

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 31, 2018

Findings Date: July 31, 2018

Project Analyst: Tanya S. Rupp

Chief: Martha J. Frisone

Project ID #: Q-11486-18

Facility: FMC Dialysis Services East Carolina University

FID #: 960406

County: Pitt

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

Project: Add three dialysis stations for a total of 41 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to the new FKC Captains Cove facility)

### 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.

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Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Dialysis Services East Carolina University (“the applicant” or “FMC ECU”) proposes to add three dialysis stations to the existing facility pursuant to the facility need methodology in the 2018 State Medical Facilities Plan (SMFP), for a total of 41 certified dialysis stations upon completion of this project and Project ID #Q-11304-17 (develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center), which was approved on June 13, 2017.

**Need Determination**

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Pitt County. An applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology if the facility’s utilization rate as reported in the latest SDR is at least 3.2 patients per station per week. In this case, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for FMC ECU in the January 2018 SDR is 3.58. This utilization rate was calculated based on 147 in-center dialysis patients and 41 certified dialysis stations as of June 30, 2017 (147 patients / 41 stations = 3.5853 patients per station per week). Application of the facility need methodology indicates that a total of seven additional stations are needed for this facility, as illustrated in the following table:

<b>APRIL 1 REVIEW-JANUARY SDR</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		89.63%
Certified Stations		41
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>41</b>
In-Center Patients as of 6/30/17 (SDR2)		147
In-Center Patients as of 12/31/16 (SDR1)		141
<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 12/31/16	0.0851
(ii)	Divide the result of step (i) by 12	0.0071
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0426
(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	153.2553
(v)	Divide the result of step (iv) by 3.2 patients per station	47.8923
	and subtract the number of certified and pending stations to determine the number of stations needed	<b>7</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 2018 SDR. 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 three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

## **Policies**

There is one policy in the 2018 SMFP, Policy GEN-3, Basic Principles, which is applicable to this review.

*Policy GEN-3: Basic Principles*, on page 33, 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.”*

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), page 8, Section O, pages 57 - 60, and Exhibit O-1. 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), page 9, Section C.3, page 18, Section L, pages 50 - 54, and Exhibit L-1. 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 10 - 11 and Section N, page 56. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

## **Conclusion**

The Agency reviewed the:

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

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

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

### C

The applicant proposes to add three dialysis stations to the existing facility pursuant to the facility need methodology in the 2018 SMFP, for a total of 41 certified dialysis stations upon completion of this project and Project ID #Q-11304-17 (develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center), which was approved on June 13, 2017.

#### **Patient Origin**

On page 365, the 2018 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 Pitt County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 21, the applicant provides patient origin for FMC ECU as of December 31, 2017, summarized in the following table:

**FMC ECU  
Historical Patient Origin as of 12/31/17**

COUNTY OF RESIDENCE	# IN-CENTER PATIENTS	# HOME HEMODIALYSIS PATIENTS	# PERITONEAL DIALYSIS PATIENTS
Pitt	125	5	20
Beaufort	5	0	3
Bertie	1	0	1
Carteret	0	1	0
Chowan	0	0	1
Craven	2	0	2
Dare	0	0	1
Duplin	0	0	1
Edgecombe	2	0	2
Greene	0	0	2
Hoke	0	1	0
Lenoir	1	1	0
Martin	3	0	3
Nash	0	1	0
Pamlico	0	0	1
Washington	1	0	0
Wayne	0	0	1
Wilson	2	0	1
<b>Total</b>	<b>142</b>	<b>9</b>	<b>39</b>

In Section C.1, page 14, the applicant projects in-center patient origin for FMC ECU for the first two operating years (OY) following project completion, as follows:

**FMC ECU Projected Patient Origin**

COUNTY OF RESIDENCE	OY 1 (CY 2019)			OY 2 (CY 2020)			COUNTY PATIENTS AS % OF TOTAL	
	# IN-CTR PTS	# PD PATIENTS	# HHD PATIENTS	# IN-CTR PTS	# PD PATIENTS	# HHD PATIENTS	OY 1 (CY 2019)	OY 2 (CY 2020)
Pitt	120.9	21.5	5.4	125.4	22.3	5.6	78.7%	79.3%
Beaufort	5	3	0	5	3	0	4.3%	4.1%
Bertie	1	1	0	1	1	0	1.1%	1.0%
Carteret	0	0	1	0	0	1	0.5%	0.5%
Chowan	0	1	0	0	1	0	0.5%	0.5%
Craven	2	2	0	2	2	0	2.1%	2.1%
Dare	0	1	0	0	1	0	0.5%	0.5%
Duplin	0	1	0	0	1	0	0.5%	0.5%
Edgecombe	2	2	0	2	2	0	2.1%	2.1%
Greene	0	2	0	0	2	0	1.1%	1.0%
Hoke	0	0	1	0	0	1	0.5%	0.5%
Lenoir	1	0	1	1	0	1	1.1%	1.0%
Martin	3	3	0	3	3	0	3.2%	3.1%
Nash	0	0	1	0	0	1	0.5%	0.5%
Pamlico	0	1	0	0	1	0	0.5%	0.5%
Washington	1	0	0	1	0	0	0.5%	0.5%
Wayne	0	1	0	0	1	0	0.5%	0.5%
Wilson	2	1	0	2	1	0	1.6%	1.6%
<b>Total</b>	<b>137</b>	<b>40</b>	<b>9</b>	<b>142</b>	<b>41</b>	<b>9</b>	<b>100.0%</b>	<b>100.0%</b>

Note: numbers may not sum due to rounding

The applicant rounds down to the nearest whole patient in its projections. In addition, the applicant provides the assumptions and methodologies used to project in-center patient origin in Section C.1, pages 15 - 17. The applicant adequately identifies the population to be served.

### **Analysis of Need**

In Section C.1, page 14, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 15 - 17, the applicant describes its need methodology assumptions for projecting in-center utilization as follows:

1. The applicant begins its projections of future patients at FMC ECU with the facility census as of December 31, 2017, as reflected in the January 2018 SDR.
2. The applicant states this project is projected to be complete on December 31, 2018, following the projected certification date for FKC Captains Cove (Project ID #Q-11304-17).
3. Operating Year One is projected to be Calendar Year 2019 (January 1, 2019 – December 31, 2019), and Operating Year Two is projected to be Calendar Year 2020 (January 1, 2020 – December 31, 2020).
4. The applicant projects the Pitt County patient population currently dialyzing at FMC ECU will increase at a rate of 3.7%, consistent with the Five Year Average Annual Change Rate (AACR) as published in the January 2018 SDR.
5. The applicant states the 17 in-center patients who dialyze at FMC ECU who reside in other counties will continue to dialyze at the facility following the addition of stations proposed in this application. The applicant does not project growth in that patient population, but adds them to the Pitt County population at the end of each growth calculation.
6. In Project ID #Q-11304-17 (FKC Captains Cove), the applicant projected that 13 dialysis patients who reside in Pitt County and dialyze at FMC ECU would transfer their care to FKC Captains Cove when that facility is certified. The applicant thus subtracts those 13 patients from future projections beginning December 31, 2018, the projected certification date for FKC Captains Cove.
7. A total of 19 home peritoneal (PD) patients from counties outside of Pitt County were served at FMC ECU as of December 31, 2017. The applicant does not project growth of this patient population but adds them to the growth projections.

8. A total of four home hemo-dialysis (HD) patients from counties outside of Pitt County were served at FMC ECU as of December 31, 2017. The applicant does not project growth of this patient population but adds them to the growth projections.
9. The applicant projects growth in Pitt County PD and HHD patients using the 3.7% Pitt County Five Year AACR found in the January 2018 SDR.

Projected Utilization of In-Center Patients

In Section C.1, page 16, the applicant provides the methodology used to project in-center patient utilization, as illustrated in the following table:

<b>FMC ECU In-Center Patients, OY 1 and OY 2</b>	
Begin with Pitt County in-center patients as of December 31, 2017.	125
Project growth of Pitt County in-center patients for one year, to December 31, 2018, using the Pitt County Five Year AACR of 3.7%.	$125 \times 1.037 = 129.6$
Subtract 13 Pitt County residents projected to transfer to FKC Captains Cove, pursuant to Project ID #Q-11304-17.	$129.6 - 13 = 116.6$
Add 17 patients from other counties. This is the beginning census for this project.	$116.6 + 17 = 133.6$
Project growth of Pitt County in-center patients for one year, to December 31, 2019, using the Pitt County Five Year AACR of 3.7%.	$116.6 \times 1.037 = 120.9$
Add 17 patients from other counties. This is the ending census for operating year one.	$120.9 + 17 = 137.9$
Project growth of Pitt County in-center patients for one year, to December 31, 2020, using the Pitt County Five Year AACR of 3.7%.	$120.9 \times 1.037 = 125.4$
Add 17 patients from other counties. This is the ending census for operating year two.	$125.4 + 17 = 142.4$

On page 15, the applicant projects to serve 137 in-center dialysis patients on 41 stations at the end of OY 1, and 142 in-center dialysis patients on 41 stations at the end of OY 2, which is 3.41 patients per station per week at the end of OY 1 [137 patients / 41 stations = 3.41 patients per station per week], and 3.46 patients per station per week at the end of OY 2 [142 patients / 41 stations = 3.46 patients per station per week].

The applicant’s projected in-center utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Projected Utilization of Peritoneal Dialysis and Home Hemo-Dialysis Patients

In Section C, page 16, the applicant projects utilization of the PD patients who will be served at FMC ECU, as shown in the following table:

**FMC ECU PD Patients, OY 1 and OY 2**

Begin with 20 Pitt County PD dialysis patients as of December 31, 2017.	20
Project growth of Pitt County PD patients for one year, to December 31, 2018, using the Pitt County Five Year AACR of 3.7%.	$20 \times 1.037 = 20.7$
Add 19 patients from other counties. This is the beginning census for this project.	$20.7 + 19 = 39.7$
Project growth of Pitt County PD patients for one year, to December 31, 2019, using the Pitt County Five Year AACR of 3.7%.	$20.7 \times 1.037 = 21.5$
Add 19 patients from other counties. This is the ending census for operating year one.	$21.5 + 19 = 40.5$
Project growth of Pitt County PD patients for one year, to December 31, 2020, using the Pitt County Five Year AACR of 3.7%.	$21.5 \times 1.037 = 22.3$
Add 19 patients from other counties. This is the ending census for operating year two.	$22.3 + 19 = 41.3$

In Section C, page 17, the applicant projects utilization of the HHD patients who will be served at FMC ECU, as shown in the following tables:

**FMC ECU HHD Patients, OY 1 and OY 2**

Begin with five Pitt County HHD dialysis patients as of December 31, 2017.	5
Project growth of Pitt County HHD patients for one year, to December 31, 2018, using the Pitt County Five Year AACR of 3.7%.	$5 \times 1.037 = 5.2$
Add four patients from other counties. This is the beginning census for this project.	$5.2 + 4 = 9.2$
Project growth of Pitt County HHD patients for one year, to December 31, 2019, using the Pitt County Five Year AACR of 3.7%.	$5.2 \times 1.037 = 5.4$
Add four patients from other counties. This is the ending census for operating year one.	$5.4 + 4 = 9.4$
Project growth of Pitt County HHD patients for one year, to December 31, 2020, using the Pitt County Five Year AACR of 3.7%.	$5.4 \times 1.037 = 5.6$
Add four patients from other counties. This is the ending census for operating year two.	$5.6 + 4 = 9.6$

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

- The applicant bases projected utilization of dialysis services upon the facility's historical patient utilization, and
- The applicant utilizes the Pitt County Five Year AACR of 3.7% to project growth in patient utilization at the facility.



### Access

In Section C.3, page 18, the applicant states that Fresenius related facilities have a long history of serving the underserved population in the state and that it is corporate policy to serve “*all patients regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.*” The applicant further states that it will continue to provide access to low income and medically underinsured persons. In Section L.7, page 54, the applicant states that 89.59% of FMC ECU’s total patients and 92.24% of the facility’s in-center patients were Medicare or Medicaid recipients in CY 2017. In Section L.1, page 51, the applicant projects the same payor mix in OY 2.

The projected payor mix is reasonable and adequately supported.

### Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- 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.

NA

The applicant does not propose to

- Reduce a service
- eliminate a service
- relocate a facility or 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

The applicant proposes to add three dialysis stations to the existing facility pursuant to the facility need methodology in the 2018 SMFP, for a total of 41 certified dialysis stations upon completion of this project and Project ID #Q-11304-17 (develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center), which was approved on June 13, 2017.

In Section E.1, page 25, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because the additional stations are needed at this facility to ensure patients will have continued access to dialysis care at times and a location that are convenient for the patients.
- Apply for more than three stations – The applicant states it considered applying for more than three stations but rejected that alternative because physical plant limitations prohibit adding more than three stations at this facility.
- Relocate Stations from Other BMA Facilities in Pitt County – The applicant states that it considered relocating dialysis stations from its other existing dialysis facilities in Pitt County but rejected that alternative because those facilities are already experiencing high utilization and the applicant will apply for additional stations there, or there are not enough stations to allow for a relocation (FMC Farmville has only ten stations).

On page 25, the applicant states that its proposal is the most effective alternative because the project will not have any capital costs associated with it, and this project seeks to ensure continued provision of dialysis services to BMA patients in Pitt County.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative.

#### **Conclusion**

The Agency reviewed the:

- Application

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

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

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Dialysis Services East Carolina shall materially comply with all representations made in the certificate of need application.**
  - 2. Pursuant to the facility need determination in the January 2018 SDR, Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Dialysis Services East Carolina shall develop no more than three additional dialysis stations for a total of no more than 41 certified stations at Fresenius Medical Care Dialysis Services East Carolina upon completion of this project and Project ID #Q-11304-17, which shall include any home hemodialysis training or isolation stations.**
  - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Dialysis Services East Carolina shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

BMA Lumberton proposes to add three dialysis stations to the existing facility, for a total of 41 certified dialysis stations upon completion of this project and Project ID #Q-11304-17 (develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center), which was approved on June 13, 2017.

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

In Section F.1, page 26, the applicant states that there will be no capital cost for the project. In Sections F.10 - F.12, page 29, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project since FMC ECU is an existing operational facility.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first two operating years of the project following completion. In Section R, Form A and Form B, pages 66 and 69, the applicant projects that revenues will exceed operating expenses in each of the first two operating years, as shown in the table below.

<b>FMC ECU</b>		
	<b>OY 1 (CY 2019)</b>	<b>OY 2 (CY 2020)</b>
Total Gross Revenues (Charges)	\$108,744,784	\$111,699,892
Deductions from Gross Revenues	\$100,646,581	\$103,392,807
Total Net Revenue	\$ 8,098,203	\$ 8,307,085
Total Operating Expenses (Costs)	\$ 7,225,544	\$ 7,414,464
<b>Net Income (loss)</b>	<b>\$ 872,659</b>	<b>\$ 892,620</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
- 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 reason:

- 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 to the existing facility, for a total of 41 certified dialysis stations upon completion of this project and Project ID #Q-11304-17 (develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center), which was approved on June 13, 2017.

On page 365 the 2018 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 Pitt County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, which reports information from the facilities as of June 30, 2017, there are five existing or approved dialysis facilities in Pitt County, all of which are operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Pitt County Dialysis Facilities  
Certified Stations and Utilization as of June 30, 2017**

DIALYSIS FACILITY	LOCATION	# CERTIFIED STATIONS	# STATIONS APPROVED, NOT CERTIFIED	# PATIENTS	UTILIZATION
FMC Care of Ayden	Ayden	16	-6	61	95.31%
FMC Dialysis Services East Carolina	Greenville	41	-3	147	89.63%
FMC Farmville	Farmville	10	0	29	72.50%
Fresenius Kidney Care Captains Cove*	Winterville	0	12	0	0.00%
Greenville Dialysis Center	Greenville	51	-3	175	85.78%

Source: January 2018 SDR, Table B, page 44.

\* Fresenius Kidney Care Captains Cove is under development.

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Pitt County. On page 35, the applicant states:

*“...this application seeks to ensure that adequate dialysis resources are available for the patient population choosing to dialyze at FMC ECU.”*

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

- The applicant adequately demonstrates the need for three additional dialysis stations at FMC ECU pursuant to the facility need methodology in the 2018 SMFP.
- The applicant adequately demonstrates that the three new dialysis stations proposed at FMC ECU are needed in addition to the existing or approved dialysis stations.
- Projected utilization at the end of OY 1 exceeds the minimum standard for in-center patients per station per week required by 10A NCAC 14C .2203(b).

**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 35, the applicant provides the current and projected staffing for the facility, as shown in the following table:

**FMC ECU Staffing**

<b>POSITION</b>	<b>CURRENT FTE POSITIONS</b>	<b>PROJECTED FTE POSITIONS</b>
Registered Nurse	9.00	9.00
Home Training Nurse	5.00	5.00
Patient Care Technician	16.00	16.00
Dietician	1.750	1.750
Social Worker	1.75	1.75
Clinical Manager	1.00	1.00
Administrative (FMC Dir. of Ops)	0.15	0.15
In-Service	0.20	0.20
Clerical	2.00	2.00
Chief Technician	0.15	0.15
Equipment Technician	1.00	1.00
<b>Total</b>	<b>38.00</b>	<b>38.00</b>

As shown in the table above, the applicant does not propose any new FTE positions as a result of this project. The facility is currently certified for 41 stations, the same number it will have upon completion of this project and Project ID #Q-11304-17.

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 35 - 36, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 40, the applicant identifies the current medical director. In Exhibit I-5, the applicant provides a letter from the medical director that confirms her interest in continuing to serve as medical director for the facility.

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

**Conclusion**

The Agency reviewed the:

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

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

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

C

In Section I.1, page 39, the applicant includes a list of providers of the necessary ancillary and support services, summarized as follows:

<b>FMC ECU ANCILLARY AND SUPPORT SERVICES</b>	
<b>SERVICES</b>	<b>PROVIDER</b>
In-center dialysis/maintenance	BMA – on site
Self-care training (in-center)	BMA – on site
<b>Home training</b>	
HH PD Accessible follow-up program	BMA – on site
Psychological counseling	Pitt County Mental Health Services
Isolation – hepatitis	BMA – on site
Nutritional counseling	BMA – on site
Social Work services	BMA – on site
Acute dialysis in an acute care setting	Vidant Health Systems
Emergency care	BMA – on site / 911 / hospital
Blood bank services	Vidant Health Systems
Diagnostic and evaluation services	Vidant Health Systems / Physician's East Medical Services
X-ray services	Vidant Health Systems / Physician's East Medical Services
Laboratory services	Spectra Labs (See Exhibit I-3)
Pediatric nephrology	Vidant Health Systems
Vascular surgery	FK Azura Access Center / Greenville Surgical Specialty / Dr. Barry Hastings
Transplantation services	Vidant Health Systems
Vocational rehabilitation & counseling	East Carolina Vocational Rehabilitation Center
Transportation	Pitt Area Transit System (PATS) / Door-to-Door / Jackie McNear / Care First / Med One

The applicant provides supporting documentation in Exhibits I-1, I-2, I-3 and I-4. In addition, on page 41, the applicant provides a list of nephrologists who have agreed to provide medical coverage at the facility and who have expressed support for the project.

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

### **Conclusion**

The Agency reviewed the following:

- 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.

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

NA

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

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



NA

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

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

NA

The applicant does not propose to construct any new space nor renovate any 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.7, page 54, the applicant provides the historical payor mix during CY 2017 at FMC ECU, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL	% IN-CTR.	% HHD	% PD
Self Pay/Indigent/Charity	0.52%	0.78%	0.32%	0.32%
Medicare	72.40%	74.29%	67.09%	67.09%
Medicaid	11.98%	11.70%	11.59%	11.59%
Commercial Insurance	7.81%	4.33%	16.97%	16.97%
Medicare/Commercial	5.21%	6.25%	3.56%	3.56%
Miscellaneous (Incl. VA)	2.08%	2.66%	0.47%	0.47%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

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
Pitt	12%	53%	45%	26%	9%	13%
Beaufort	23%	52%	34%	19%	14%	13%
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 geographic 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.

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.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by

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

minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 52, the applicant states:

*“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”*

In Section L, page 53, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA North Carolina facilities.

The Agency reviewed the:

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

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

- (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 51, 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 ECU  
In-Center Patients Payor Mix  
OY 2 (CY 2020)**

<b>PAYOR CATEGORY</b>	<b>% OF TOTAL</b>	<b>% IN-CTR.</b>	<b>% HHD</b>	<b>% PD</b>
Self Pay/Indigent/Charity	0.52%	0.78%	0.32%	0.32%
Medicare	72.40%	74.29%	67.09%	67.09%
Medicaid	11.98%	11.70%	11.59%	11.59%
Commercial Insurance	7.81%	4.33%	16.97%	16.97%
Medicare/Commercial	5.21%	6.25%	3.56%	3.56%
Miscellaneous (Incl. VA)	2.08%	2.66%	0.47%	0.47%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

Numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 77.61% of total services will be provided to Medicare (Medicare and Medicare/Commercial) patients and 11.98% to Medicaid patients.

On page 52, the applicant states projected payor mix is based on the facility's historical payor mix throughout 2017. Therefore, the projected payor mix is reasonable and adequately supported.

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.

- (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 53, the applicant adequately describes the range of means by which patients will have access to the proposed services, including physician referral.

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.

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

The Agency reviewed the application and supporting exhibits. 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 January 1, 1987.  
(16) Repealed effective January 1, 1987.  
(17) Repealed effective January 1, 1987.  
(18) Repealed effective January 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care Dialysis Services East Carolina proposes to add three dialysis stations to the existing facility for a total of 41 certified dialysis stations upon completion of this project and Project ID #Q-11304-17 (develop a new 12-station dialysis facility by relocating 6 stations from FMC Care of Ayden, 3 stations from FMC Dialysis Services East Carolina University, and 3 stations from Greenville Dialysis Center), which was approved on June 13, 2017.

On page 365 the 2018 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 Pitt County. Facilities may serve residents of counties not included in their service area.

According to the January 2018 SDR, which reports information from the facilities as of June 30, 2017, there are five existing or approved dialysis facilities in Pitt County, all of which are operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Pitt County Dialysis Facilities  
 Certified Stations and Utilization as of June 30, 2017**

DIALYSIS FACILITY	LOCATION	# CERTIFIED STATIONS	# STATIONS APPROVED, NOT CERTIFIED	# PATIENTS	UTILIZATION
FMC Care of Ayden	Ayden	16	-6	61	95.31%
FMC Dialysis Services East Carolina	Greenville	41	-3	147	89.63%
FMC Farmville	Farmville	10	0	29	72.50%
Fresenius Kidney Care Captains Cove*	Winterville	0	12	0	0.00%
Greenville Dialysis Center	Greenville	51	-3	175	85.78%

Source: January 2018 SDR, Table B, page 44.

\* Fresenius Kidney Care Captains Cove is under development.

In Section N.1, page 56, 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:

*“BMA is not projecting any impact on competition. Currently BMA is the sole provider of dialysis services within Pitt County.”*

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

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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.

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

C

In Section O.3, page 60, the applicant states there are more than 100 Fresenius related dialysis facilities located in North Carolina. Exhibit A-4 contains a list of the Fresenius dialysis facilities located in North Carolina.

In Section O.3, page 60, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities, BMA East Rocky Mount. The applicant states that BMA East Rocky Mount is currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS conditions for Coverage for the BMA East Rocky Mount facility in Exhibit O-3(a) and (b). After reviewing and considering information provided by the applicant and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

**10 NCAC 14C .2203 PERFORMANCE STANDARDS**

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- The applicant does not propose to establish a new End Stage Renal Disease facility.

Therefore, this performance standard is not applicable to this review.

- .2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C.1, page 14, the applicant projects to serve 137 in-center patients on 41 in-center stations by the end of OY 1 (CY 2019), which is 3.34 patients per station per week [ $137 / 41 = 3.34$ ]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 15 - 17, 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.