

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 14, 2018

Findings Date: August 14, 2018

Project Analyst: Gregory F. Yakaboski

Section Chief: Martha J. Frisone

Project ID #: Q-11484-18

Facility: Greenville Dialysis Center

FID #: 944657

County: Pitt

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

Project: Add three dialysis stations for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to 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) d/b/a Greenville Dialysis Center proposes to add three dialysis stations for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to FKC Captains Cove). The parent company of BMA is Fresenius Medical Care Holdings, Inc. (Fresenius).

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. However, the applicant is eligible to

apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Greenville Dialysis Center in the January 2018 SDR is 3.4314 patients per station per week. This utilization rate was calculated based on 175 in-center dialysis patients and 51 certified dialysis stations as of June 30, 2017 (175 patients /51 stations = 3.4314 patients per station per week). Application of the facility need methodology indicates that 5 additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/17		85.78%
Certified Stations		51
Pending Stations		
Total Existing and Pending Stations		51
In-Center Patients as of 6/30/17 (SDR2)		175
In-Center Patients as of 12/31/16 (SDR1)		170
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.0588
(ii)	Divide the result of step (i) by 12	0.0049
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/17 until 12/31/17)	0.0294
(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	180.1471
(v)	Divide the result of step (iv) by 3.2 patients per station	56.2960
	and subtract the number of certified and pending stations to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 5 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 3 new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*. Policy GEN-3, 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 57-61, 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), pages 9-10, 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, Section C, pages 14-17, 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.

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.

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 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 three dialysis stations the Greenville Dialysis Center facility for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to FKC Captains Cove).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients at Greenville Dialysis Center.

County	Current* December 31, 2017				OY2** Calendar Year 2020			
	IC	HH	PD	% of Total	IC	HH	PD	% of Total
Pitt	143	12	23	79.11%	146.6	13.4	25.6	80.80%
Beaufort	7	1	0	3.55%	7	1	0	3.50%
Bertie	0	0	2	0.88%	0	0	2	0.90%
Chowan	0	1	0	0.44%	0	1	0	0.40%
Craven	1	0	1	0.88%	1	0	1	0.90%
Duplin	0	0	1	0.44%	0	0	1	0.40%
Edgecombe	0	1	2	1.33%	0	1	2	1.30%
Greene	2	1	1	1.77%	2	1	1	1.70%
Lenoir	1	0	0	0.44%	1	0	0	0.40%
Martin	8	1	2	4.88%	8	1	2	4.80%
Nash	0	1	0	0.44%	0	1	2	0.40%
Washington	1	0	0	0.44%	1	0	0	0.40%
Wayne	2	0	1	1.33%	2	0	1	1.30%
Wilson	3	1	2	2.66%	3	1	2	2.60%
Georgia	1	0	0	0.44%	0	0	0	0.00%
South Carolina	1	0	0	0.44%	0	0	0	0.00%
Other States	1	0	0	0.44%	0	0	0	0.00%
Total	171	19	35	100.00%	172	20	38	100.0%

*Source: Table in Section C.8, page 21 of the application.

**Source: Table in Section C.1, page 14 of the application.

In Section C, pages 14-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 14-18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 15-16, describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

1. The applicant projects the first two full operating years of the project will be January 1, 2019 – December 31, 2019 (CY2019) and January 1, 2020 – December 31, 2020 (CY2020).
2. As of December 31, 2017, the current patient census of Pitt county residents at Greenville Dialysis Center was 143 in-center patients.
3. As of December 31, 2017, the patient census of non-Pitt county residents at Greenville Dialysis Center was a total of 28 in-center patients from other NC counties and other states, as follows:
 - a. 3 in-center patients from Other States: BMA assumes that these three IC patients were transient dialysis patients and will not project these patients to continue dialyzing at Greenville Dialysis Center.
 - b. 25 in-center patients from other North Carolina counties. BMA assumes that these patients will continue dialyzing at Greenville Dialysis Center however, no patient growth is projected for this segment of the patient population.
4. The applicant projects growth of the Pitt county residents at 3.7% which is the Pitt County Five Year Average Annual Change Rate (AACR) per the January 2018 SDR.
5. BMA subtracts 12 patients from the patient census of Greenville Dialysis Center as of December 31, 2018 because BMA projects that 12 patients will transfer their care to FKC Captains Cove upon completion of that project, which is expected to be December 31, 2018.

Projected Utilization

Projected IC Utilization

The applicant's methodology for in-center patients is shown in the following table.

Begin with Pitt County patients dialyzing at the facility as of December 31, 2017.	143
Project Pitt County patient census forward one year to December 31, 2018 using the 5 year AACR of 3.7% for Pitt County.	$143 \times 1.037 = 148.3$
Subtract the 12 patients projected to transfer to FKC Captains Cove.	$148.3 - 12 = 136.3$
Project Pitt County patient census forward one year to December 31, 2019 using the 5 year AACR of 3.7% for Pitt County.	$136.3 \times 1.037 = 141.3$
Add the 25 patients from other North Carolina counties. This is the ending census for OY1 (CY2019).	$141.3 + 25 = \mathbf{166.3}$
Project the Pitt County patient census forward one year to December 31, 2020.	$141.3 \times 1.037 = 146.5$
Add the 25 patients from other North Carolina counties. This is the ending census for OY2 (CY2020).	$146.5 + 25 = \mathbf{171.5}$

Source: Table in Section C, page 16.

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 166 in-center patients and at the end of OY2 (CY2020) the facility is projected to serve 171 in-center patients.

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

- OY1: 3.2549 patients per station per week or 81.37% ($166 \text{ patients} / 51 \text{ stations} = 3.2549 / 4 = 0.8137$ or 81.37%).
- OY2: 3.3529 patients per station per week or 83.82% ($171 \text{ patients} / 51 \text{ stations} = 3.3529 / 4 = 0.8382$ or 83.82%).

The projected utilization of 3.2549 patients per station per week at the end of OY1 is equal to or exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected Utilization for PD patients and HH patients.

BMA states that PD and HH patient utilization is expected to increase at the Pitt County Five Year AACR of 3.7%. The same methodology used to project IC patient utilization was used to project HH and PD patient utilization.

Projected PD Utilization

The applicant’s methodology for peritoneal dialysis patients is shown in the following table.

Begin with Pitt County PD patients dialyzing at the facility as of December 31, 2017.	23
Project Pitt County PD patient census forward one year to December 31, 2018 using the 5 year AACR of 3.7% for Pitt County.	$23 \times 1.037 = 23.9$
Project Pitt County patient census forward one year to December 31, 2019 using the 5 year AACR of 3.7% for Pitt County.	$23.9 \times 1.037 = 24.78$
Add the 12 PD patients from other North Carolina counties. This is the ending census for OY1 (CY2019).	$24.78 + 12 = \mathbf{36.78}$
Project the Pitt County PD patient census forward one year to December 31, 2020.	$24.78 \times 1.037 = 25.69$
Add the 12 PD patients from other North Carolina counties. This is the ending census for OY2 (CY2020).	$25.69 + 12 = \mathbf{37.69}$

Source: Table in Section C, page 16.

Projected HH Utilization

The applicant’s methodology for home hemodialysis patients is shown in the following table.

Begin with Pitt County HH patients dialyzing at the facility as of December 31, 2017.	12
Project Pitt County HH patient census forward one year to December 31, 2018 using the 5 year AACR of 3.7% for Pitt County.	$12 \times 1.037 = 12.44$
Project Pitt County HH patient census forward one year to December 31, 2019 using the 5 year AACR of 3.7% for Pitt County.	$12.44 \times 1.037 = 12.9$
Add the 12 HH patients from other North Carolina counties. This is the ending census for OY1 (CY2019).	$12.9 + 7 = \mathbf{19.9}$
Project the Pitt County HH patient census forward one year to December 31, 2020.	$12.9 \times 1.037 = 13.37$
Add the 7 HH patients from other North Carolina counties. This is the ending census for OY2 (CY2020).	$13.37 + 7 = \mathbf{20.37}$

Source: Table in Section C, page 17.

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

- The applicant adequately identifies the patients to be served.
- The applicant assumes a projected annual rate of growth of 3.7 percent for the in-center Pitt County patient census at Greenville Dialysis Center, which is equal to the Pitt County Five Year Average Annual Change Rate as published in the January 2018 SDR.
- The applicant adequately demonstrates the need for three additional dialysis stations at Greenville Dialysis Center pursuant to the facility need methodology in the 2018 SMFP. Projected utilization at the end of OY1 exceeds the minimum standard for in-center patients per week required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 18, the applicant states each of BMA’s 112 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L.1, page 51, the

applicant projects the following payor mix during the second full fiscal year of operation (CY2020) following completion of the project, as illustrated in the following table.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/Indigent/Charity	0.44%
Medicare	69.60%
Medicaid	5.29%
Commercial Insurance	10.57%
Medicare/Commercial	10.57%
Miscellaneous (Incl. VA)	3.52%
Total	100.00%

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 or eliminate a service, nor does the applicant propose to 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

BMA proposes to add three dialysis stations to Greenville Dialysis Center for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to FKC Captains Cove).

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 due to the fact that Greenville Dialysis Center is projected to need the additional stations to assure patients of access to dialysis care at a convenient location and times.
- Apply for more than three additional stations- Pursuant to the Facility Need Methodology, Greenville Dialysis Center showed a need for five additional dialysis stations. However, only three additional dialysis could be applied for due to physical plant limitations.
- Relocate stations from another BMA facility in Pitt County- The applicant states that all BMA facilities in Pitt County are operating at above 80% utilization except for FMC Farmville. However, FMC Farmville only has 10 dialysis stations, the minimum number of dialysis stations required at a facility. Therefore, it is not the most effective alternative to relocate stations from another BMA facility in Pitt County.

On page 25, the applicant states that its proposal is the most effective alternative because BMA is replacing three stations which are being relocated to FKC Captains Cove (Project ID# Q-11304-17) with no capital expenditure since the space for the stations already exists at the facility.

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. 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. shall develop no more than 3 additional dialysis stations for a total of no more than 51 certified stations at Greenville Dialysis Center upon completion of this project and Project ID# Q-11304-17 (relocate three stations to 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 three dialysis stations to Greenville Dialysis Center for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to FKC Captains Cove).

Capital and Working Capital Costs

In Section F, pages 26 and 29, the applicant states that the proposed project will not involve any capital expenditures or initial operating expenses.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, Form B, page 69, the applicant projects that revenues will exceed operating expenses in the second operating year of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	32,306	33,344
Total Gross Revenues (Charges)	\$128,836,328	\$132,975,872
Total Net Revenue	\$11,166,520	\$11,522,708
Average Net Revenue per treatment	\$345.65	\$345.57
Total Operating Expenses (Costs)	\$9,571,897	\$9,848,068
Average Operating Expense per treatment	\$296.29	\$295.35
Net Income	\$1,594,623	\$1,674,639

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 reasons:

- 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

BMA proposes to add three dialysis stations to Greenville Dialysis Center for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to FKC Captains Cove).

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR, Table B, indicates there are five dialysis facilities (four existing and one approved) in Pitt County, as follows:

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

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
FMC Care of Ayden	BMA	61	Ayden	16	-6 and +6*	95.31%
FMC Dialysis Services of East Carolina	BMA	147	Greenville	41	-3*	89.63%
FMC Farmville**	BMA	29	Farmville	10	0	72.50%
Fresenius Kidney Care Captains Cove*	BMA	0	Winterville	0	12	0.00%
Greenville Dialysis Center	BMA	175	Greenville	51	-3*	85.78%

*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. Project ID # Q-11391-17 (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 FKC Captains Cove) was conditionally approved and a Certificate of Need was issued on January 26, 2018.

**While FMC Farmville’s utilization is 72.5%, no dialysis stations can be relocated from FMC Farmville since 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 85.0% utilization or above. In addition, as shown in the table above, each of the facilities currently operating at a utilization of 85.0% or above will lose stations upon completion of the Fresenius Kidney Care Captains Cove project (Project ID # Q-113094-17) and FMC Care of Ayden was approved to add 6 dialysis stations back (Project ID# Q-11391-17) based on the facility need methodology. Therefore, the facilities are well utilized.

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 34, the applicant states:

“The Pitt County ESRD population is increasing at a rate of 3.7%, meaning that new dialysis stations and new facilities will be needed... BMS is not creating unnecessary duplication of existing or approved health services. Rather this application seeks to ensure that adequate dialysis resources are available for the patient population choosing to dialyze at the BMA Greenville facility.”

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 Greenville Dialysis Center pursuant to the facility need methodology in the 2018 SMFP.

- The applicant adequately demonstrates that the proposed 3 new dialysis stations at Greenville Dialysis Center is needed in addition to the existing or approved dialysis stations.
- Projected utilization at the end of OY1 exceeds the minimum standard for in-center patients 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 staffing for the facility, and states that Greenville Dialysis Center is not projected to add any full time equivalent (FTE) positions as a result of this proposal. The facility is currently certified for 51 stations and will have 51 stations upon completion of this project and Project I.D. #Q-11304-17. The applicant states the facility currently employs 49.75 FTE positions.

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 36-37, 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 indicating an 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 as shown in the table below.

Greenville Dialysis Center Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Greenville Dialysis Center
Self-care training (in-center)	Greenville Dialysis Center
Home training HH PD Accessible follow-up program	Greenville Dialysis Center
Psychological counseling	Pitt County Mental Health Services
Isolation – hepatitis	Greenville Dialysis Center
Nutritional counseling	Greenville Dialysis Center
Social Work services	Greenville Dialysis Center
Acute dialysis in an acute care setting	Vidant Health Systems
Emergency care	All BMA staff trained to respond and fully stocked crash cart available, Ambulance transport to hospital
Blood bank services	Vidant Health Systems
Diagnostic and evaluation services	Vidant Health Systems or Physicians East Medical Services
X-ray services	Vidant Health Systems or Physicians East Medical Services or Eastern Radiology
Laboratory services	SPECTRA
Pediatric nephrology	Vidant Health Systems
Vascular surgery	FK Azura Access Center, Greenville Surgery Specialty, or Dr. Barry Hastings
Transplantation services	Vidant Health Systems
Vocational rehabilitation & counseling	East Carolina Vocational Rehabilitation Center
Transportation	Pitt Area Transit (PATS), Door-to-Door, Jackie McNear; Care First and Med One

In Section I.1-2, pages 39-40, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1, I-2, I-3 and I-4.

In Section I, pages 40-42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3 and I-4.

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

Conclusion

The Agency reviewed the:

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

NA

The applicant does not propose to construct any new space 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 Greenville Dialysis Center, as shown in the table below.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/Indigent/Charity	0.44%
Medicare	69.60%
Medicaid	5.29%
Commercial Insurance	10.57%
Medicare/Commercial	10.57%
Miscellaneous (Incl. VA)	3.52%
Total	100.00%

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
Mecklenburg	11%	52%	53%	12%	6%	12%
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 2016 Annual 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 2016 Annual Report (pages 25-26¹) 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.

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, 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.

PAYOR CATEGORY	% OF TOTAL PATIENTS
Self Pay/Indigent/Charity	0.44%
Medicare	69.60%
Medicaid	5.29%
Commercial Insurance	10.57%
Medicare/Commercial	10.57%
Miscellaneous (Incl. VA)	3.52%
Total	100.00%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.44% of total services will be provided to self-pay/indigent/charity patients, 80.17% to Medicare patients and 5.29% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for Greenville Dialysis Center.

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.4, page 53, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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
- 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 demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

BMA proposes to add three dialysis stations the Greenville Dialysis Center facility for a total of 51 stations upon completion of this project and Project ID# Q-11304-17 (relocate three stations to FKC Captains Cove).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus,

the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR, Table B, indicates there are five dialysis facilities (four existing and one approved) in Pitt County, as follows:

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

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
FMC Care of Ayden	BMA	61	Ayden	16	-6 and +6*	95.31%
FMC Dialysis Services of East Carolina	BMA	147	Greenville	41	-3*	89.63%
FMC Farmville**	BMA	29	Farmville	10	0	72.50%
Fresenius Kidney Care Captains Cove*	BMA	0	Winterville	0	12	0.00%
Greenville Dialysis Center	BMA	175	Greenville	51	-3*	85.78%

*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. Project ID # Q-11391-17 (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 FKC Captains Cove) was conditionally approved and a Certificate of Need was issued on January 26, 2018.

**While FMC Farmville’s utilization is 72.5%, no dialysis stations can be relocated from FMC Farmville since the facility only has the required minimum of ten dialysis stations.

In Section N.1, pages 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. On page 56, the applicant 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 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 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.

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

C

In Section O.3, page 60, the applicant identifies 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 59, 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. 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 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 14-18, the applicant demonstrates that Greenville Dialysis Center will serve 166 in-center patients at the end of OY1 (CY2019) for a utilization rate of 81.37% or 3.2549 patients per station per week ($166 \text{ patients} / 51 \text{ stations} = 3.2549 / 4 = 0.8137$ or 81.37%). 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.