

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 22, 2017

Findings Date: December 22, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: Q-11391-17

Facility: FMC Care of Ayden

FID #: 011155

County: Pitt

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

Project: Add six dialysis stations for a total of 16 stations upon completion of this project and Project ID #Q-11304-17 (relocate six stations to the new FKC Captains Cove)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to add six dialysis stations to the FMC Care of Ayden (FMC Ayden) facility for a total of 16 certified dialysis stations upon completion of this project and Project ID# Q-11304-17 (relocate six stations to the new FKC Captains Cove). Fresenius Medical Care Holdings, Inc. (Fresenius) is the parent company of BMA.

FMC Ayden does not currently offer either home hemodialysis or a peritoneal dialysis program and does not propose to add either program as part of the proposed project.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), Table D, the county need methodology shows there is a surplus of four dialysis stations in Pitt County. In order for there to be a county station need determination in the SDR the county’s projected station deficit must be 10 stations or greater, thus the applicant cannot apply to add any additional stations based on the county need methodology. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for FMC Ayden in the July 2017 SDR, Table B, is 4.0 patients per station per week, or 100.0% (4.0/ 4 patients per station = 1.0 or 100.0%). This utilization rate was calculated based on 64 in-center dialysis patients and 16 certified dialysis stations (64 patients / 16 stations = 4.0 patients per station per week).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/16		100.0%
Certified Stations		16
Pending Stations		
Total Existing and Pending Stations		16
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		64
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		60
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.1333
(ii)	Divide the result of Step (i) by 12	0.0111
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.1333
(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	72.5333
(v)	Divide the result of Step (iv) by 3.2 patients per station	22.6667
	and subtract the number of certified and pending stations to determine the number of stations needed	6.6667

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven stations. Step (C) of the facility need methodology states, “The facility may apply to expand to meet the need established . . . , up to a maximum of

ten stations.” The applicant proposes to add six new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, page 8, Section K.1(g), page 42, Section N.1, page 52 and Section O, pages 53-57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, pages 9-10, Section I, pages 36-38, Section L, pages 46-50, and referenced exhibits and Section N.1, page 52. 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, pages 10-11, Section F, Section K and Section N, page 52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

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

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

This determination is based on a review of the:

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

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

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

C

BMA proposes to add six dialysis stations to FMC Ayden for a total of 16 certified dialysis stations upon completion of this project and Project ID# Q-11304-17 (relocate six stations to the new FKC Captains Cove).

FMC Ayden does not currently offer either home hemodialysis or a peritoneal dialysis program and does not propose to add either program as part of the proposed project.

Patient Origin

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

In Section C.8, page 18, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by FMC Ayden, as shown below:

Dialysis Patients as of 12/31/2016

COUNTY	IC	HH	PD
Pitt	60	0	0
Craven	2	0	0
Green	1	0	0
Lenoir	1	0	0
Totals	64	0	0

In Section C, page 14, the applicant identifies the in-center (IC), home hemodialysis (HH) and peritoneal (PD) patient population it proposes to serve during operating year one (OY1) and operating year two (OY2) following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 (CY2019)			OPERATING YEAR 2 (CY2020)			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Pitt	51.4	0	0	53.3	0	0	92.8%	93.0%
Craven	2	0	0	2	0	0	3.6%	3.5%
Green	1	0	0	1	0	0	1.8%	1.8%
Len	1	0	0	1	0	0	1.8%	1.8%
Totals	55.4	0	0	57.3	0	0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 14-18. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B.2, page 6, the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C.2, pages 16-17 and Section E, page 21.

In Section C, pages 14-18, the applicant provides the assumptions used to project utilization as follows:

- OY1 is Calendar Year 2019 (CY2019)
- OY2 is Calendar Year 2020 (CY2020)
- FMC Ayden had 60 in-center patients who are residents of Pitt County as of December 31, 2016.
- BMA projects Pitt County resident patient growth by applying the five year average annual change rate (AACR) for Pitt County, which is 3.7% (See July 2017 SDR). BMA starts projecting patient census utilizing the FMC Ayden Pitt County patient census as of December 31, 2016.
- FMC Ayden had four in-center patients who were not residents of Pitt County as of December 31, 2016. These in-center patients were residents of Carven, Green and

Lenoir counties. BMA does not project any growth of these four patients but does assume that they will continue to dialyze at FMC Ayden as a function of patient choice.

- BMA subtracts 15 in-center patients from FMC Ayden’s patient census as of December 31, 2018: BMA was approved to develop a new facility, FKC Captains Cove, Project ID #Q-11304-17. That approved project included the transfer of six dialysis stations from FMC Ayden and the assumption that 15 in-center patients currently dialyzing at FMC Ayden would transfer their care to FKC Captains Cove. FKC Captains Cove is projected for certification as of December 31, 2018.

Projected Utilization

In Section C, page 15, the applicant the methodology used to project utilization summarized as follows:

Begin with the in-center patients from Pitt County utilizing FMC Ayden as of December 31, 2016.	60
Project the Pitt County patient population forward for one year to December 31, 2017 using the Pitt County Five Year AACR of 3.7%.	$1.037 \times 60 = 62.2$
Project the Pitt County patient population forward for one year to December 31, 2018 using the Pitt County Five Year AACR of 3.7%.	$1.037 \times 62.2 = 64.52214$
Subtract the 15 patients who are residents of Pitt County projected to transfer to FKC Captains Cove.	$64.5 - 15 = 49.52214$
Project the Pitt County patient population forward for one year to December 31, 2019 using the Pitt County Five Year AACR of 3.7%.	$1.037 \times 49.5 = 51.35445$
Add in the 4 patients from Craven, Green and Lenoir Counties. This is the projected ending census for Operating Year 1 (CY 2019).	$51.35445 + 4 = 55.35445$
Project the Pitt County patient population forward for one year to December 31, 2020 using the Pitt County Five Year AACR of 3.7%.	$1.037 \times 51.3 = 53.25457$
Add in the 4 patients from Craven, Green and Lenoir Counties. This is the projected ending census for Operating Year 2 (CY 2020).	$53.25457 + 4 = 57.25457$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) the facility is projected to serve 55 in-center patients and at the end of OY2 (CY2020) the facility is projected to serve 57 in-center patients.

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

- OY1: 3.4375 patients per station per week or 85.94% ($55 \text{ patients} / 16 \text{ stations} = 3.4375 / 4 = 0.85937$ or 85.94%).
- OY2: 3.563 patients per station per week or 89.08% ($57 \text{ patients} / 16 \text{ stations} = 3.563 / 4 = 0.89075$ or 89.08%).

The projected utilization of 3.4375 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at FMC Ayden.

Access

In Section L.1, page 46, the applicant states that Fresenius operates 109 facilities in 48 North Carolina counties (includes its affiliations with RRI facilities). The applicant states “*Fresenius related facilities have a long history of providing dialysis services to the underserved populations of North Carolina. ... Each of the Fresenius related facilities has a patient population which includes low-income, racial and ethnic minorities, women, handicapped persons, elderly, or other underserved persons.*” Furthermore, the applicant states: “*It is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*” (See application page 46)

In Section L, page 50, the applicant reports that 97.9% of the patients who received treatments at FMC Ayden had some or all of their services paid for by Medicare or Medicaid in CY2016, as illustrated in the table below:

FMC Ayden Historical Payor Mix CY2016

Payment Source	Percent of Total Patients
Medicare	94.58%
Medicaid	2.84%
Medicare/ Commercial	0.48%
Commercial Insurance	0.86%
Self Pay/Indigent/Charity*	-0.65%
Misc. (incl. VA)	1.89%
Total	100.00%

*The negative number is a result of an accounting function generally related to a prior year, or out of period adjustments. (See full explanation page 50.)

In Section L, page 47, the applicant projects 94.86% of its patients will be Medicare or Medicaid recipients in OY2 (CY2020). The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

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

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.

- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

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

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

- (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 or relocate a facility or service. Therefore, this Criterion is not applicable to this review.

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

CA

In Section E-1, page 21, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – based on the facility need methodology BMA qualifies for six additional dialysis stations and additional dialysis stations are needed at FMC Ayden. Without additional stations utilization at FMC Ayden will exceed 100% and force some patients to a third shift. Therefore, maintaining the status quo is not the most effective alternative.
2. Apply for Less Than Six Stations- based on the facility need methodology FMC Ayden has demonstrated the need for six additional dialysis stations. Therefore, applying for less than six dialysis stations is not the most effective alternative.

After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add six additional stations to ensure adequate access for the patients dialyzing at FMC Ayden.

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

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

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

This determination is based on a review of the:

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

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, Bio-Medical Applications of North Carolina, Inc. shall develop no more than 6 additional dialysis stations for a total of no more than 16 certified stations at FMC Care of Ayden upon completion of this project and Project ID# Q-111304-17 (relocate six stations to the new FKC Captains Cove), which shall include any home hemodialysis training or isolation stations.**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 proposes to add six dialysis stations to FMC Ayden for a total of 16 certified dialysis stations upon completion of this project and Project ID# Q-11304-17 (relocate six stations to the new FKC Captains Cove.)

FMC Ayden does not currently offer either home hemodialysis or a peritoneal program and does not propose to add either home hemodialysis or a peritoneal program as part of the proposed project.

Capital and Working Capital Costs

In Section F, page 23, the applicant states that there will be no capital costs associated with the proposed project. In Section F, page 26, the applicant states that there will be no working capital costs for the proposed project since FMC Ayden is an existing facility.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (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.

	Operating Year 1 (CY2019)	Operating Year 2 (CY2020)
Total Treatments	8,001	8,299
Total Gross Revenues (Charges)	\$31,911,976	\$33,096,412
Total Net Revenue	\$2,168,161	\$2,248,634
Average Revenue per Treatment	\$270.98	\$270.96
Total Operating Expenses (Costs)	\$2,163,656	\$2,228,224
Average Expense per Treatment	\$270.42	\$268.49
Net Income	\$4,405	\$20,410

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

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

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

- (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

BMA proposes to add six dialysis stations to FMC Ayden for a total of 16 certified dialysis stations upon completion of this project and Project ID# Q-11304-17 (relocate six stations to the new FKC Captains Cove.)

FMC Ayden does not currently offer either home hemodialysis or a peritoneal program and does not propose to add either program as part of the proposed project.

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

The July 2017 SDR, Table D, indicates there are five dialysis facilities (four existing and one approved) in Pitt County, as follows:

**Pitt County Dialysis Facilities
 December 31, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
FMC Care of Ayden	BMA	64	Ayden	16	-6*	100.00%
FMC Dialysis Services of East Carolina	BMA	141	Greenville	41	-3*	85.98%
FMC Farmville**	BMA	26	Farmville	10	0	65.00%
Fresenius Kidney Care Captains Cove*	BMA	0	Winterville	0	12	0.00%
Greenville Dialysis Center	BMA	170	Greenville	51	-3*	83.33%

*Note: 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) was conditionally approved and a Certificate of Need was issued on June 13, 2017.

**While FMC Farmville’s utilization is 65.0% no dialysis stations can be transferred from FMC Farmville as the facility only has the required minimum of ten dialysis stations.

As shown in the table above all of the existing and approved facilities in Pitt County are operated by BMA. Based on the most recent SDR, three of the four existing facilities operate at 83.0% utilization or above. In addition, as shown in the table above, each of the facilities currently operating at a utilization of 83.0% or above will lose stations upon completion of the Fresenius

Kidney Care Captains Cove facility (Project ID # Q-113094-17). Therefore, the facilities are well utilized.

In Section C, pages 14-18, the applicant demonstrates that FMC Ayden will service a total of 55 in-center patients at the end of OY1 (CY2019) for a utilization rate of 85.94% or 3.4375 patients per station per week ($55 \text{ patients} / 16 \text{ stations} = 3.4375 / 4 = .85937$ or 85.94%). The projected utilization of 3.4375 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant states that the projected utilization rates are based on patients currently dialyzing at FMC Ayden.

The applicant proposes to add six dialysis stations to the existing FMC Ayden facility in Ayden, in Pitt County. The applicant adequately demonstrates the need to add six additional stations at FMC Ayden based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference.

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

- The applicant uses established methodologies and uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

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

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

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

C

In Section H, page 33, the applicant provides the following table to illustrate current and projected staffing in full time equivalents (FTEs) for FMC Ayden. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECTED # FTES
Registered Nurse	2.00		2.00
LPN	1.00		1.00
Technician (PCT))	6.50		6.50
Clinical Manager	1.00		1.00
Administrator	0.15		0.15
Dietician	0.50		0.50
Social Worker	0.50		0.50
Chief Tech	0.15		0.15
Equipment Tech	0.67		0.67
In-Service	0.15		0.15
Clerical	0.75		0.75
Total	13.37	0.00	13.37

As illustrated in the table above, the applicant does not project to add any FTEs at FMC Ayden as a result of the proposed project.

In Section H, page 35, the applicant provides the projected direct care staff for FMC Ayden in OY2 (CY2020).

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	2.00	2,080	4,160	3,432	1.21
Technician (PCT)	6.50	2,080	13,520	3,432	3.94
LPN	1.00	2,080	2,080	3,432	0.61
Total	9.50	2,080	19,760	3,432	5.76

In Section H.6, page 37, the applicant states dialysis services will be available from 5:00 AM to 5:00 PM, Monday through Saturday for a total of 12 hours per day/ 72 hours per week.

In Section I.3, page 37, the applicant identifies Dr. Kristel McLawhorn as the Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. McLawhorn of Eastern Nephrology Associates supporting the project and confirming her commitment to continue to serve as Medical Director. In Section H.3, pages 33-34, the applicant describes the methods used to recruit and fill vacant or new positions.

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

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

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

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

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

C

In Section I-1, page 36, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. The applicant discusses coordination with the existing health care system on pages 37-38. Exhibits I-2 through I-4, respectively, contain copies of agreements with FMC Pitt County Dialysis for home training, for Spectra laboratories services, Pitt County Memorial Hospital (now Vidant Medical Center) for a transfer agreement for transplant services. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. McLawhorn of Eastern Nephrology Associates supporting the project and confirming her commitment to continue to serve as Medical Director.

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

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed dialysis services.
- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

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

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

- (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.

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

NA

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

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

NA

The applicant does not propose any construction or renovation to the existing facility. 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 50, the applicant reports that 97.9% of the patients who received treatments at FMC Ayden had some or all of their services paid for by Medicare or Medicaid in CY2016, as illustrated in the table below:

FMC Ayden Historical Payor Mix CY2016

Payment Source	Percent of Total Patients
Medicare	94.58%
Medicaid	2.84%
Medicare/ Commercial	0.48%
Commercial Insurance	0.86%
Self Pay/Indigent/Charity*	-0.65%
Misc. (incl. VA)	1.89%
Total	100.00%

*The negative number is a result of an accounting function generally related to a prior year, or out of period adjustments. (See full explanation page 50.)

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Pitt	12%	53%	45%	26%	9%	13%
Statewide	16%	51%	37%	16%	10%	13%

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

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

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

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc.*

*2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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

- The applicant's historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

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

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

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

C

In Section L.3(e), page 48 the applicant states, "*Fresenius related facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.*" In Section L.6, page 49, the applicant states, "*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*"

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

- The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.

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

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

- The applicant states it has not had any civil rights access complaints filed against it within the last five years.

This determination is based on a review of the:

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

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

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

C

In Section L.1, page 46, the applicant states: *“It is policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”* In Section L, page 46, the applicant projects that 94.86% of all patients in OY2 (CY2020) will have all or part of their services paid for by Medicare and or Medicaid, as indicated in the table below:

FMC Ayden Projected Payor Mix OY2 (CY2020)

Payment Source	Percent of Total Patients
Medicare	92.13%
Medicaid	1.52%
Medicare/ Commercial	1.21%
Commercial Insurance	2.37%
Self Pay/Indigent/Charity	0.15%
Misc. (Incl. VA)	2.63%
Total	100.00%

Projected payor mix is based on historical data as shown in Criterion 13(a).

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed services.

This determination is based on a review of the:

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

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

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

C

In Section L.4, page 49, the applicant states, *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Ayden will have an open policy, which means that any Nephrologist may apply to admit patients to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”*

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

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

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

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

C

In Section M.1, page 51, the applicant states that it has offered FMC Ayden as a clinical training site for nursing students from East Carolina University’s College of Nursing. A copy of a letter sent by the applicant to the college, dated September 14, 2017, is included in Exhibit M-1.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

This determination is based on a review of the:

- Information in the application, including any exhibits.

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

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

- (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

BMA proposes to add six dialysis stations to FMC Ayden for a total of 16 certified dialysis stations upon completion of this project and Project ID# Q-11304-17 (relocate six stations to the new FKC Captains Cove.)

FMC Ayden does not currently offer either home hemodialysis or a peritoneal dialysis program and does not propose to add either program as part of the proposed project.

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

The July 2017 SDR, Table D, indicates there are five dialysis facilities (four existing and one approved) in Pitt County, as follows:

**Pitt County Dialysis Facilities
 December 31, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
FMC Care of Ayden	BMA	64	Ayden	16	-6*	100.00%
FMC Dialysis Services of East Carolina	BMA	141	Greenville	41	-3*	85.98%
FMC Farmville**	BMA	26	Farmville	10	0	65.00%
Fresenius Kidney Care Captains Cove	BMA	0	Winterville	0	12	0.00%
Greenville Dialysis Center	BMA	170	Greenville	51	-3*	83.33%

*Note: 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) was conditionally approved and a Certificate of Need was issued on June 13, 2017.

**While FMC Farmville’s utilization is 65.0% no dialysis stations can be transferred from FMC Farmville as the facility only has the required minimum of ten dialysis stations.

As shown in the table above all of the existing and approved facilities in Pitt County are operated by BMA. Based on the most recent SDR, three of the four existing facilities operate at 83.0% utilization or above. In addition, as shown in the table above, each of the facilities currently operating at a utilization of 83.0% or above will lose stations upon completion of the Fresenius Kidney Care Captains Cove facility (Project ID # Q-113094-17). Therefore, the facilities are well utilized.

In Section C, pages 14-18, the applicant demonstrates that FMC Ayden will service a total of 55 in-center patients at the end of OY1 (CY2019) for a utilization rate of 85.94% or 3.4375 patients per station per week (55 patients / 16 stations = 3.4375 / 4 = .85937 or 85.94%). The projected utilization of 3.4375 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant states that the projected utilization rates are based on patients currently dialyzing at FMC Ayden.

In Section N, pages 52, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services and states:

“The applicant does not expect this proposal to have effect on the competitive climate in Pitt County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the FMC Ayden facility begins with patients currently served by BMA, and a growth of that patient population consistent with the Pitt County five year average annual change rate of 3.7% as published within the July 2017 SDR.”

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

This determination is based on a review of the:

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

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

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

C

Fresenius Medical Care Holdings, Inc. owns and operates over 100 facilities in North Carolina as of September 15, 2017. In Section O and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period.

In Section B, page 8, Section O, pages 53-57 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-2, the applicant provides a document indicating that a survey of Metrolina Kidney Center was completed on May 30, 2013 and no condition level deficiencies were cited. On page 55, that applicant states "*FMC Ayden meets the Conditions for Coverage for ESRD facilities.*"

In Section O, pages 56-57, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two listed below were not

in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
RAI West College-Warsaw	3/15/2016	Yes	4/11/2016
BMA East Rocky Mount	1/25/2017	Yes	3/2/2017

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

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

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

This determination is based on a review of the:

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

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

(21) Repealed effective July 1, 1987.

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

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
- NA- The applicant is not proposing to establish a new End Stage Renal Disease facility
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- C- In Section C, pages 14-17, the applicant demonstrates that FMC Ayden will service a total of 55 in-center patients at the end of OY1 (CY2019) for a utilization rate of 85.94% or 3.4375 patients per station per week ($55 \text{ patients} / 16 \text{ stations} = 3.4375 / 4 = .85937$ or 85.94%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section C, pages 14-18, 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.

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

- The applicant provides adequate and credible documentation that it meets the performance standard required by this Rule.
- The applicant provides all documentation of its assumptions and methodology required by this Rule.

This determination is based on a review of the:

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

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