

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 28, 2019

Findings Date: June 28, 2019

Project Analyst: Tanya M. Saporito

Co-Signer: Lisa Pittman

Project ID #: M-11663-19

Facility: FMC Dialysis Services South Ramsey

FID #: 070203

County: Cumberland

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

Project: Add no more than 3 dialysis stations and relocate 3 dialysis stations from Dunn Kidney Center (Harnett County) for a total of no more than 47 stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations)

### 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., the applicant, currently operates FMC Dialysis Services South Ramsey (FMC South Ramsey), a 51-station dialysis facility located in Fayetteville, Cumberland County. The applicant proposes to add three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of

47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations).

### **Need Determination**

The 2019 SMFP provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 11 dialysis stations in Cumberland County. Additionally, Table B in the January 2019 SDR shows that one Cumberland County facility's utilization was below 80%. Therefore, there is no county need determination for new dialysis stations for Cumberland County.

However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for FMC South Ramsey in the January 2019 SDR is 3.25 patients per station per week. This utilization rate was calculated based on 166 in-center dialysis patients and 51 certified dialysis stations. (166 patients / 51 stations = 3.25 patients per station per week). The facility need methodology requires a facility's utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a maximum of three additional stations are needed for this facility, as illustrated in the following table.

**APRIL 1 REVIEW-JANUARY SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		81.37%
Certified Stations		51
Pending Stations		
<b>Total Existing and Pending Stations</b>		<b>51</b>
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		166
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		160
<b>Step</b>	<b>Description</b>	<b>Result</b>
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.0750
(ii)	Divide the result of step (i) by 12	0.0063
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0375
(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	172.2250
(v)	Divide the result of step (iv) by 3.2 patients per station	53.8203
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>3</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to three stations (rounding to the nearest whole number is allowed only in Step (v), where fractions of 0.5 and greater shall be rounded to the next highest whole number.) The applicant proposes to add three stations, pursuant to the facility need methodology. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application is consistent with the facility need determination for dialysis stations.

**Policies**

There are two policies in the 2019 SMFP that are applicable to this review, Policy GEN-3: Basic Principles and Policy ESRD-2: Relocation of Dialysis Stations.

Policy GEN-3: Basic Principles, page 31 of the 2019 SMFP, 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 10 - 11. The information provided by the applicants 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 11 - 12, and Section N.1, page 60. 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), page 12, and Section N.1, page 60. 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 FMC South Ramsey’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Policy ESRD-2: Relocation of Dialysis Stations, on page 25 of the 2019 SMFP, states:

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

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

*stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate three existing dialysis stations from Dunn Kidney Center (DKC) in Harnett County to FMC South Ramsey in Cumberland County, pursuant to Policy ESRD-2.

In Section B, page 9, the applicant states that Dunn Kidney Center, the Harnett County facility losing dialysis stations to Cumberland County, was serving five Cumberland County residents as of June 30, 2018, and six Cumberland County residents as of March 1, 2019. Therefore, the Harnett County facility losing dialysis stations is currently serving Cumberland County residents.

In Section B, page 9, the applicant states that the relocation of three dialysis stations from DKC in Harnett County to FMC South Ramsey in Cumberland County will reduce the current Harnett County surplus of five stations reported in the January 2019 SDR to two stations. Therefore, the proposal will not result in a deficit, or increase in an existing deficit in the number of dialysis stations that will be losing stations as a result of the proposed project.

In Section B, page 10, the applicant states that the relocation of three dialysis stations from DKC in Harnett County to FMC South Ramsey in Cumberland County will reduce the current Cumberland County 11-station deficit reported in the January 2019 SDR by three stations. Therefore, the proposal will 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.

Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective 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 three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations). The following table, summarized from data on page 4 of the application, Table B of the January 2019 SDR, and publicly available data, illustrates the current and projected number of dialysis stations at FMC South Ramsey and DKC:

**FMC South Ramsey**

# OF STATIONS	DESCRIPTION	PROJECT ID #
51	Total # of existing certified stations as of most recent SDR	N/A
6	# stations to be added as part of this project	M-11663-19
5	# stations previously approved to be deleted but not yet certified	M-11286-17
5	# stations previously approved to be deleted but not yet certified	M-11344-17*
47	Total # stations upon completion of all projects	N/A

\*Note: Project ID#M-11344-17 was approved to develop a 10-station facility, FKC Hope Mills. The applicant was also approved in Project ID #M-11286-17 to develop a new 10-station facility, FKC Rockfish. Through a change of scope application, the applicant was approved on August 14, 2018 to combine the two approved projects into one 20-station dialysis facility, FKC Hope Mills.

**Dunn Kidney Center**

# OF STATIONS	DESCRIPTION	PROJECT ID #
35	Total # of existing certified stations as of most recent SDR	N/A
-3	# stations to be deleted as part of this project	M-11663-19
-3	# stations proposed to be deleted in an application under review	M-11634-18
+3	Applicant voluntarily relinquished Project ID #M-11634-18 (5/20/19)	N/A
32	Total # stations upon completion of all projects	N/A

Patient Origin

On page 369, the 2019 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.” FMC South Ramsey is located in Cumberland County; therefore, 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 20, the applicants provide the historical patient origin for the in-center (IC) dialysis services provided at FMC South Ramsey, as summarized in the following table.

**FMC South Ramsey Patient Origin as of March 14, 2019**

COUNTY OF RESIDENCE	# IN-CTR PTS
Cumberland	162
Robeson	1
Sampson	1
<b>Total</b>	<b>164</b>

On page 15, the applicant states the facility is not certified to provide home dialysis services.

In Section C.1, page 15, the applicants provide the projected IC patient origin for FMC South Ramsey for operating year one (OY 1), January 1, 2021 – December 31, 2021, and operating year two (OY 2), January 1, 2022 – December 31, 2022, the first two full operating years following project completion, as shown in the following table:

**FMC Ramsey Projected Patients, OY 1 and OY 2**

COUNTY	OY 1	OY 2	COUNTY PATIENTS AS % OF TOTAL	
	1/1/20 – 12/31/20*	1/1/21 – 12/31/21*	OY 1	OY 2
	IN-CENTER PTS.	IN-CENTER PTS.		
Cumberland	164.3	169.7	99.4%	99.4%
Sampson	1	1	0.6%	0.6%
<b>Total</b>	<b>165</b>	<b>170</b>	<b>100.0%</b>	<b>100.0%</b>

\*The applicant states CY 2021 is OY 1 and CY 2022 is OY 2 on page 15; however, elsewhere in the application, including the Pro Formas, the applicant states OY 1 is CY 2020 and OY 2 is CY 2021. Therefore, the reference in the table on page 15 is a typographical error.

Totals may not sum due to rounding

The applicant does not propose to serve HH patients.

In Section C, pages 15 - 16, the applicant provides the assumptions and methodology used to project FMC South Ramsey’s patient origin.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

The applicant proposes to add three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP) and relocate three dialysis stations pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon project completion. In Section C.1, pages 15 - 18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- The applicant states FMC South Ramsey’s census reported in the January 2019 SDR was 166 patients dialyzing on 51 in-center stations, for a utilization rate of 81.37%, or 3.2549 patients per station per week [ $166 / 51 = 3.2549$ ;  $3.2549 / 4 = 0.8137$ ].

- The applicant states the facility census as of December 31, 2018 decreased to 147 patients, for a utilization rate of 72.1%, or 2.88 patients per station per week [ $147 / 51 = 2.88$ ;  $2.88 / 4 = 0.721$ ].
- The applicant states the facility census as of March 5, 2019, the date the application was prepared, was 164 patients, for a utilization rate of 80.39%, or 3.2157 patients per station per week [ $164 / 51 = 3.2157$ ;  $3.2157 / 4 = 0.8039$ ]. The applicant's mention of the lower utilization rate is not relevant to this review. This application is based on the data reported in the January 2019 SDR, which was 166 in-center patients on 51 stations, as stated above. Furthermore, the past five SDRs show a 26% increase in utilization at FMC South Ramsey, as shown in the table below, prepared by the Project Analyst:

**FMC South Ramsey Historical Utilization, 6/30/16 – 6/30/18**

	<b>JANUARY 2017 SDR</b>	<b>JULY 2017 SDR</b>	<b>JANUARY 2018 SDR</b>	<b>JULY 2018 SDR</b>	<b>JANUARY 2019 SDR</b>	<b>% GROWTH</b>
# Patients	132	138	154	160	166	26%
# Stations	51	51	51	51	51	
# Pts. / Station	2.5882	2.7059	3.0196	3.1373	3.2549	
% Utilization	64.71%	67.65%	75.49%	78.43%	81.37%	

Source: January 2017 through January 2019 Semiannual Dialysis Reports

The data reported by the facility in the SDRs for the past three years show an overall 26% increase in patient census.

In Section C, pages 16 – 17, the applicant provides the assumptions it used to project utilization, summarized as follows:

- The applicant begins its projections by using the census as of March 5, 2019, and increases it by the Cumberland County Five Year Average Annual Change Rate (AACR) of 3.3% as reported in the January 2019 SDR.
- The applicant does not project growth of patients who reside in other counties but dialyze at FMC South Ramsey; the applicant adds those patients at the appropriate time to the facility census.
- The applicant projects that the Robeson County patient who currently dialyzes at FMC South Ramsey will transfer care to the new FKC Rockfish facility when it becomes operational (projected for December 31, 2019).
- The applicant states the Sampson County patient will remain at FMC South Ramsey.
- The applicant states that Project ID #M-11502-18 combined two previously approved new 10-station facility projects into one new 20-station dialysis facility, FKC Rockfish. As part of the projections for that project, the applicant

projected a total of seven Cumberland County patients and one Robeson County patient would transfer their care from FMC South Ramsey to the new FKC Rockfish facility. The applicant confirms that projection in this application and subtracts those patients at the appropriate time.

- The applicant projects this project to be complete by December 31, 2019.
- The first Operating Year (OY) for this project is thus calendar year (CY) 2020, and the second OY is CY 2021.

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

- the facility is currently operating at 81.37% capacity with 51 stations,
- the applicant bases the future need for services upon the facility's current patient utilization, applying the 5-year county average annual change rate (AACR) of 3.3% to project growth in patient need at the facility.

Projected Utilization

In Section C, page 15, the applicant provides its projected utilization methodology, based on its stated assumptions, as illustrated in the following table.

<b>FMC SOUTH RAMSEY IN-CENTER PATIENTS</b>	
Begin with facility census of Cumberland County patients as of March, 2019.	162
Project this population forward nine months to December 31, 2019, using the Cumberland County Five Year AACR of 3.3%.	$162 \times 1.02475 = 166.0095$
Subtract seven Cumberland County patients projected to transfer to FKC Rockfish.	$166 - 7 = 159.0$
Add one patient from Sampson County. This is the starting census for the project.	$159.0 + 1 = 160.0$
Project Cumberland County patients forward one year to December 31, 2020, using the Cumberland County Five Year AACR of 3.3%.	$159.0 \times 1.033 = 164.3$
Add one patient from Sampson County. This is the ending census for OY 1.	$164.3 + 1 = 165.3$
Project Cumberland County patients forward one year to December 31, 2021, using the Cumberland County Five Year AACR of 3.3%.	$164.3 \times 1.033 = 169.7$
Add one patient from Sampson County. This is the ending census for OY 2.	$169.7 + 1 = 170.7$

Source: Table in Section C, page 17

Projected patients for OY 1 and OY 2 are rounded down to the nearest whole number. Therefore, at the end of OY 1 (CY 2020) FMC South Ramsey is projected to serve 165 in-center patients on 47 stations; and at the end of OY 2 (CY 2021) the facility is projected to serve 170 in-center patients on 47 stations.

The projected utilization rates for the first two operating years are as follows:

- OY 1: 3.51 patients per station per week, or 87.76% utilization [ $165 / 47 = 3.510$ ;  $3.510 / 4 = 0.8776$ ].

- OY 2: 3.62 patients per station per week, or 90.43% utilization [170 patients / 47 stations = 3.617; 3.617 / 4 = 0.90425].

The projected utilization of 3.51 patients per station per week at the end of OY 1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- FMC South Ramsey was operating at 81.37% capacity as of June 30, 2018, as reported in the January 2019 SDR.
- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the patient population using the Cumberland County Five Year AACR of 3.3%, as published in the January 2019 SDR.
- Projected utilization at the end of OY 1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

### Access

In Section C.3, pages 18 - 19, the applicant states:

*“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally undeserved persons.*

...

*Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an undeserved person.”*

In Section L, page 55, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**FMC South Ramsey  
Projected Payor Mix CY 2022**

<b>Payment Source</b>	<b>% of Total</b>
Self-pay/Indigent/Charity	0.64%
Medicare	65.12%
Medicaid	7.47%
Commercial Insurance	3.82%
Medicare/Commercial	18.50%
Miscellaneous (incl. VA)	4.45%
<b>Total</b>	<b>100.00%</b>

Note: numbers may not sum due to rounding

The projected payor mix is reasonable and adequately supported.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

## C

The applicant proposes to add three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations from Dunn Kidney Center pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations).

In Section D, pages 23 - 24, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project. According to the January 2019 SDR, DKC is certified for 35 in-center stations. On page 23, the applicant states that after the current application was submitted, Project ID #M-11634-18 was approved (March 20, 2019) to relocate three dialysis stations from Dunn Kidney Center to another Cumberland County dialysis facility, FMC North Ramsey. Therefore, the applicant states in this application that the net reduction of stations will be six, for a facility total of 29 in-

center stations at DKC following completion of all projects. However, on May 20, 2019, after this application was submitted, the applicant voluntarily relinquished the certificate of need for Project ID #M-11634-18. Therefore, the remainder of this analysis will be based on a reduction of three stations from DKC rather than six stations, and projections will be based on a facility total of 32 stations rather than 29 as reported by the applicant in Section D [35 current stations – 3 = 32 stations].

The applicant states on page 23 that the projections of future patients at DKC will begin with the DKC patient census, including in-center (IC), peritoneal (PD) and home hemodialysis (HHD) patients as of December 31, 2018, as shown in the following table, from page 23:

**Dunn Kidney Center Patient Census December 31, 2018**

COUNTY	IC PATIENTS	PD PATIENTS	HHD PATIENTS
Harnett	81	2	9
Cumberland	6	0	0
Johnston	5	0	1
Sampson	14	2	0
<b>Total</b>	<b>106</b>	<b>4</b>	<b>10</b>

The applicant states it will project future population of in-center patients only, and will use the 8.2% Harnett County Five Year AACR as published in the January 2019 SDR. Those projections are summarized in the following table, from page 24:

Begin with Harnett County patient census as of December 31, 2018.	81
Project this population forward 12 months to December 31, 2019, using the Harnett County Five Year AACR of 8.2%.	$81 \times 1.082 = 87.6$
Add 25 patients residing in Cumberland, Johnston and Sampson counties.	$87.6 + 25 = 112.6$
Projected patient census for DKC as of 12/31/19, the projected completion date for FMC South Ramsey.	112.6

Therefore, as of December 31, 2019, the projected completion date for this project, the patient census at DKC will be 113 patients, rounded up to the nearest whole number, which is a utilization rate of 87.5%, or 3.5 patients per station per week [ $112 / 32 = 3.5$ ;  $3.5 / 4 = 0.875$ ].

In Section D, page 24, the applicant states that BMA operates three other Harnett County dialysis facilities, each of which has capacity for additional patients. The applicant also states:

*“The relocation of stations will not have any effect upon the ability of low income persons, racial or ethnic minorities, women, handicapped persons, the elderly and other underserved groups to obtain needed health care. Patients needing dialysis services will continue to have access to dialysis at*

*either their current dialysis facility, or in a BMA facility close to their residence location.”*

### **Conclusion**

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- Information publicly available during the review and used by the Agency.

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

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

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

### CA

The applicant proposes to add three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations from Dunn Kidney Center pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations) .

In Section E, page 25 - 27, the applicant states it considered four alternatives, summarized as follows:

1. Maintain the status quo – the applicant states this was not a reasonable alternative because it ignores the growth of the Cumberland County ESRD patient population and the patient population at FMC South Ramsey. The applicant states maintaining the status quo would result in FMC South Ramsey reaching 100% utilization, which is not an acceptable alternative.
2. Forego the relocation of stations and apply for three stations only, pursuant to the facility need determination – the applicant states the projected utilization at FMC South Ramsey would result in a facility without the capacity needed to serve its patients.

3. Relocate stations from another BMA facility in Cumberland County – the applicant states all of the BMA facilities in Cumberland County are well utilized. Only one facility, FMC North Ramsey, was operating at less than 80% as reported in the January 2019 SDR; however, the utilization was 76.25%. The applicant states that utilization in all of the applicant's Cumberland County facilities has increased since December 31, 2018. There is no Cumberland County facility that can stand to lose dialysis stations.
4. Relocate more than three stations from Dunn Kidney Center – the applicant states the relocation of additional stations from Dunn Kidney Center would result in increased utilization at that facility, with potentially adverse impact on patient admissions. That is not an acceptable alternative for the patients who dialyze at DKC.

In Section E, page 27, the applicant states that the current proposal is the most cost-effective alternative because it requires no construction, no capital cost, and will simply replace stations in existing space.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided credible information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the January 2019 SDR, Bio-Medical Applications of North Carolina, Inc. shall add no more than three additional dialysis stations pursuant to Policy ESRD-2, and relocate no more than three stations from Dunn Kidney Center for a total of no more than 47 certified stations at FMC Dialysis Services South Ramsey upon completion of this project, Project ID #M-11286-17, and Project ID #M-**

**11502-18, which shall include any home hemodialysis training or isolation stations.**

- 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify three dialysis stations at Dunn Kidney Center in Harnett County for a total of no more than 32 dialysis stations.**
  - 4. 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 three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations from Dunn Kidney Center pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations).

### **Capital and Working Capital Costs**

In Section F.5, page 31, the applicant states there is no capital cost associated with this project.

In Sections F.10 and F.11, page 33, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

**FMC South Ramsey Projected Revenue and Operating Expenses**

	<b>OY 1 CY 2020</b>	<b>OY 2 CY 2021</b>
Total Treatments	24,008	24,897
Total Gross Revenue (charges)	\$95,743,904	\$99,289,236
Total Net Revenue	\$6,387,382	\$6,623,902
Average Net Revenue per Treatment	\$266.05	\$266.05
Total Operating Expenses (costs)	\$5,433,440	\$5,752,729
Average Operating Expense per Treatment	\$226.32	\$231.06
<b>Net Income / Profit</b>	<b>\$953,941</b>	<b>\$871,173</b>

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

**C**

The applicant proposes to add three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations from Dunn Kidney Center pursuant to Policy ESRD-2 in the 2019 SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations).

On page 369, the 2019 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.*” Thus, the service area is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant is the only provider of dialysis services in Cumberland County. Currently there are four existing facilities and one approved but not yet developed facility in the county, all of which are located in the greater Fayetteville area. See the following table that shows the existing and approved dialysis facilities in Cumberland County, from Table B of the January 2019 SDR:

FACILITY	PROVIDER	LOCATION	# STATIONS	UTILIZATION
Fayetteville Kidney Center	Fresenius Medical Care	Fayetteville	50	86.00%
FMC North Ramsey	Fresenius Medical Care	Fayetteville	40	76.25%
FMC South Ramsey	Fresenius Medical Care	Fayetteville	51	81.37%
FMC West Fayetteville	Fresenius Medical Care	Fayetteville	40	97.50%
FKC Rockfish*	Fresenius Medical Care	Fayetteville	20	0.00%

\*FKC Rockfish was approved pursuant to Project ID#M-11502-18 to combine two previously approved projects (Project ID #M-11286-17 and M-11344-17) into one 20-station facility.

In Section G, page 38, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Cumberland County. The applicant states:

*“BMA notes that there is not a dialysis facility east of I-95. The area east of I-95 is largely rural and does not have large ESRD patient populations. This area does have some small numbers of ESRD patients, but not enough to warrant development of a new facility east of I-95. As Fresenius is the only provider of dialysis services in Cumberland County, Fresenius is aware of where the dialysis patients reside. ... At the time this application is prepared, there is not a patient population of sufficient size which would allow the applicant to meet and exceed the performance standard rules at 10A NCAC 14C .2203.”*

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

- There is a facility need determination at FMC South Ramsey, as calculated using the methodology in the January 2019 SDR, for the proposed additional dialysis stations.
- The applicant adequately demonstrates that the six proposed dialysis stations are needed in addition to the existing or approved additional dialysis stations.

### **Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

### C

In Section H.1, page 40, the applicant provides a table illustrating current staffing in full time equivalents (FTEs) for FMC South Ramsey. The applicant does not propose to add any FTE equivalent positions as part of this project. The assumptions and methodology used to project existing staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, Section R. In Exhibit H-2, the applicant provides an outline of its continuing education programs. In Section I.3, page 44, the applicant identifies the current medical director for the facility. In Exhibit I-5, the applicant provides a letter from the medical director indicating his interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section I, page 43, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

<b>FMC ANSON COUNTY – ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
In-center dialysis/maintenance	FMC South Ramsey
Self-care training (in-center)	Referral to Fayetteville Kidney Center
Home training HH PD Accessible follow-up program	Referral to Fayetteville Kidney Center
Psychological counseling	Fayetteville Psychiatric Associates
Isolation – hepatitis	FMC South Ramsey
Nutritional counseling	FMC South Ramsey
Social Work services	FMC South Ramsey
Acute dialysis in an acute care setting	Cape Fear Valley Hospital
Emergency care	BMA staff; transport to hospital
Blood bank services	Cape Fear Valley Hospital
Diagnostic and evaluation services	Cape Fear Valley Hospital / Imaging Center /
X-ray services	Valley Radiology
Laboratory services	Spectra
Pediatric nephrology	UNC Pediatric Nephrology
Vascular surgery	Village Surgical; various nephrologists; patient choice
Transplantation services	UNC / Pitt County Memorial Hospital
Vocational rehabilitation & counseling	NC Vocational Rehabilitation
Transportation	Cumberland County Department of Social Services; Fayetteville Area Transit System; FAMIK Transportation

Source: Table in Section I, page 43

In Section I, page 44, the applicant describes its existing and proposed relationships with other local health care and social service providers. In Exhibit I-1, I-3 through I-4, the applicant provides supporting documentation for other established relationships with local health care providers.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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 HMOs. 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 any new construction or renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 58, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below.

**FMC South Ramsey  
Historical Payor Mix CY 2018**

<b>Payment Source</b>	<b>% of Total</b>
Self-pay/Indigent/Charity	0.09%
Medicare	67.26%
Medicaid	6.09%
Commercial Insurance	3.84%
Medicare/Commercial	17.87%
Miscellaneous (Incl. VA)	4.85%
<b>Total</b>	<b>100.00%</b>

Note: numbers may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance **
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Cumberland	12%	50%	57%	19%	12%	11%
Sampson	17%	51%	49%	20%	14%	19%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>; Latest Data 7/1/17 as of 7/17/18

\*Excludes "White alone, not Hispanic or Latino"

\*\* "Estimates are not comparable to other geographical levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g. V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 Annual Report (pages 25-26<sup>1</sup>) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

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

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 56, that it has no obligation in any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 57, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 55, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**FMC South Ramsey  
Projected Payor Mix CY 2021**

<b>Payment Source</b>	<b>% of Total</b>
Self-pay/Indigent/Charity	0.64%
Medicare	66.12%
Medicaid	7.47%
Commercial Insurance	3.82%
Medicare/Commercial	18.50%
Miscellaneous (Incl. VA)	4.45%
<b>Total</b>	<b>100.00%</b>

Note: numbers may not sum due to rounding

As shown in the table above, during the second year of operation, the applicant projects that 0.64% of total services will be provided to self-pay/indigent/charity patients, 84.62% to Medicare patients (includes Medicare and Medicare/Commercial), and 7.47% to Medicaid patients.

On page 55, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.
- The applicant's proposed patient origin is based on historical patient origin of the facility.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

**C**

In Section L, page 57, the applicant adequately describes the range of means by which patients will have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 59, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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 three dialysis stations pursuant to the facility need methodology in the 2019 State Medical Facilities Plan (SMFP), and relocate three dialysis stations from Dunn Kidney Center pursuant to Policy ESRD-2 in the 2019

SMFP, to the existing FMC South Ramsey facility for a total of 47 certified dialysis stations upon completion of this project, Project ID #M-11286-17 (relocate five stations) and Project ID #M-11502-18 (relocate five stations).

On page 369, the 2019 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.*” Thus, the service area is Cumberland County. Facilities may serve residents of counties not included in their service area.

The applicant is the only provider of dialysis services in Cumberland County. Currently there are four existing facilities and one approved but not yet developed facility in the county, all of which are located in the greater Fayetteville area. The following table shows the existing and approved dialysis facilities in Cumberland County, from Table B of the January 2019 SDR:

<b>FACILITY</b>	<b>PROVIDER</b>	<b>LOCATION</b>	<b># STATIONS</b>	<b>UTILIZATION</b>
Fayetteville Kidney Center	Fresenius Medical Care	Fayetteville	50	86.00%
FMC North Ramsey	Fresenius Medical Care	Fayetteville	40	76.25%
FMC South Ramsey	Fresenius Medical Care	Fayetteville	51	81.37%
FMC West Fayetteville	Fresenius Medical Care	Fayetteville	40	97.50%
FKC Rockfish*	Fresenius Medical Care	Fayetteville	20	0.00%

\*FKC Rockfish was approved pursuant to Project ID#M-11502-18 to combine two previously approved projects (Project ID #M-11286-17 and M-11344-17) into one 20-station facility.

In Section N, page 60, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

*“FMC Dialysis Services South Ramsey does not expect this proposal to have effect on the competitive climate in Cumberland County. All of the dialysis facilities in Cumberland County are operated by Fresenius Medical Care, parent to FMC Dialysis Services South Ramsey. BMA does not project to serve dialysis patients currently served by another provider in a contiguous county. The projected patient population for FMC Dialysis Services South Ramsey begins with patients currently served by BMA, and a growth of that patient population using a five year average annual change rate of 3.3% for the Cumberland County patients.*

...

*BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.*

*BMA facilities have done an exceptional job of containing operation costs while continuing to provide outstanding care and treatment to patients.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Exhibit A-4, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies more than 100 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O, page 64, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 114 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. 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 application is conforming to all applicable criteria, as discussed below.

#### **10 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- FMC Services South Ramsey is an existing 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, page 15, the applicant projects that FMC Services South Ramsey will serve 165 in-center patients on 47 stations, or a rate of 3.51 patients per station per week, as of the end of the first operating year following project completion. 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 15 - 17, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.