</b>	<b>PERCENT OF TOTAL PATIENTS</b>
Self-Pay / Indigent / Charity	0.60%
Medicare	71.11%
Medicaid	7.11%
Commercial Insurance	4.94%
Medicare / Commercial	11.84%
Miscellaneous (Incl. VA)	4.41%
<b>Total</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**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Cumberland	12%	52%	56%	19%	11%	11%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

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

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) 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 information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility's historical payor mix, and
- the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

<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)



- (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), page 51 the applicant states, “*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*”. In Section L.6, page 51, the applicant states, “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*”

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant does not have any obligation to provide uncompensated care or community service under any federal regulations, and
- The applicant states that no BMA North Carolina facility has had any civil rights complaints filed against it in the past five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section L.1, page 49, the applicant states, “*It is BMA 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 49, the applicant projects that 89.61% 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:

**Projected Payor Mix, FMC North Ramsey  
OY 2 (CY 2020)**

<b>PAYMENT SOURCE</b>	<b>PERCENT OF TOTAL PATIENTS</b>
Self-Pay / Indigent / Charity	0.24%
Medicare	69.92%
Medicaid	7.37%
Commercial Insurance	5.87%
Medicare / Commercial	12.32%
Miscellaneous (Incl. VA)	4.27%
<b>Total</b>	<b>100.00%</b>

Totals may not sum due to rounding

On page 49, the applicant states projected payor mix is based on the historical experience of FMC North Ramsey, as shown in Criterion (13a).

The information in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding:

- the facility's projected payor mix demonstrates adequate access for the medically underserved, and
- the facility's projected payor mix is consistent with the facility's historical payor mix.

This determination is based on a review of:

- the information in the application, including any exhibits, and
- the information which was publicly available during the review and used by the Agency

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section L.4, page 51, the applicant states, *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC North Ramsey has 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 FMC North Ramsey offers a range of means by which a person can access the services.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- nephrologists may apply to receive medical staff privileges at the facility,
- any Nephrologist may apply to admit patients at the facility, and
- attending physicians may receive referrals from other sources.

This determination is based on a review of:

- the information in the application, including any exhibits, and
- the information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section M.1, page 53, the applicant states, “*the applicant has communicated with the local student nursing programs encouraging those programs to utilize the resources of the [FMC North Ramsey] facility to enhance the educational opportunities for the nursing student.*” In Exhibit M-1, the applicant provides a September 14, 2017 letter to Fayetteville Technical Community College which invites the college to include FMC North Ramsey in student clinical rotations.

The information provided in the application, including any exhibits, is based on reasonable and adequately supported assumptions regarding health professional training programs in the area because it shows the applicant offered the facility as a clinical training site for area health professional training programs.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

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

C

The applicant proposes to add five dialysis stations to its existing facility for a total of 40 certified dialysis stations upon completion of this project and Project I.D. # M-11344-17 (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).

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 facilities in Cumberland County, and has been approved to develop three additional dialysis facilities in the county. The applicant is the only provider of dialysis services in the county. The existing and approved Cumberland County dialysis facilities are shown below:

**Existing and Approved Cumberland County Dialysis Facilities per the July 2017 SDR, Table B**

DIALYSIS FACILITY	# CERTIFIED STATIONS 12/31/2016	# IN-CTR. PATIENTS AS OF 12/31/16	CON ISSUED NOT CERTIFIED	% UTILIZATION	# PATIENTS PER STATION
BMA of Fayetteville*	0	0	50	0.00%	0
Fayetteville Kidney Center	39	137	-39	87.82%	3.5
FMC Dialysis Services North Ramsey	40	141	0	88.13%	3.5
FMC Dialysis Services South Ramsey	51	138	-5	67.65%	2.7
FMC Services of West Fayetteville	40	166	-5	103.75%	4.2
Fresenius Kidney Care Hope Mills*	0	0	10	0.00%	0
FKC Rockfish	0	0	10	0.00%	0

\*These stations were not certified when that data for the July 2017 SDR was collected

\*\*a Certificate of Need was issued to develop a new 10-station facility on August 22, 2017.

As shown in the table above, three of the four operational Cumberland County dialysis facilities were operating above 80% utilization (3.2 patients per station) as of December 31, 2016.

The data shows that utilization at FMC South Ramsey was 67.7% in the July 2017 SDR; however, the applicant proposes to relocate stations from that facility to FKC Rockfish and FKC Hope Mills. Following the station relocation, FMC South Ramsey will have 41 in-center

stations after the proposed station relocation, which the applicant states will increase utilization at that facility. If no growth in patient census occurred at FMS South Ramsey, then the utilization following the relocation of stations to FMC North Ramsey would be 3.36 patients per station per week, or 84% [ $138 / 41 = 3.365$ ;  $3.365 / 4 = 0.841$ ].

In Section N.1, page 61, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

*“BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 89% of the In-center patients will be relying upon government payors (Medicare/Medicaid/VA). The facility must capitalize upon every opportunity for efficiency.*

*BMA facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. ... This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering another convenient venue for dialysis care and treatment.”*

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

The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality and access to the proposed services in Section N, page 54. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative.
- The applicant adequately demonstrates that FMC North Ramsey will continue to provide quality dialysis services.
- The applicant demonstrates that FMC North Ramsey will continue to provide adequate access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.4, pages 9 - 12, Section O, pages 56 - 60 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in all of its dialysis facilities.

In Exhibit A-4, the applicant provides a listing of the Fresenius-related owned and operated ESRD facilities in North Carolina. In Section O.3, pages 59 - 60, and Exhibits O-3 and O-4, the applicant identifies two of over 100 kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application and provides copies of letters to each facility from the Divisions of Health Service Regulation's Acute and Home Care Licensure and Certification Section that confirm each facility is back in compliance. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- the applicant provides adequate and credible documentation of its current policies with regard to providing quality care, and
- the applicant provides accurate information regarding past deficiencies and how those deficiencies were addressed.

This determination is based on a review of the:

- information in the application, including any exhibits, and
- information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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.

-NA- The applicant does not propose to develop a new End Stage Renal Disease Facility.

- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.1, pages 14 - 15, the applicant adequately demonstrates that FMC North Ramsey projects to serve a total of 142 in-center patients at the end of OY 1 (CY 2019) for a utilization rate of 88.75% or 3.5 patients per station per week (142 patients / 40 stations = 3.55;  $3.55 / 4 = 0.8875$  or 82.75%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 14 - 15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.